Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Notice of Award
FAIN# R01HD082554
Federal Award Date
04/29/2022

Recipient Information

1. Recipient Name
CHILDRENS HOSPITAL LOS ANGELES
4650 W SUNSET BLVD

LOS ANGELES, 90027

2. Congressional District of Recipient
28

3. Payment System Identifier (ID)
1956121916A1

4. Employer Identification Number (EIN)
956121916

5. Data Universal Numbering System (DUNS)
052277936

6. Recipient's Unique Entity Identifier
DVL1CMRMWRN9

7. Project Director or Principal Investigator
Johanna L Olson-Kennedy, MD (Contact)
Medical Director
jolson@chla.usc.edu
(b)(6)

8. Authorized Official
Ms. Naghma Ahmad

Federal Agency Information

9. Awarding Agency Contact Information
(b)(6)
Grants Management Specialist
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
(b)(6)
(b)(6)

10. Program Official Contact Information
KAREN WINER
Program Official
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
winerk@mail.nih.gov
(301) 435-6877

Federal Award Information

11. Award Number
5R01HD082554-07

12. Unique Federal Award Identification Number (FAIN)
R01HD082554

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
The Impact of Early Medical Treatment in Transgender Youth

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
Non-Competing Continuation

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 02/01/2022 – **End Date** 01/31/2023	
20. Total Amount of Federal Funds Obligated by this Action	$968,635
20 a. Direct Cost Amount	$811,317
20 b. Indirect Cost Amount	$157,318
21. Authorized Carryover	$0
22. Offset	$0
23. Total Amount of Federal Funds Obligated this budget period	$968,635
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$968,635
26. Project Period Start Date 08/01/2015 – **End Date** 01/31/2026	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$2,028,263

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Mario Martinez

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

RESEARCH
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 5R01HD082554-07

Principal Investigator(s):
Yee-Ming Chan, MD
Robert Garofalo, MD
Johanna L Olson-Kennedy (contact), MD
STEPHEN M ROSENTHAL, MD

Award e-mailed to: CHLAAWARDS@CHLA.USC.EDU

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $968,635 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to CHILDREN'S HOSPITAL LOS ANGELES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R01HD082554. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

(b)(6)
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$ (b)(4)
Fringe Benefits	$ (b)(4)
Personnel Costs (Subtotal)	$ (b)(4)
Materials & Supplies	$ (b)(4)
Travel	$ (b)(4)
Other	$ (b)(4)
Subawards/Consortium/Contractual Costs	$ (b)(4)
Publication Costs	$ (b)(4)

Federal Direct Costs	$811,317
Federal F&A Costs	$157,318
Approved Budget	$968,635
Total Amount of Federal Funds Authorized (Federal Share)	$968,635
TOTAL FEDERAL AWARD AMOUNT	$968,635

AMOUNT OF THIS ACTION (FEDERAL SHARE)	$968,635

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
7	$968,635	$968,635
8	$ (b)(4)	$ (b)(4)
9	$ (b)(4)	$ (b)(4)
10	$ (b)(4)	$ (b)(4)

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1956121916A1
Document Number:	RHD082554B
PMS Account Type:	P (Subaccount)
Fiscal Year:	2022

IC	CAN	2022	2023	2024	2025
HD	8014702	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
MH	8022575	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: PGNB -KW / **OC**: 41025 / **Released**: (b)(6) 04/28/2022
Award Processed: 04/29/2022 12:14:07 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01HD082554-07

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R01HD082554-07

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01HD082554. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

Eunice Kennedy Shriver National Institute Of Child Health & Human Development (NICHD) National Institute Of Mental Health (NIMH)

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the

most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 5R01HD082554-07

Clinical Trial Indicator: No

This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

COVID-19 NOTICE

Due to the impact of the Coronavirus disease 2019 (COVID-19) outbreak, NICHD will consider providing greater flexibilities to recipients in meeting administrative, financial management and audit requirements. For further information, please contact the Grants Management Specialist and Program Official indicated in Section IV of this Notice of Award.

FOA

This award is subject to the requirements indicated in the PA18-729, which are hereby incorporated by reference. Copies of this Funding Opportunity Announcement are available at http://grants.nih.gov/grants/guide/index.html.

MULTI-PI

The recipient is required to follow the Multiple Principal Investigator Leadership Plan included in the application dated **03/05/20** and may not implement any changes in the plan without the written prior approval of NICHD.

Although the signatures of all PIs are not required on prior approval requests submitted to NICHD, the recipient institution must secure and retain the signatures of all of PIs within their own internal processes. See NIH Guide Notice NOT-OD-06-054 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html).

SPREADSHEET SUMMARY

AWARD NUMBER: 5R01HD082554-07

INSTITUTION: CHILDREN'S HOSPITAL LOS ANGELES

Budget	Year 7	Year 8	Year 9	Year 10
Salaries and Wages	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
Fringe Benefits	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
Personnel Costs (Subtotal)	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
Materials & Supplies	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
Travel	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
Other	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
Subawards/Consortium/Contractual Costs	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
Publication Costs	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
TOTAL FEDERAL DC	$811,317	$ (b)(4)	$ (b)(4)	$ (b)(4)
TOTAL FEDERAL F&A	$157,318	$ (b)(4)	$ (b)(4)	$ (b)(4)
TOTAL COST	$968,635	$ (b)(4)	$ (b)(4)	$ (b)(4)

Facilities and	Year 7	Year 8	Year 9	Year 10

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Administrative Costs				
F&A Cost Rate 1	(b)(4)%	(b)(4)%	(b)(4)%	(b)(4)%
F&A Cost Base 1	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
F&A Costs 1	$157,318	$ (b)(4)	$ (b)(4)	$ (b)(4)

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Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Notice of Award
FAIN# R01HD082554
Federal Award Date
05/05/2021

Recipient Information

1. Recipient Name
CHILDRENS HOSPITAL LOS ANGELES
4650 SUNSET BLVD

LOS ANGELES, CA 90027

2. Congressional District of Recipient
28

3. Payment System Identifier (ID)
1956121916A1

4. Employer Identification Number (EIN)
956121916

5. Data Universal Numbering System (DUNS)
052277936

6. Recipient's Unique Entity Identifier

7. Project Director or Principal Investigator
Johanna L Olson-Kennedy, MD (Contact)
Medical Director
jolson@chla.usc.edu
(b)(6)

8. Authorized Official
Ms. Naghma Ahmad

Federal Agency Information

9. Awarding Agency Contact Information
(b)(6)
Grants Management Specialist
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
(b)(6)
(b)(6)

10. Program Official Contact Information
KAREN WINER
Program Official
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
winerk@mail.nih.gov
(301) 435-6877

Federal Award Information

11. Award Number
2R01HD082554-06A1

12. Unique Federal Award Identification Number (FAIN)
R01HD082554

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
The Impact of Early Medical Treatment in Transgender Youth

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
Competing Continuation

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 05/05/2021 – **End Date** 01/31/2022	
20. Total Amount of Federal Funds Obligated by this Action	$1,059,628
20 a. Direct Cost Amount	$830,194
20 b. Indirect Cost Amount	$229,434
21. Authorized Carryover	$0
22. Offset	$0
23. Total Amount of Federal Funds Obligated this budget period	$1,059,628
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$1,059,628
26. Project Period Start Date 08/01/2015 – **End Date** 01/31/2026	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$1,059,628

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
(b)(6)

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

RESEARCH
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 2R01HD082554-06A1

Principal Investigator(s):
Yee-Ming Chan, MD
Robert Garofalo, MD
Johanna L Olson-Kennedy (contact), MD
STEPHEN M ROSENTHAL, MD

Award e-mailed to: CHLAAWARDS@CHLA.USC.EDU

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $1,059,628 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to CHILDREN'S HOSPITAL LOS ANGELES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R01HD082554. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

(b)(6)
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$ (b)(4)
Fringe Benefits	$ (b)(4)
Personnel Costs (Subtotal)	$ (b)(4)
Materials & Supplies	$ (b)(4)
Travel	$ (b)(4)
Other	$ (b)(4)
Subawards/Consortium/Contractual Costs	$ (b)(4)
Publication Costs	$ (b)(4)

Federal Direct Costs	$830,194
Federal F&A Costs	$229,434
Approved Budget	$1,059,628
Total Amount of Federal Funds Authorized (Federal Share)	$1,059,628
TOTAL FEDERAL AWARD AMOUNT	$1,059,628
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$1,059,628

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
6	$1,059,628	$1,059,628
7	(b)(4)	(b)(4)
8	(b)(4)	(b)(4)
9	(b)(4)	(b)(4)
10	(b)(4)	(b)(4)

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1956121916A1
Document Number:	RHD082554B
PMS Account Type:	P (Subaccount)
Fiscal Year:	2021

IC	CAN	2021	2022	2023	2024	2025
HD	8014702	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
MH	8022575	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: PGNB -KW / **OC**: 41022 / **Released**: (b)(6) 05/04/2021
Award Processed: 05/05/2021 12:04:21 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 2R01HD082554-06A1

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 2R01HD082554-06A1

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01HD082554. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

Eunice Kennedy Shriver National Institute Of Child Health & Human Development (NICHD) National Institute Of Mental Health (NIMH)

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in

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the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 2R01HD082554-06A1

Clinical Trial Indicator: No

This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

BUDGET CYCLE

This award includes funds for twelve months of support. The competing budget period is awarded for less than 12 months. Continuation awards will cycle on February 1. Allowable pre-award costs may be charged to this award, in accordance with institutional requirements for prior approval and the conditions outlined in the NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf).

FUNDING PLAN

In order to meet Institute program objectives within FY2021 budget constraints, this grant is reduced 41.55 percent below the level recommended by peer review. Future year levels of support are determined by applying the same administrative reduction.

ESCALATION

In accordance with the NICHD FY2020 fiscal policy, escalation on recurring costs has been removed.

FOA

This award is subject to the requirements indicated in the PA18-729, which are hereby incorporated by reference. Copies of this Funding Opportunity Announcement are available at http://grants.nih.gov/grants/guide/index.html.

MULTI-PI

The recipient is required to follow the Multiple Principal Investigator Leadership Plan included in the application dated 3/5/20 and may not implement any changes in the plan without the written prior approval of NICHD.

Although the signatures of all PIs are not required on prior approval requests submitted to NICHD, the recipient institution must secure and retain the signatures of all of PIs within their own internal processes. See NIH Guide Notice NOT-OD-06-054 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html).

COVID-19 NOTICE

Due to the impact of the Coronavirus disease 2019 (COVID-19) outbreak, NICHD will consider providing greater flexibilities to recipients in meeting administrative, financial management and audit requirements. For further information, please contact the Grants Management Specialist and Program Official indicated in Section IV of this Notice of Award.

SPREADSHEET SUMMARY

AWARD NUMBER: 2R01HD082554-06A1

INSTITUTION: CHILDREN'S HOSPITAL LOS ANGELES

Budget	Year 6	Year 7	Year 8	Year 9	Year 10
Salaries and Wages	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
Fringe Benefits	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
Personnel Costs (Subtotal)	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
Materials & Supplies	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
Travel	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
Other	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
Subawards/Consortium/Contractual Costs	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
Publication Costs	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
TOTAL FEDERAL DC	$830,194	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
TOTAL FEDERAL F&A	$229,434	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
TOTAL COST	$1,059,628	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)

Facilities and Administrative Costs	Year 6	Year 7	Year 8	Year 9	Year 10
F&A Cost Rate 1	(b)(4)%	(b)(4)%	(b)(4)%	(b)(4)%	(b)(4)%
F&A Cost Base 1	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
F&A Costs 1	$229,434	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)

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Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Notice of Award
FAIN# R01HD082554
Federal Award Date
05/05/2021

Recipient Information

1. Recipient Name
CHILDRENS HOSPITAL LOS ANGELES
4650 SUNSET BLVD

LOS ANGELES, CA 90027

2. Congressional District of Recipient
28

3. Payment System Identifier (ID)
1951690977A1

4. Employer Identification Number (EIN)
951690977

5. Data Universal Numbering System (DUNS)
052277936

6. Recipient's Unique Entity Identifier

7. Project Director or Principal Investigator
Johanna L Olson-Kennedy, MD (Contact)
Associate Professor
jolson@chla.usc.edu
(b)(6)

8. Authorized Official
(b)(6)

Federal Agency Information

9. Awarding Agency Contact Information
(b)(6)
Grants Management Specialist
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
(b)(6)
301-435-6978

10. Program Official Contact Information
KAREN WINER
Program Official
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
winerk@mail.nih.gov
(301) 435-6877

Federal Award Information

11. Award Number
5R01HD082554-05

12. Unique Federal Award Identification Number (FAIN)
R01HD082554

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
The Impact of Early Medical Treatment in Transgender Youth

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 07/01/2019 – **End Date** 05/04/2021	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	$0
22. Offset	$0
23. Total Amount of Federal Funds Obligated this budget period	$1,111,300
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$1,111,300
26. Project Period Start Date 08/01/2015 – **End Date** 05/04/2021	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$5,720,204

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
(b)(6)

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

RESEARCH
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 5R01HD082554-05 REVISED

Principal Investigator(s):
Yee-Ming Chan, MD
ROBERT GAROFALO, MD
Johanna L Olson-Kennedy (contact), MD
STEPHEN M ROSENTHAL, MD

Award e-mailed to: CHLAAWARDS@CHLA.USC.EDU

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to CHILDREN'S HOSPITAL LOS ANGELES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R01HD082554. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

(b)(6)
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

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Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$ (b)(4)
Fringe Benefits	$ (b)(4)
Personnel Costs (Subtotal)	$ (b)(4)
Travel	$ (b)(4)
Other	$ (b)(4)
Subawards/Consortium/Contractual Costs	$ (b)(4)

Federal Direct Costs	$912,305
Federal F&A Costs	$198,995
Approved Budget	$1,111,300
Total Amount of Federal Funds Authorized (Federal Share)	$1,111,300
TOTAL FEDERAL AWARD AMOUNT	$1,111,300

AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
5	$1,111,300	$1,111,300

Fiscal Information:

Payment System Identifier:	1951690977A1
Document Number:	RHD082554A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2019

IC	CAN	2019
HD	8014702	$1,111,300

NIH Administrative Data:
PCC: PGNB -KW / **OC**: 41025 / **Released**: (b)(6) 05/04/2021
Award Processed: 05/05/2021 12:01:06 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01HD082554-05 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R01HD082554-05 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01HD082554. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) quarterly cash transaction data. A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not

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apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.*

NIH strongly encourages electronic submission of the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

Email: The final invention statement may be e-mailed as PDF attachments to: NIHCloseoutCenter@mail.nih.gov.

Hard copy: Paper submissions of the final invention statement may be faxed to the NIH Division of Central Grants Processing, Grants Closeout Center, at 301-480-2304, or mailed to:

National Institutes of Health
Office of Extramural Research
Division of Central Grants Processing
Grants Closeout Center
6705 Rockledge Drive
Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and should be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 5R01HD082554-05 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISION: This revised award terminates this project on **05/04/21 to allow issuance of 2-RO1 HD 082554-01A1**

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This award is subject to the requirements indicated in PA12-111, which are hereby incorporated by reference. Copies of this Funding Opportunity Announcement are available at http://grants.nih.gov/grants/guide/index.html.

The recipient is required to follow the Multiple Principal Investigator Leadership Plan included in the application dated 11/05/2014 and may not implement any changes in the plan without the written prior approval of NICHD.

Although the signatures of all PIs are not required on prior approval requests submitted to NICHD, the recipient institution must secure and retain the signatures of all of PIs within their own internal processes. See NIH Guide Notice NOT-OD-06-054 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html).

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01HD082554-05 REVISED

INSTITUTION: CHILDREN'S HOSPITAL LOS ANGELES

Budget	Year 5
Salaries and Wages	$ (b)(4)
Fringe Benefits	$ (b)(4)
Personnel Costs (Subtotal)	$ (b)(4)
Travel	$ (b)(4)
Other	$ (b)(4)
Subawards/Consortium/Contractual Costs	$ (b)(4)
TOTAL FEDERAL DC	$912,305
TOTAL FEDERAL F&A	$198,995
TOTAL COST	$1,111,300

(b)(4)

Facilities and Administrative Costs	Year 5
F&A Cost Rate 1	%
F&A Cost Base 1	$ (b)(4)
F&A Costs 1	$198,995

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RESEARCH
Department of Health and Human Services
National Institutes of Health

Federal Award Date: 06/21/2019

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Grant Number: 5R01HD082554-05
FAIN: R01HD082554

Principal Investigator(s):
Yee-Ming Chan, MD
ROBERT GAROFALO, MD
Johanna L Olson-Kennedy (contact), MD
STEPHEN M ROSENTHAL, MD

Project Title: The Impact of Early Medical Treatment in Transgender Youth

(b)(6)
Manager, Sponsored Projects Team
4650 Sunset Boulevard, Mailstop #97
Los Angeles, CA 900276062

Award e-mailed to: CHLAAWARDS@CHLA.USC.EDU

Period Of Performance:
Budget Period: 07/01/2019 – 06/30/2020
Project Period: 08/01/2015 – 06/30/2020

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $1,111,300 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to CHILDREN'S HOSPITAL LOS ANGELES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R01HD082554. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

(b)(6)
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

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SECTION I – AWARD DATA – 5R01HD082554-05

Award Calculation (U.S. Dollars)

Salaries and Wages	$ (b)(4)
Fringe Benefits	$ (b)(4)
Personnel Costs (Subtotal)	$ (b)(4)
Travel	$ (b)(4)
Other	$ (b)(4)
Subawards/Consortium/Contractual Costs	$ (b)(4)

Federal Direct Costs	$912,305
Federal F&A Costs	$198,995
Approved Budget	$1,111,300
Total Amount of Federal Funds Obligated (Federal Share)	$1,111,300
TOTAL FEDERAL AWARD AMOUNT	$1,111,300

AMOUNT OF THIS ACTION (FEDERAL SHARE)	$1,111,300

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
5	$1,111,300	$1,111,300

Fiscal Information:

CFDA Name:	Child Health and Human Development Extramural Research
CFDA Number:	93.865
EIN:	1951690977A1
Document Number:	RHD082554A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2019

IC	CAN	2019
HD	8014702	$1,111,300

NIH Administrative Data:
PCC: PGNB -KW / **OC**: 414E / **Released**: (b)(6) 06/21/2019
Award Processed: 06/21/2019 07:01:44 PM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01HD082554-05

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – TERMS AND CONDITIONS – 5R01HD082554-05

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01HD082554. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) quarterly cash transaction data. A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience.*

NIH strongly encourages electronic submission of the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

Email: The final invention statement may be e-mailed as PDF attachments to: NIHCloseoutCenter@mail.nih.gov.

Hard copy: Paper submissions of the final invention statement may be faxed to the NIH Division of Central Grants Processing, Grants Closeout Center, at 301-480-2304, or mailed to:

National Institutes of Health
Office of Extramural Research
Division of Central Grants Processing
Grants Closeout Center
6705 Rockledge Drive
Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and should be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – HD Special Terms and Conditions – 5R01HD082554-05

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

This award is subject to the requirements indicated in PA12-111, which are hereby incorporated by reference. Copies of this Funding Opportunity Announcement are available at http://grants.nih.gov/grants/guide/index.html.

The recipient is required to follow the Multiple Principal Investigator Leadership Plan included in the application dated 11/05/2014 and may not implement any changes in the plan without the written prior approval of NICHD.

Although the signatures of all PIs are not required on prior approval requests submitted to NICHD, the recipient institution must secure and retain the signatures of all of PIs within their own internal processes. See NIH Guide Notice NOT-OD-06-054 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html).

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: (b)(6)
Email: (b)(6) **Phone**: (b)(6)

Program Official: Karen Winer
Email: winerk@mail.nih.gov **Phone**: (301) 435-6877 **Fax**: (301) 480-9791

SPREADSHEET SUMMARY
GRANT NUMBER: 5R01HD082554-05

INSTITUTION: CHILDREN'S HOSPITAL LOS ANGELES

Budget	Year 5
Salaries and Wages	$ (b)(4)
Fringe Benefits	$
Personnel Costs (Subtotal)	$
Travel	$
Other	$
Subawards/Consortium/Contractual Costs	$
TOTAL FEDERAL DC	$912,305
TOTAL FEDERAL F&A	$198,995
TOTAL COST	$1,111,300

Facilities and Administrative Costs	Year 5
F&A Cost Rate 1	(b)(4)%
F&A Cost Base 1	$ (b)(4)
F&A Costs 1	$198,995

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RESEARCH
Department of Health and Human Services
National Institutes of Health

Federal Award Date: 06/21/2018

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Grant Number: 5R01HD082554-04
FAIN: R01HD082554

Principal Investigator(s):
Yee-Ming Chan, MD
ROBERT GAROFALO, MD
Johanna L Olson-Kennedy (contact), MD
STEPHEN M ROSENTHAL, MD

Project Title: The Impact of Early Medical Treatment in Transgender Youth

(b)(6)
Manager, Sponsored Projects Team
4650 Sunset Boulevard, Mailstop #97
Los Angeles, CA 900276062

Award e-mailed to: CHLAAWARDS@CHLA.USC.EDU

Period Of Performance:
Budget Period: 07/01/2018 – 06/30/2019
Project Period: 08/01/2015 – 06/30/2020

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $1,209,157 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to CHILDREN'S HOSPITAL OF LOS ANGELES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R01HD082554. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

(b)(6)
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

NIH NGA R | Version: 1 - 01/16/2018 12:52:00| Generated on: 6/21/2018 7:02:13 PM

SECTION I – AWARD DATA – 5R01HD082554-04

Award Calculation (U.S. Dollars)

Salaries and Wages	$ (b)(4)
Fringe Benefits	$ (b)(4)
Personnel Costs (Subtotal)	$ (b)(4)
Travel	$ (b)(4)
Other	$ (b)(4)
Subawards/Consortium/Contractual Costs	$ (b)(4)

Federal Direct Costs	$987,383
Federal F&A Costs	$221,774
Approved Budget	$1,209,157
Total Amount of Federal Funds Obligated (Federal Share)	$1,209,157
TOTAL FEDERAL AWARD AMOUNT	$1,209,157

AMOUNT OF THIS ACTION (FEDERAL SHARE)	$1,209,157

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
4	$1,209,157	$1,209,157
5	$ (b)(4)	$ (b)(4)

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Name:	Child Health and Human Development Extramural Research
CFDA Number:	93.865
EIN:	1951690977A1
Document Number:	RHD082554A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2018

IC	CAN	2018	2019
HD	8014702	$1,209,157	$ (b)(4)

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: CDBB -LF / **OC**: 414E / **Released**: (b)(6) 06/20/2018
Award Processed: 06/21/2018 07:02:13 PM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01HD082554-04

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – TERMS AND CONDITIONS – 5R01HD082554-04

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.

e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01HD082554. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

This award is subject to the requirements indicated in PA12-111, which are hereby incorporated by reference. Copies of this Funding Opportunity Announcement are available at http://grants.nih.gov/grants/guide/index.html.

The recipient is required to follow the Multiple Principal Investigator Leadership Plan included in the application dated 11/05/2014 and may not implement any changes in the plan without the written prior approval of NICHD.

Although the signatures of all PIs are not required on prior approval requests submitted to NICHD, the recipient institution must secure and retain the signatures of all of PIs within their own internal processes. See NIH Guide Notice NOT-OD-06-054 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html).

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: (b)(6)
Email: (b)(6) **Phone**: (b)(6)

Program Official: Lisa S Freund
Email: freundl@mail.nih.gov **Phone**: (301) 435-6879 **Fax**: (301) 480-0230

SPREADSHEET SUMMARY
GRANT NUMBER: 5R01HD082554-04

INSTITUTION: CHILDREN'S HOSPITAL OF LOS ANGELES

Budget	Year 4	Year 5
Salaries and Wages	$ (b)(4)	$ (b)(4)
Fringe Benefits	$	$
Personnel Costs (Subtotal)	$	$
Travel	$	$
Other	$	$
Subawards/Consortium/Contractual Costs	$	$
TOTAL FEDERAL DC	$987,383	$
TOTAL FEDERAL F&A	$221,774	$
TOTAL COST	$1,209,157	$

Facilities and Administrative Costs	Year 4	Year 5
F&A Cost Rate 1	(b)(4)%	(b)(4)%
F&A Cost Base 1	$ (b)(4)	$ (b)(4)
F&A Costs 1	$221,774	$ (b)(4)

NIH NGA R | Version: 1 - 01/16/2019 12:52:00 Generated on: 6/21/2019 7:02:13 PM

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

Federal Award Date: 06/30/2017

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Grant Number: 5R01HD082554-03
FAIN: R01HD082554

Principal Investigator(s):
Yee-Ming Chan, MD
ROBERT GAROFALO, MD
Johanna L Olson (contact), MD
STEPHEN M ROSENTHAL, MD

Project Title: The Impact of Early Medical Treatment in Transgender Youth

(b)(6)
Manager, Sponsored Projects Team
4650 Sunset Boulevard, Mailstop #97
Los Angeles, CA 900276062

Award e-mailed to: CHLAAWARDS@CHLA.USC.EDU

Period Of Performance:
Budget Period: 07/01/2017 – 06/30/2018
Project Period: 08/01/2015 – 06/30/2020

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $1,226,865 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to CHILDREN'S HOSPITAL OF LOS ANGELES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R01HD082554. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

NIH NGA R | Version: 1 - 03/15/2017 15:13:00 Generated on: 6/30/2017 12:34:37 AM

Sincerely yours,

(b)(6)
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

NIH NGA R | Version: 1 - 03/15/2017 15:13:00| Generated on: 6/30/2017 12:34:37 AM

SECTION I – AWARD DATA – 5R01HD082554-03

Award Calculation (U.S. Dollars)

Salaries and Wages	$ (b)(4)
Fringe Benefits	$ (b)(4)
Personnel Costs (Subtotal)	$ (b)(4)
Travel	$ (b)(4)
Other	$ (b)(4)
Subawards/Consortium/Contractual Costs	$ (b)(4)

Federal Direct Costs	$998,019
Federal F&A Costs	$228,846
Approved Budget	$1,226,865
Total Amount of Federal Funds Obligated (Federal Share)	$1,226,865
TOTAL FEDERAL AWARD AMOUNT	$1,226,865

AMOUNT OF THIS ACTION (FEDERAL SHARE)	$1,226,865

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$1,226,865	$1,226,865
4	$ (b)(4)	$ (b)(4)
5	$ (b)(4)	$ (b)(4)

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Name:	Child Health and Human Development Extramural Research
CFDA Number:	93.865
EIN:	1951690977A1
Document Number:	RHD082554A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2017

IC	CAN	2017	2018	2019
HD	8014702	$1,226,865	$ (b)(4)	$ (b)(4)

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: CDBB -LF / **OC**: 414E / **Released**: (b)(6) 06/29/2017
Award Processed: 06/30/2017 12:34:37 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01HD082554-03

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – TERMS AND CONDITIONS – 5R01HD082554-03

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget

period.

e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01HD082554. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

This award is subject to the requirements indicated in PA12-111, which are hereby incorporated by reference. Copies of this Funding Opportunity Announcement are available at http://grants.nih.gov/grants/guide/index.html.

The recipient is required to follow the Multiple Principal Investigator Leadership Plan included in the application dated 11/05/2014 and may not implement any changes in the plan without the written prior approval of NICHD.

Although the signatures of all PIs are not required on prior approval requests submitted to NICHD, the recipient institution must secure and retain the signatures of all of PIs within their own internal processes. See NIH Guide Notice NOT-OD-06-054 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html).

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: (b)(6)
Email: (b)(6) **Phone**: (b)(6) **Fax**: 301-451-5510

Program Official: Lisa S Freund
Email: freundl@mail.nih.gov **Phone**: (301) 435-6879 **Fax**: (301) 480-0230

SPREADSHEET SUMMARY
GRANT NUMBER: 5R01HD082554-03

INSTITUTION: CHILDREN'S HOSPITAL OF LOS ANGELES

Budget	Year 3	Year 4	Year 5
Salaries and Wages	$ (b)(4)	$ (b)(4)	$ (b)(4)
Fringe Benefits	$	$	$
Personnel Costs (Subtotal)	$	$	$
Travel	$	$	$
Other	$	$	$
Subawards/Consortium/Contractual Costs	$	$	$
TOTAL FEDERAL DC	$998,019	$	$
TOTAL FEDERAL F&A	$228,846	$	$
TOTAL COST	$1,226,865	$ (b)(4)	$ (b)(4)

Facilities and Administrative Costs	Year 3	Year 4	Year 5
F&A Cost Rate 1	(b)(4) %	(b)(4) %	(b)(4) %
F&A Cost Base 1	$ (b)(4)	$ (b)(4)	$ (b)(4)
F&A Costs 1	$228,846	$ (b)(4)	$ (b)(4)

NIH SGA R | Version: 1 - 03/15/2017 15:13:00 Generated on: 4/30/2017 12:34:37 AM

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

Federal Award Date: 07/09/2016

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Grant Number: 5R01HD082554-02
FAIN: R01HD082554

Principal Investigator(s):
Yee-Ming Chan, MD
ROBERT GAROFALO, MD
Johanna L Olson (contact), MD
STEPHEN M ROSENTHAL, MD

Project Title: The Impact of Early Medical Treatment in Transgender Youth

(b)(6)
Manager, Sponsored Projects Team
4650 Sunset Boulevard, Mailstop #97
Los Angeles, CA 900276062

Award e-mailed to: CHLAAWARDS@CHLA.USC.EDU

Period Of Performance:
Budget Period: 07/01/2016 – 06/30/2017
Project Period: 08/01/2015 – 06/30/2020

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $1,220,340 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to CHILDREN'S HOSPITAL OF LOS ANGELES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R01HD082554. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

NIH NGA R | Version: 1 - 02/17/2016 12:29:00 Generated on: 7/9/2016 12:00:44 AM

Sincerely yours,

(b)(6)
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

NIH NGA R | Version: 1 - 02/17/2016 12:29:00| Generated on: 7/9/2016 12:00:44 AM

SECTION I – AWARD DATA – 5R01HD082554-02

Award Calculation (U.S. Dollars)

Salaries and Wages	$ (b)(4)
Fringe Benefits	$ (b)(4)
Personnel Costs (Subtotal)	$ (b)(4)
Materials & Supplies	$ (b)(4)
Travel	$ (b)(4)
Other	$ (b)(4)
Subawards/Consortium/Contractual Costs	$ (b)(4)

Federal Direct Costs	$991,416
Federal F&A Costs	$228,924
Approved Budget	$1,220,340
Total Amount of Federal Funds Obligated (Federal Share)	$1,220,340
TOTAL FEDERAL AWARD AMOUNT	$1,220,340

AMOUNT OF THIS ACTION (FEDERAL SHARE)	$1,220,340

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$1,220,340	$1,220,340
3	$ (b)(4)	$ (b)(4)
4	$ (b)(4)	$ (b)(4)
5	$ (b)(4)	$ (b)(4)

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Name:	Child Health and Human Development Extramural Research
CFDA Number:	93.865
EIN:	1951690977A1
Document Number:	RHD082554A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2016

IC	CAN	2016	2017	2018	2019
HD	8014702	$1,220,340	$ (b)(4)	$ (b)(4)	$ (b)(4)

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: CDBB -LF / **OC**: 414E / **Released**: (b)(6) 07/07/2016
Award Processed: 07/09/2016 12:00:44 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01HD082554-02

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – TERMS AND CONDITIONS – 5R01HD082554-02

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.

d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01HD082554. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

In accordance with the NIH FY2016 fiscal policy, this non-competing award is reduced below the committed funding level on the FY2015 Notice of Award. See NIH Guide Notice NOT-OD-16-046 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-046.html) and the NICHD FY16 Funding Policy (https://www.nichd.nih.gov/grants-funding/policies-strategies/strategies/Pages/2016.aspx) for additional information.

****

This award is subject to the requirements indicated in PA12-111, which are hereby incorporated by reference. Copies of this Funding Opportunity Announcement are available at http://grants.nih.gov/grants/guide/index.html.

****

The recipient is required to follow the Multiple Principal Investigator Leadership Plan included in the application dated 11/05/2014 and may not implement any changes in the plan without the written prior approval of NICHD.

Although the signatures of all PIs are not required on prior approval requests submitted to NICHD, the recipient institution must secure and retain the signatures of all of PIs within their own internal processes. See NIH Guide Notice NOT-OD-06-054 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html).

****

This award includes funds awarded for consortium activity with:

Boston Children's Hospital, Boston, MA
Lurie Children's Hospital of Chicago, Chicago, IL
University of California at San Francisco, San Francisco, CA

Consortia are to be established and administered as described in the NIH Grants Policy Statement (rev. 11/15) (http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf).

****

NIH requires the use of the eRA Research Performance Progress Report (RPPR) Module for the submission of all Non-Competing Continuation (Type 5) Progress Reports. See NIH Guide Notice NOT-OD-15-014 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-014.html).

****

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These

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individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: (b)(6)
Email: (b)(6) **Phone**: (b)(6) **Fax**: (301) 402-0915

Program Official: Lisa S Freund
Email: freundl@mail.nih.gov **Phone**: (301) 435-6879 **Fax**: (301) 480-0230

SPREADSHEET SUMMARY
GRANT NUMBER: 5R01HD082554-02

INSTITUTION: CHILDREN'S HOSPITAL OF LOS ANGELES

Budget	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
Fringe Benefits	$	$	$	$
Personnel Costs (Subtotal)	$	$	$	$
Materials & Supplies	$			
Travel	$	$	$	$
Other	$	$	$	$
Subawards/Consortium/Contractual Costs	$	$	$	$
TOTAL FEDERAL DC	$991,416	$	$	$
TOTAL FEDERAL F&A	$228,924	$	$	$
TOTAL COST	$1,220,340	$	$	$

Facilities and Administrative Costs	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	(b)(4)%	(b)(4)%	(b)(4)%	(b)(4)%
F&A Cost Base 1	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
F&A Costs 1	$228,924	$ (b)(4)	$ (b)(4)	$ (b)(4)

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Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

Federal Award Date: 07/07/2016

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Grant Number: 1R01HD082554-01A1 REVISED
FAIN: R01HD082554

Principal Investigator(s):
Yee-Ming Chan, MD
ROBERT GAROFALO, MD
Johanna Olson (contact), MD
STEPHEN M ROSENTHAL, MD

Project Title: The Impact of Early Medical Treatment in Transgender Youth

(b)(6)
Manager, Sponsored Projects Team
4650 Sunset Boulevard, Mailstop #97
Los Angeles, CA 900276062

Award e-mailed to: CHLAAWARDS@CHLA.USC.EDU

Period Of Performance:
Budget Period: 08/01/2015 – 06/30/2016
Project Period: 08/01/2015 – 06/30/2020

Dear Business Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to CHILDREN'S HOSPITAL OF LOS ANGELES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R01HD082554. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

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Sincerely yours,

(b)(6)
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

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SECTION I – AWARD DATA – 1R01HD082554-01A1 REVISED

Award Calculation (U.S. Dollars)

Salaries and Wages	$ (b)(4)
Fringe Benefits	$ (b)(4)
Personnel Costs (Subtotal)	$ (b)(4)
Supplies	$ (b)(4)
Travel Costs	$ (b)(4)
Other Costs	$ (b)(4)
Consortium/Contractual Cost	$ (b)(4)

Federal Direct Costs	$732,833
Federal F&A Costs	$219,709
Approved Budget	$952,542
Total Amount of Federal Funds Obligated (Federal Share)	$952,542
TOTAL FEDERAL AWARD AMOUNT	$952,542

AMOUNT OF THIS ACTION (FEDERAL SHARE) $0

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$952,542	$952,542
2	$ (b)(4)	$ (b)(4)
3	$ (b)(4)	$ (b)(4)
4	$ (b)(4)	$ (b)(4)
5	$ (b)(4)	$ (b)(4)

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Name:	Child Health and Human Development Extramural Research
CFDA Number:	93.865
EIN:	1951690977A1
Document Number:	RHD082554A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2015

IC	CAN	2015	2016	2017	2018	2019
HD	8014702	$952,542	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: CDBB -LF / **OC**: 414A / **Released**: (b)(6) 07/07/2016
Award Processed: 07/07/2016 07:01:11 PM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01HD082554-01A1 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – TERMS AND CONDITIONS – 1R01HD082554-01A1 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.

c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01HD082554. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

SECTION IV – HD Special Terms and Conditions – 1R01HD082554-01A1 REVISED

REVISION: This revised award reflects NICHD acceptance of the following documentation/information and releases the restriction indicated on the Notice of Award issued on 07/31/2015:

1. Requirements for Human Subject Research has been provided to and approved by NIH

2. Received Current IRB Approval Date

REVISION: This revised award also reflects NICHD approval of the change of co-principal investigator from Dr. Spack to Dr. Chan as requested in the correspondence dated 03/03/2016.

The previous terms and conditions of award remain in effect as stated below.

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In order to meet Institute program objectives within FY2015 budget constraints, this grant is reduced 17 percent below the level recommended by peer review. Future year levels of support are determined by applying the same administrative reduction.

****

This award is subject to the requirements indicated in FOA PA12-111, which are hereby incorporated by reference. Copies of this Funding Opportunity Announcement are available at http://grants.nih.gov/grants/guide/index.html.

****

In accordance with the NICHD FY2015 fiscal policy, escalation on recurring costs has been removed.

****

The grantee is required to follow the Multiple Principal Investigator Leadership Plan included in the application dated 11/05/2014 and may not implement any changes in the plan without the written prior approval of NICHD.

Although the signatures of all PIs are not required on prior approval requests submitted to NICHD, the grantee institution must secure and retain the signatures of all of PIs within their own internal processes. See NIH Guide Notice NOT-OD-06-054 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html).

****

This award includes funds for twelve months of support. The competing budget period is awarded for less than 12 months. Continuation awards will cycle on July 1. [NICHD is taking this action to redistribute start dates more evenly throughout the year.] Allowable preaward costs may be charged to this award, in accordance with institutional requirements for prior approval and the conditions outlined in the NIH Grants Policy Statement (rev. 3/15) (http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf).

****

This award includes funds awarded for consortium activity with the Boston Children's Hospital in the amount of $ (b)(4) ($ (b)(4) direct costs + $ (b)(4) facilities and administrative costs)].

Consortia are to be established and administered as described in the NIH Grants Policy Statement (rev. 3/15) (http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf).

****

This award includes funds awarded for consortium activity with the Regents of the University of California at San Francisco in the amount of $ (b)(4) ($ (b)(4) direct costs + $ (b)(4) facilities and administrative costs)].

Consortia are to be established and administered as described in the NIH Grants Policy Statement (rev. 3/15) (http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf).

****

This award includes funds awarded for consortium activity with the Ann and Robert H. Lurie Children's Hospital of Chicago in the amount of $ (b)(4) ($ (b)(4) direct costs + $ (b)(4) facilities and administrative costs)].

Consortia are to be established and administered as described in the NIH Grants Policy Statement (rev. 3/15) (http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf).

****

NIH requires the use of the eRA Research Performance Progress Report (RPPR) Module for the submission of all Non-Competing Continuation (Type 5) Progress Reports. See NIH Guide Notice NOT-OD-15-014 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-014.html).

****

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: (b)(6)
Email: (b)(6) **Phone**: (b)(6) **Fax**: (301) 402-0915

Program Official: Lisa S Freund
Email: freundl@mail.nih.gov **Phone**: (301) 435-6879 **Fax**: (301) 480-0230

SPREADSHEET SUMMARY
GRANT NUMBER: 1R01HD082554-01A1 REVISED

INSTITUTION: CHILDREN'S HOSPITAL OF LOS ANGELES

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$	$	$	$	$
Fringe Benefits	$	$	$	$	$
Personnel Costs (Subtotal)	$	$	$	$	$
Supplies	$ (b)(4)	$			
Travel Costs	$	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
Other Costs	$	$	$	$	$
Consortium/Contractual Cost	$	$	$	$	$
TOTAL FEDERAL DC	$732,833	$	$	$	$
TOTAL FEDERAL F&A	$219,709	$	$	$	$

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TOTAL COST	$952,542	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	(b)(4)%	(b)(4)%	(b)(4)%	(b)(4)%	(b)(4)%
F&A Cost Base 1	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
F&A Costs 1	$219,709	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)

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RESEARCH
Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Federal Award Date: 07/31/2015

Grant Number: 1R01HD082554-01A1
FAIN: R01HD082554

Principal Investigator(s):
ROBERT GAROFALO, MD
Johanna Olson (contact), MD
STEPHEN M ROSENTHAL, MD
Norman Spack

Project Title: The Impact of Early Medical Treatment in Transgender Youth

(b)(6)
Manager, Sponsored Projects Team
4650 Sunset Boulevard, Mailstop #97
Los Angeles, CA 900276062

Award e-mailed to: CHLAAWARDS@CHLA.USC.EDU

Period Of Performance:
Budget Period: 08/01/2015 – 06/30/2016
Project Period: 08/01/2015 – 06/30/2020

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $952,542 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to CHILDREN'S HOSPITAL OF LOS ANGELES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R01HD082554. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

(b)(6)
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

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SECTION I – AWARD DATA – 1R01HD082554-01A1

Award Calculation (U.S. Dollars)

Salaries and Wages	$ (b)(4)
Fringe Benefits	$ (b)(4)
Supplies	$ (b)(4)
Travel Costs	$ (b)(4)
Other Costs	$ (b)(4)
Consortium/Contractual Cost	$ (b)(4)

Federal Direct Costs	$732,833
Federal F&A Costs	$219,709
Approved Budget	$952,542
Total Amount of Federal Funds Obligated (Federal Share)	$952,542
TOTAL FEDERAL AWARD AMOUNT	$952,542

AMOUNT OF THIS ACTION (FEDERAL SHARE)	$952,542

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$952,542	$952,542
2	$ (b)(4)	$ (b)(4)
3	$ (b)(4)	$ (b)(4)
4	$ (b)(4)	$ (b)(4)
5	$ (b)(4)	$ (b)(4)

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Name:	Child Health and Human Development Extramural Research
CFDA Number:	93.865
EIN:	1951690977A1
Document Number:	RHD082554A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2015

IC	CAN	2015	2016	2017	2018	2019
HD	8014702	$952,542	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: CDBB -LF / **OC**: 414A / **Released**: (b)(6) 07/27/2015
Award Processed: 06/15/2015 11:31:44 PM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01HD082554-01A1

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – TERMS AND CONDITIONS – 1R01HD082554-01A1

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.

d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01HD082554. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

Treatment of Program Income:
Additional Costs

SECTION IV – HD Special Terms and Conditions – 1R01HD082554-01A1

RESTRICTION: This award is issued with the knowledge that subjects may be involved within the period of support, but definite plans were not set forth in the application as per 45 CFR 46.118. No human subjects may be involved in any project supported by this award until all requirements for human subjects research as identified in the PHS398/SF424 instructions have been provided to and approved by NIH.

RESTRICTION: The present award is being made without a currently valid certification of Institutional Review Board (IRB) approval for this project with the following restriction: Only activities that are clearly severable and independent from activities that involve human subjects may be conducted pending NICHD acceptance of the certification of IRB review and approval.

No funds may be drawn down from the payment system and no obligations may be made against Federal funds for any research involving human subjects prior to NICHD notification to the grantee that the identified issues have been resolved and this restriction removed.

Failure to comply with the above requirements may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

****

In order to meet Institute program objectives within FY2015 budget constraints, this grant is reduced 17 percent below the level recommended by peer review. Future year levels of support are determined by applying the same administrative reduction.

****

This award is subject to the requirements indicated in FOA PA12-111, which are hereby incorporated by reference. Copies of this Funding Opportunity Announcement are available at http://grants.nih.gov/grants/guide/index.html.

****

In accordance with the NICHD FY2015 fiscal policy, escalation on recurring costs has been removed.

****

The grantee is required to follow the Multiple Principal Investigator Leadership Plan included in the application dated 11/05/2014 and may not implement any changes in the plan without the written prior approval of NICHD.

Although the signatures of all PIs are not required on prior approval requests submitted to NICHD, the grantee institution must secure and retain the signatures of all of PIs within their own internal processes. See NIH Guide Notice NOT-OD-06-054 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html).

****

This award includes funds for twelve months of support. The competing budget period is awarded for less than 12 months. Continuation awards will cycle on July 1. [NICHD is taking this action to redistribute start dates more evenly throughout the year.] Allowable preaward costs may be charged to this award, in accordance with institutional requirements for prior approval and the conditions outlined in the NIH Grants Policy Statement (rev. 3/15) (http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf).

****

This award includes funds awarded for consortium activity with the Boston Children's Hospital in the amount of $ (b)(4) ($ (b)(4) direct costs + $ (b)(4) facilities and administrative costs)].

Consortia are to be established and administered as described in the NIH Grants Policy Statement (rev. 3/15) (http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf).

****

This award includes funds awarded for consortium activity with the Regents of the University of California at San Francisco in the amount of $ (b)(4) ($ (b)(4) direct costs + $ (b)(4) facilities and administrative costs)].

Consortia are to be established and administered as described in the NIH Grants Policy Statement (rev. 3/15) (http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf).

****

This award includes funds awarded for consortium activity with the Ann and Robert H. Lurie Children's Hospital of Chicago in the amount of $ (b)(4) ($ (b)(4) direct costs + $ (b)(4) facilities and administrative costs)].

Consortia are to be established and administered as described in the NIH Grants Policy Statement (rev. 3/15) (http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf).

****

NIH requires the use of the eRA Research Performance Progress Report (RPPR) Module for the submission of all Non-Competing Continuation (Type 5) Progress Reports. See NIH Guide Notice NOT-OD-15-014 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-014.html).

****

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: (b)(6)
Email: (b)(6) **Phone**: (b)(6) **Fax**: (301) 402-0915

Program Official: Lisa S Freund
Email: freundl@mail.nih.gov **Phone**: (301) 435-6879 **Fax**: (301) 480-0230

SPREADSHEET SUMMARY
GRANT NUMBER: 1R01HD082554-01A1

INSTITUTION: CHILDREN'S HOSPITAL OF LOS ANGELES

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
Fringe Benefits	$	$	$	$	$
Supplies	$	$			
Travel Costs	$	$	$ (b)(4)	$ (b)(4)	$ (b)(4)
Other Costs	$	$	$	$	$
Consortium/Contractual Cost	$	$	$	$	$
TOTAL FEDERAL DC	$732,833	$	$ (b)(4)	$ (b)(4)	$ (b)(4)
TOTAL FEDERAL F&A	$219,709	$	$	$	$
TOTAL COST	$952,542	$	$	$	$

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	(b)(4)%	(b)(4)%	(b)(4)%	(b)(4)%	(b)(4)%
F&A Cost Base 1	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)
F&A Costs 1	$219,709	$ (b)(4)	$ (b)(4)	$ (b)(4)	$ (b)(4)

NIH SGA R | Version: 1 - 06/15/2015 23:32:00 Generated on: 7/31/2015 12:00:32 AM

PI: **Olson-Kennedy, Johanna L**	Title: The Impact of Early Medical Treatment in Transgender Youth	
Received: 03/05/2020	Opportunity: PA-18-729 Clinical Trial:Optional	Council: 10/2020
Competition ID: FORMS-E	FOA Title: Research on the Health of Transgender and Gender Nonconforming Populations (R01 Clinical Trial Optional)	
2R01HD082554-06A1	Dual: MD,MH	Accession Number: 4415555
IPF: 1520001	Organization: CHILDREN'S HOSPITAL OF LOS ANGELES	
Former Number: 2R01HD082554-06	Department:	
IRG/SRG: SPIP	AIDS: N	Expedited: N
Subtotal Direct Costs (excludes consortium F&A) Year 6: (b)(4) Year 7: (b)(4) Year 8: (b)(4) Year 9: (b)(4) Year 10: (b)(4)	Animals: N Humans: Y Clinical Trial: N Current HS Code: (b)(4) HESC: N HFT: N	New Investigator: N Early Stage Investigator: N
Senior/Key Personnel:	*Organization:*	*Role Category:*
Johanna Olson-Kennedy M.D.	CHILDREN'S HOSPITAL LOS ANGELES	PD/PI
STEPHEN ROSENTHAL M.D.	University of California, San Francisco	MPI
Yee-Ming Chan M.D.	Boston Children's Hospital	MPI
Robert Garofalo M.D.	LURIE CHILDREN'S HOSPITAL OF CHICAGO	MPI
Marco Hidalgo Ph.D	Children's Hospital Los Angeles	Co-Investigator
Diane Ehrensaft Ph.D	University of California, San Francisco	Co-Investigator
(b)(6)	(b)(6)	Co-Investigator
Diane Chen Ph.D	Ann & Robert H. Lurie Children's Hospital	Co-Investigator
(b)(6)	(b)(6)	Co-Investigator
Carolyn Wong Ph.D	Children's Hospital Los Angeles	Co-Investigator
Asa Radix M.D.	Callen-Lorde Community Health Center	Co-Investigator

Appendices

Appendix_A

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE | **State Application Identifier**

1. TYPE OF SUBMISSION*

❍ Pre-application ● Application ❍ Changed/Corrected Application

4.a. Federal Identifier
HD082554

b. Agency Routing Number

2. DATE SUBMITTED | **Application Identifier**

c. Previous Grants.gov Tracking Number

5. APPLICANT INFORMATION **Organizational DUNS*:** 0522779360000

Legal Name*: CHILDREN'S HOSPITAL LOS ANGELES
Department:
Division:
Street1*: 4650 Sunset Boulevard
Street2: Mailstop #97
City*: LOS ANGELES
County:
State*: CA: California
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 900276062

Person to be contacted on matters involving this application
Prefix: (b)(6) First Name*: (b)(6) Middle Name: Last Name*: (b)(6) Suffix:
Position/Title: (b)(6)
Street1*: 4650 Sunset Blvd
Street2: Mailstop #97
City*: Los Angeles
County:
State*: CA: California
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 900276062
Phone Number*: (b)(6) Fax Number: (b)(6) Email: chlaawards@chla.usc.edu

6. EMPLOYER IDENTIFICATION NUMBER *(EIN) or (TIN)** 1956121916A1

7. TYPE OF APPLICANT* M: Nonprofit with 501C3 IRS Status (Other than Institution of Higher Education)

Other (Specify):
Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

8. TYPE OF APPLICATION*
❍ New ● Resubmission
❍ Renewal ❍ Continuation ❍ Revision

If Revision, mark appropriate box(es).
❍ A. Increase Award ❍ B. Decrease Award ❍ C. Increase Duration
❍ D. Decrease Duration ❍ E. Other *(specify)* :

Is this application being submitted to other agencies?* ❍Yes ●No What other Agencies?

9. NAME OF FEDERAL AGENCY*
National Institutes of Health

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER
TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
The Impact of Early Medical Treatment in Transgender Youth

12. PROPOSED PROJECT
Start Date* Ending Date*
09/01/2020 08/31/2025

13. CONGRESSIONAL DISTRICTS OF APPLICANT
CA-028

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: Dr. First Name*: Johanna Middle Name: L Last Name*: Olson-Kennedy Suffix: M.D.

Position/Title: Associate Professor of Clinical Pediatrics
Organization Name*: CHILDREN'S HOSPITAL LOS ANGELES
Department:
Division:
Street1*: 4650 W Sunset Blvd
Street2: Mailstop 2
City*: Los Angeles
County:
State*: CA: California
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 90027-6062
Phone Number*: (b)(6) Fax Number: Email*: jolson@chla.usc.edu

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested*	$ (b)(4)
b. Total Non-Federal Funds*	$0.00
c. Total Federal & Non-Federal Funds*	$ (b)(4)
d. Estimated Program Income*	$0.00

16.IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?*

a. YES ○ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE:

b. NO ● PROGRAM IS NOT COVERED BY E.O. 12372; OR

○ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

● I agree*

** The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

18. SFLLL or OTHER EXPLANATORY DOCUMENTATION File Name:

19. AUTHORIZED REPRESENTATIVE

Prefix: (b)(6) First Name*: (b)(6) Middle Name: Last Name*: (b)(6) Suffix:

Position/Title*: (b)(6)
Organization Name*: Children's Hospital Los Angeles
Department: Research Administration
Division: The Saban Research Institute
Street1*: 4650 Sunset Blvd
Street2: Mailstop #97
City*: Los Angeles
County:
State*: CA: California
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 900276062
Phone Number*: (b)(6) Fax Number: Email*: chlaawards@chla.usc.edu

Signature of Authorized Representative* (b)(6)

Date Signed* 03/05/2020

20. PRE-APPLICATION File Name:

21. COVER LETTER ATTACHMENT File Name:Cover_Letter_with_Large_Grant_Wavier.pdf

424 R&R and PHS-398 Specific
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OMB Number: 4040-0010
Expiration Date: 10/31/2019

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	Children's Hospital Los Angeles
Duns Number:	0522779360000
Street1*:	4650 W Sunset Blvd
Street2:	Mailstop $97
City*:	Los Angeles
County:	
State*:	CA: California
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	90027-6062
Project/Performance Site Congressional District*:	CA-028

Project/Performance Site Location 1

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	The Children's Hospital Corporation
DUNS Number:	0765937220000
Street1*:	300 Longwood Avenue
Street2:	
City*:	Boston
County:	
State*:	MA: Massachusetts
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	02115-5724
Project/Performance Site Congressional District*:	MA-007

Project/Performance Site Location 2

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	Ann & Robert H Lurie Children's Hospital of Chicago
DUNS Number:	0744387550000
Street1*:	225 E Chicago Ave
Street2:	
City*:	Chicago
County:	
State*:	IL: Illinois
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	60611-2991
Project/Performance Site Congressional District*:	IL-007

Project/Performance Site Location 3

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	The Regents of the University of California, San Francisco
DUNS Number:	0948783370000
Street1*:	550 16th St
Street2:	
City*:	San Francisco
County:	
State*:	CA: California
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	94158-0434
Project/Performance Site Congressional District*:	CA-012

Project/Performance Site Location 4

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	Community Health Project, Inc.
DUNS Number:	6082374830000
Street1*:	356 W 18th St
Street2:	
City*:	New York
County:	
State*:	NY: New York
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	10011-4401
Project/Performance Site Congressional District*:	NY-010

Additional Location(s) File Name:

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ○ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ○ Yes ● No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6 _ 7 _ 8

If NO, is the IRB review Pending? ○ **Yes** ● **No**

IRB Approval Date: 02-21-2020

Human Subject Assurance Number 00001914

2. Are Vertebrate Animals Used?* ○ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ○ Yes ○ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ○ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ○ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ○ Yes ○ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ○ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ○ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	Project_Summary_Abstract.pdf
8. Project Narrative*	Project_Narrative.pdf
9. Bibliography & References Cited	Bibliography_and_References_Cited.pdf
10.Facilities & Other Resources	Facilities_and_Other_Resources.pdf
11.Equipment	Equipment.pdf

PROJECT SUMMARY/ABSTRACT

Transgender children and adolescents are a poorly understood and a distinctly understudied population in the United States. The limited available data suggest that youth with gender dysphoria are at increased risk for negative mental and medical health outcomes including anxiety, depression, HIV acquisition, suicide, and substance use compared to their peers. Therefore, medical intervention is aimed at alleviating gender dysphoria and ameliorating potential negative outcomes. In 2011, the Institute of Medicine called for research to understand and improve the lives of gender minority populations. In 2015, Children's Hospital Los Angeles/USC, Boston Children's Hospital/Harvard Medical School, Benioff Children's Hospitals/UCSF and Lurie Children's Hospital of Chicago/Northwestern University were awarded NIH grant R01HD082554 to develop and implement a multidisciplinary, prospective, observational study: The Impact of Early Medical Treatment in Transgender Youth (TYC). The original aims were to examine physiological and psychosocial effects of medical intervention for transgender and gender diverse (TGD) youth with gender dysphoria observed for 24-months. To date, TYC has successfully recruited *beyond* its targeted baseline sample in two cohorts: (i) 95 youth initiating pubertal suppression with gonadotropin releasing hormone analogs (GnRHa) along with one parent/guardian (n=95), as well as (ii) 316 youth initiating gender-affirming hormone (GAH) therapy (testosterone or estrogen). Early results have demonstrated a positive trend regarding mental health response to gender affirming interventions. The primary objective of this observational, longitudinal, multicenter renewal study is to evaluate the longer-term physiological and psychological impact of existing medical treatment protocols initiated in adolescence on youth with gender dysphoria for up to an additional 4 years. A second objective is to enhance the diversity and size of existing cohorts by enrolling additional youth of color (YOC) into both cohorts (n=89) and enroll additional assigned males at birth specifically into the GAH cohort (n=110). The final objective is to add measurements of psychosocial variables required to answer new questions posed in this renewal application. A key feature of the renewal period is that most individuals in the original GnRHa cohort will be starting GAH treatment. By examining outcomes of TGD youth who initiated GAH treatment with and without histories of puberty suppression, TYC will be well positioned to examine key questions about the sequencing of puberty suppression and GAH treatment on health outcomes. Continuing our current research is imperative to expand the scant evidence-base currently guiding the clinical care of TGD youth and thus, is of considerable public health significance. Results from this study have the potential to significantly impact services provided to TGD youth in the U.S. by making available rigorous scientific evidence outlining the longer-term impact and safety of early treatments based on pubertal development stage.

PROJECT NARRATIVE

The Institute of Medicine's report "The Health of Lesbian, Gay, Bisexual, and Transgender (LGBT) People," published in 2011, called for the development of evidence-based and rigorous research aimed at understanding the health implications of hormone use in transgender individuals. The goal of the proposed research is to extend follow-up data collection over an additional 4 years for this multi-site, observational study examining the physiological and psychosocial outcomes of existing medical treatment protocols for gender dysphoria in two cohorts: early pubertal and late pubertal transgender and gender diverse youth. Results from this study have the potential to significantly impact the medical and mental health services provided to transgender and gender diverse youth in the U.S. by making available rigorous scientific evidence outlining the longer-term impact and safety of early treatments based on pubertal development stage.

FACILITIES & OTHER RESOURCES

CHILDREN'S HOSPITAL LOS ANGELES (CHLA)

Established in 1901, Children's Hospital Los Angeles, located in the heart of metropolitan Los Angeles, is one of the nation's largest pediatric hospitals. It is ranked by U.S. News and World Report as among the top 5 pediatric hospitals for clinical excellence in the nation. With an established track record of high-quality, patient-centered research, it is currently eighth in funding by the National Institutes of Health among children's hospitals. CHLA is also one of America's premier teaching hospitals through its affiliation since 1932 with Keck School of Medicine of the University of Southern California (USC). It is also an active partner in USC's Southern California Clinical and Translational Science Institute.

A private, non-profit hospital, CHLA provides care to a large and highly diverse pediatric population, treating more than 107,000 individual patients annually, with nearly 14,600 inpatient admissions and 72,000 Emergency Department visits every year. Over 16,000 pediatric surgeries are performed annually, including heart and lung transplants, cardiac catheterizations, cancer and neurosurgeries, and orthopaedic procedures. The institution is designated as a Level I Pediatric Trauma Center, and has a 365-bed capacity, including 106 pediatric critical-care beds – more than any other hospital in the Western United States.

One of CHLA's overarching aims is to foster innovative research to improve the health and wellness of children, as well as ensuring the delivery of culturally competent care for diverse pediatric populations. This is achieved through a combination of basic, clinical and translational research studies focused on developing and improving diagnostics and therapeutics – research conducted under the auspices of The Saban Research Institute, one of the largest and most productive pediatric research facilities in the United States.

The Saban Research Institute

The Saban Research Institute is one of the few freestanding research centers in the U.S. where scientific inquiry is combined with clinical care and is devoted exclusively to children. Our goal is to improve the health and wellness of children through a combination of basic, clinical and translational studies. Research is performed at the lab bench, in the clinic and in the community. The Saban Research Institute maintains strong scientific and strategic affiliations with the University of Southern California (USC) and, in particular, the Keck School of Medicine of USC. All of the Institute's principal investigators (clinical investigators, physician-scientists and PhD scientists) are USC faculty, and many have collaborative projects with scientists at the Keck School of Medicine and other departments at USC. The Institute's researchers also are involved in collaborative projects with academic institutions throughout the U.S. and abroad. CHLA is currently ranked 7th in NIH funding among freestanding children's hospitals.

TSRI is responsible for providing administrative support for all research activities at CHLA. This facility occupies a total of 198,000 net sq. ft. of research space on the CHLA campus including a 10 story Smith Research Tower, a 5 story Saban Research Building, an 8,000 sq. ft. Clinical Investigation Center, and a 10,000 sq. ft. Community Health, Outcomes and Intervention Research Unit. The Research Institute is home to a centralized Sponsored Projects Office, which is responsible for proposal and award administration as well as financial management. The Institute also supports a series of core facilities fully equipped with state of the art instrumentation to facilitate research at CHLA and USC.

A central initiative of TSRI seeks to understand the childhood and developmental origins of health and disease across the lifespan. The Institute's interdisciplinary research is organized around three synergistic areas of focus

that together fully explore the developmental origins of health and disease while addressing the most pressing issues of children's health. These three areas are: The Institute for the Developing Mind; Metabolism, Immunity, Infection and Inflammation; Regenerative Medicine and Cellular Therapies. Research Programs also include 1) Cancer and Blood Diseases, 2) Community, Health Outcomes and Intervention Research, 3) Developmental Biology and Regenerative Medicine, 4) Developmental Neuroscience, 5) Diabetes and Obesity, 6) Human Physiology and Imaging, and 7) Immunology, Infectious Disease and Pathogens. Additionally, TSRI has committed resources to the following strategies in pursuit of our goal of becoming a top 5 nationally ranked stand-alone children's academic health center: 1) recruiting and retaining outstanding junior and senior faculty from all groups; 2) expanding the scientific infrastructure and research facilities to promote synergy and interaction and to enhance translational research; 3) training and mentoring the next generation of pediatric scientists; and 4) promoting innovative and interactive research.

TSRI Clinical Research Support Office

The Clinical Research Support Office (CRSO) of TSRI, in collaboration with the Southern California Clinical and Translational Science Institute, provides efficient and cost-effective research support to facilitate efficient, high-quality, and safe clinical research and trials throughout CHLA. CRSO staff are experts in implementing, conducting, and monitoring clinical research studies and trials from start-up to close-out, supporting both novice and experienced clinical investigators and study teams.

Research Navigation: Our Research Navigator connects investigators with the services and support needed to conduct efficient, safe and high-quality clinical research and trials at CHLA. This includes study design, feasibility assessment, regulatory and IRB approval, participant recruitment, study implementation and coordination, registration and billing, study closeout, etc.

Study Start-up:	***Study Implementation:***	***Study Closeout:***
• Study design • Feasibility assessment • Identifying collaborators/community partners • Scientific review • IRB review • Regulatory documents • Recruitment and accrual planning • Source documents • Biostatistical consultation	• Research coordination • Research nursing • Neuropsychological assessment • Participant recruitment and retention • Participant registration and billing • Study documentation • Informed consent • Regulatory binders • Adverse events • Study drug accountability • Internal and external audits	• Sponsor and monitoring visits • IRB closeout • Case Report Form storage • Biostatistical analysis • Publication of study findings

Research Regulatory Support: Regulatory support is critical for any clinical research involving children. Each study requires rigorous institutional and federal regulatory review and documentation, including approval of human subjects protection by the Institutional Review Board (IRB). Our Regulatory and IRB Support Specialist provides the clinical research community at CHLA with support and information, as well as fee-for-services to coordinate regulatory affairs for clinical research studies and trails. Support includes preparation and submission of study protocol to Institutional Review Board (IRB); preparation and filing of Investigational New Drug/Investigational Device Exemption (IND/IDE) initial submissions to the Food and Drug Administration (FDA) as well as yearly reports; and completion of essential study regulatory documents.

Biostatistical Support: Our Biostatisticians support clinical research across CHLA by providing expert consultation services for sample size calculation, analysis of data, and publication development, as well as educating the research community, and collaborating on active research projects.

Division of Adolescent and Young Adult Medicine

The proposed research will be conducted within the Division of Adolescent and Young Adult Medicine at CHLA under the direction of Contact Multiple Principal Investigator Dr. Johanna Olson-Kennedy. The Division of Adolescent and Young Adult Medicine (DAYAM), established in 1963, is known for its innovative service models, leadership in community collaboration, training programs in adolescent health care, and research regarding adolescent issues. The mission of the DAYAM is to advance the health and well-being of adolescents by integrating health care, health promotion and prevention, youth development, professional education, advocacy, and research and evaluation in response to the needs of young people and their communities.

Since the early 1980s, the DAYAM has had a special focus on at-risk youth and has developed model programs to serve targeted groups of vulnerable youth. These youth include transgender youth, homeless and runaway youth, substance-using youth, youth with mental health problems, youth at-risk for and infected with HIV, pregnant teens and teen parents, and youth at-risk for violence. Through these programs, the DAYAM provides health care, mental health and substance abuse treatment, case management, and health education services to over 7,000 youth annually. The DAYAM operates an outpatient clinic for youth ages 10 to 24, and through a mental health contract from the County, provides individual, family, group, and multi-family treatment to over 300 youth annually. Since 1982, the DAYAM has established itself as a leader in needs assessments, epidemiologic and ethnographic studies, and research and evaluation projects focused on adolescents and young adults from diverse communities throughout Los Angeles County and the Southern California region.

The DAYAM has an accredited adolescent medicine fellowship program, one of only two in California, and an American Psychological Association accredited pre-doctoral internship and post-doctoral fellowship program. In fiscal year 2018-19, the DAYAM's total operating budget exceeded 13 million dollars of which 4.1 million dollars were dedicated to a wide range of research activities, including research associated with the national Adolescent Trials Network; the development and evaluation of an evidence-based HIV/AIDS prevention intervention that is being adapted for application with youth from middle and high schools and with emerging adults; epidemiologic and intervention research related to substance use and misuse; service needs assessment of homeless and runaway youth; and evaluation research related to DAYAM programs.

The DAYAM's key programs for this research study are:

The Center for Transyouth Health and Development: The Center for Transyouth Health and Development promotes healthy futures for transyouth by providing services, research, training, and capacity building that are developmentally informed, affirmative, compassionate, and holistic for gender diverse children and transyouth. The Center includes the nation's largest pediatric clinic for transgender youth and gender diverse children. The Center also houses the DAYAM's mental health, health education, research, and capacity building assistance focused on transgender youth and children. The Medical Director, Dr. Johanna Olson-Kennedy, is the PI of this proposal, and Dr. Marco Hidalgo (Co-I) is the licensed psychologist for the Center. He is also the Contact MPI for a multi-site R01 that is establishing a national cohort of prepubertal transgender and gender diverse youth and following them to better understand how these children report their gender identity over time and their psychosocial health and wellbeing.

The Research and Evaluation Program: The Research and Evaluation Program conducts mixed and single-method epidemiologic and evaluation research related to issues affecting the health and well-being of

adolescents and young adults. Past and current research foci include, but are not limited to, substance use and misuse, HIV/AIDS, reproductive health, relationship violence, transition of youth with chronic illness and special needs to adult care, and service needs of disenfranchised or marginalized youth. The Research and Evaluation Program also develops and conducts research for each DAYAM service program to support the development and document the impact of our prevention and intervention programs and increase our understanding of the youth utilizing DAYAM services.

Additional programs include:

The Teenage and Young Adult Health Center: health care for youth with complex medical and psychosocial problems. In addition to the health care services offered through the health center, we provide health care at the Los Angeles and Long Beach Job Corps and in community clinics. The clinical space for outpatient medical services is 3,314 square feet. Clinical space includes eight exam rooms, two laboratories for collection of lab specimens and a utility room containing storage for immunizations and lab collection materials. Access to radiologic services is located at the main campus of CHLA approximately one-half mile from the DAYAM.

The Behavioral Health Program: mental health services for youth 12-21 including assessment; individual, family, and group counseling; and case management services funded by Medi-Cal and under the auspice of the Department of Mental Health;

The HIV Care Program: The HIV Care program provides specialty health care, mental health counseling, case management, and support for HIV positive youth and HIV prevention services for transgender youth and young gay men. The DAYAM has a harm reduction program for transgender youth offering hormone treatment, case management, mental health services, and youth leadership opportunities. Division Director (b)(6) serves as the Site Principal Investigator for research related to the Adolescent Trials Network (ATN), an NIH-supported national consortium of academic institutions throughout the US. The ATN has put forth a broad research agenda calling for "interventional studies, conducted collaboratively and independently when needed, aimed at the primary, secondary, and tertiary prevention of HIV infection in pre-adolescents, adolescents, and young adults at the trial units in the network." CHLA has been engaged in dozens of ATN studies over the past 16 years as a primary or collaborative research site.

The Homeless Adolescent Wellness Clinic: health care, mental health counseling, case management and support for homeless youth provided at the DAYAM, at local homeless organizations, and on the streets. The project is a member of the six agency Hollywood Homeless Youth Partnership and the countywide LA Coalition to End Youth Homelessness.

Adolescent Transition Clinic: in collaboration with CHLA sub-specialty clinics, the Adolescent Transition Team caters to teens and young adults with special health issues and their families to facilitate transition into adulthood and adult healthcare. Provides comprehensive, individualized mental, physical, and social evaluation and planning that emphasizes empowering each young adult to take control of his/her own health issues to ensure successful transition. Tools include health passports, interactive web programs, financial counseling, individual therapy, and peer support.

Project NATEEN: case management and support for pregnant and parenting teens and young adults with an on-site school, a special employment and life skills program for young parents, and specialized services for young fathers; and

The Substance Abuse Prevention and Treatment Program: no-cost outpatient services for youth ages 10-25 and community health education and promotion. Services include walk-in screenings and short and long-term individual, family, and group sessions.

While the Division Director oversees all divisional activities, the DAYAM operates with a 25-member Management Team that includes the managers of each of the community based programs, medical directors, the Director of Behavioral Health, the Director of Research, the Fiscal Administrator, the Associate Director, and the Division Director. A seven person senior management team provides oversight for clinical, research, and training activities, as well as finance and administration, and includes the Director, Associate Director, Fiscal Administrator, Director of Research, and Director of Behavioral Health Services.

Computers: CHLA research investigators have access to research computing facilities at their workstations in their offices and at PC workstations in the Biostatistics lab located at CHLA. A computer lab is designated for data entry, management, and statistical support staff. The DAYAM and CHOIR provide statistical database, spreadsheet, word-processing, desktop publishing, accounting, and a variety of utility software programs to all platforms. E-mail and internet access are provided to all staff. In addition, the USC University Computing Services provides a comprehensive computing environment to support instructional and research goals of the University and its affiliated campuses, including CHLA. Facilities and services include campus-wide networking, a variety of central host systems, public user rooms, and support for distributed systems, hardware maintenance, and user support services. It provides support for and access to departmental and shared campus computing resources, library information systems, and regional, national, and international information resources. USC utilizes the most up-to-date hardware equipment and supports a variety of communication and scientific hardware and software systems. CHLA is connected to USC's health sciences network. Every research faculty and staff member have a computer on his or her desk for database and statistical analysis, simulation, spreadsheet work, and text processing and has the capability to communicate electronically.

Offices: CHLA is in the Los Angeles community known as East Hollywood, approximately eight miles from the USC Health Sciences Campus and the Keck School of Medicine. The investigators and research staff will be located at the offices in the Division of Adolescent and Young Adult Medicine. The DAYAM's main administrative offices and comprehensive ambulatory health clinic, the Teenage and Young Adult Health Center, are located at 5000 Sunset Blvd., in a seven-story office building several blocks from the main campus of CHLA. The Division occupies 20,233 square feet on three floors. Offices are equipped with computers and broadband connections to the internet. There are two large multi-purpose rooms. One is 560 square feet on the fourth floor, and the other is 400 square feet on the fifth floor. Four smaller conference rooms are also available on the fourth and seventh floors.

Other

The Children's Hospital Health Sciences Library provides resources and services to CHLA staff. In addition to its collection of 3500 print books and 170+ current print journal subscriptions, the library supplies access to over 200 electronic books and 2000 electronic journals. Online access is available anywhere in the hospital or from remote computers that connect to the USC network.

In addition to books and journals, the library also provides local and remote access to various journal article databases including: Ovid MEDLINE, Ovid CINAHL, PubMed, PsycINFO, Science Citation Index, and Journal Citation Reports. The library's book and journal catalog, as well as that of the USC Norris Medical Library (with whom the CHLA library has reciprocal borrowing agreements), is searchable online as well.

Library services include mediated literature searching (searches conducted by a librarian), interlibrary loan borrowing (for obtaining materials that the CHLA library does not own), Ovid AutoAlerts (a current awareness service that delivers weekly citations that match a researcher's predefined topic), and HouseCalls (one-one-one, time-of-need meetings where the librarian can instruct users on a variety of topics including database searching, PowerPoint, or EndNote).

BOSTON CHILDREN'S HOSPITAL

Boston Children's Hospital (BCH), a teaching affiliate of Harvard Medical School, is one of the largest academic pediatric facilities in the world and home to the world's largest and most active research enterprise at a pediatric center. As such, BCH is excellently positioned to provide the scientific environment necessary for the proposed research. In addition, BCH provides significant administrative support, ranging from fund management, research administration, grant and sponsored research management, to innovation and intellectual property management, and numerous core facilities.

BCH is located within the Harvard Medical Area which encompasses several blocks surrounding Longwood Avenue in Boston, is one of the most densely concentrated biomedical research communities in the world. This area includes Harvard Medical School (HMS) and over 10 Harvard-affiliated hospitals and research institutes. A majority of the 2,500 full-time Harvard Medical School Faculty members and their trainees work in these neighboring buildings. Over 6,000 M.D.s, Ph.D.s, and M.D./Ph.D.s, including postgraduate trainees, work within the Longwood Medical Area. Investigators at BCH are members of a scientifically and intellectually rich environment, which provides plentiful opportunities for exciting research collaboration, fruitful mentoring, and collegial support.

The BCH Division of Endocrinology

The Outpatient Program of the Division of Endocrinology includes over 30 attending physicians and conducts over 33,000 outpatient visits per year. It also houses a vibrant research program. There are over 50 researchers who are working on a variety of projects spanning from basic, translational, clinical, and health services research.

The Gender Management Service (GeMS) at Boston Children's Hospital

GeMS is one of the nation's oldest multi-disciplinary clinics caring for transgender children, adolescents, and young adults. The GeMS staff includes five attending physicians, a nurse practitioner, five attending psychologists, two social workers, and two pediatric endocrinology fellows. The demand for services at GeMS continues to grow, and in 2018 GeMS had nearly 400 new patient visits.

Office Space

Co-PI Chan and Co-I (b)(6) each have 90 sq. ft. of office space, and study personnel have desks, computers, and phones for review of clinical records, recruitment of research subjects, and storage of research data on secure servers. There are many Windows-based computers with direct Ethernet connection to the Children's Hospital Clinical and Research Computing Networks.

BCH Information Services Department

The BCH Information Services Department (ISD) provides resources and assists investigators with their computational needs through programs including Research Computing and Clinical Research Information Technology (CRIT). ISD supports secure teleconferencing through Zoom. Software available through Research Computing either for free or for a nominal licensing fee includes Adobe Acrobat Pro, EndNote, and MATLAB, SAS, SPSS, Stata, GraphPad Prism, in addition to Microsoft Office, which is standard on all BCH computers. Research Computing also provides network folders for secure storage and file-sharing between research staff, as well as systems for secure file sharing outside of BCH.

ANN & ROBERT H. LURIE CHILDREN'S HOSPITAL OF CHICAGO

Established in 1882, Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's; formerly known as Children's Memorial Hospital), is a 288 bed pediatric facility with over 1,400 pediatric/adolescent specialists focusing on 70 medical specialties. Located at state of the art facilities at 225 E. Chicago Avenue in Chicago, Lurie Children's is the largest pediatric hospital in Illinois. Lurie Children's provides care to more young people than any other Chicago-area hospital or medical center with more than 330,000 outpatient visits each year and more than 9,000 inpatient visits. Lurie Children's is ranked as being one of the top ten pediatric hospitals in the Unites States by U.S. News and World Report.

Lurie is accredited by the Joint Commission on Accreditation of Healthcare Organization (JCAHO) and has a specifically designed and allocated, fully equipped ambulatory adolescent and HIV clinic located at its Dayton building. This space, opened in the fall of 2018, recognizes the unique needs of adolescents and young adults and is tailored to their needs. The Dayton building affords the opportunity for group meetings and interventions, housing three 25 person capacity conference rooms, one 50 person capacity conference room and one 100 person capacity conference room, all outfitted with state of the art audiovisual equipment allowing for presentations and web conferencing. Since 2001, Lurie Children's has had an on-going, federally-funded research center overseen by Dr. Garofalo and (b)(6) (since 2011), providing seamless services and research activities to high risk youth and young adults.

Stanley Manne Children's Research Institute

Stanley Manne Children's Research Institute (Manne Research Institute) is one of 13 interdisciplinary research centers and institutes of Northwestern University's Feinberg School of Medicine (NUFSM). It is the largest pediatric research facility in the Chicago-area with over 200 investigators, 500 staff members, and 100 trainees working together to understand, prevent, and investigate pediatric illnesses and injuries. All principal investigators at the Institute are full-time faculty members at NUFSM. The Institute is the research arm of Lurie Children's, which is the primary pediatric teaching hospital for NUFSM. A key goal of the Institute is to train the next generation of pediatric specialists while advancing children's healthcare. The Institute is one of five institutions in the United States dedicated exclusively to pediatric research.

The main laboratory of the Institute is a 71,000 square-foot facility that opened in 1995. A subdivision of the Institute, the Child Health Research Core, focuses on population-based research, including multidisciplinary investigations of children in their families and communities. As the research institute affiliated with Lurie Children's, the Institute has a long history of successfully managing large federal research projects and complements the 3 missions of the hospital: (1) providing culturally relevant child and adolescent health care services; (2) conducting research into the prevention, causes and treatment of diseases that affect children and adolescents; and (3) advocacy for the general well-being of all children/adolescents.

The Institute has a plethora of resources available to support investigators and staff in research activities, including: state of the art equipment, statistical consultation services, a comprehensive research library, a clinical research unit, and an office specializing in editorial assistance for manuscripts and grants.

Clinical & Translational Research Program

Housed within the Stanley Manne Children's Research Institute, the Clinical and Translational Research Program (CTRP) works to increase research activities to ensure that patients within Lurie Children's and beyond have access to the latest evidence-based treatments. The CTRP supports research efforts by training new

investigators, promoting collaboration, increasing institutional support, and expanding resources available with The Stanley Manne Children's Research Institute.

Biostatistics Research Core: The Biostatistics Research Core supports investigators within the Stanley Manne Children's Research Institute by providing statistical consulting from study inception through final analysis. The Biostatistics Research Core is also a partner of the Biostatistics Collaboration Center of Northwestern University and is thus able to provide investigators with a wide network of statistical experts.

Research Scientist Navigator: The research navigators at Lurie Children's utilize the hospital's extensive research infrastructure to assist investigators through the entirety of the research process. Navigators are available to consult investigators on topics such as: grant submissions, budget development, regulatory assistance, and connection with cross-campus interdisciplinary programs.

Clinical Research Unit: The Clinical Research Unit, located on the 19th floor of Lurie Children's Hospital, is a state of the art facility dedicated to facilitating seamless implementation of research protocols in a child and adolescent friendly setting. The Clinical Research Unit employs a highly trained staff to assist investigators across eight outpatient rooms, six inpatient beds, and several consultation rooms.

D2P Manuscript and Grant Editorial Services: The D2P services offers professional editorial assistance on both grants and manuscripts to investigators within Lurie Children's. The D2P services works quickly to provide revision to ensure that research ideas are expressed effectively and concisely.

Northwestern University Clinical and Translational Science Institute (NUCATS):
NUCATS, a NIH-funded Clinical and Translational Science Award (CTSA), is home for clinical and translational science at Northwestern University and its clinical affiliates, including Lurie Children's. NUCATS provides the infrastructure, services, and resources for maximizing and leveraging interdisciplinary "bench to bedside" research. NUCATS is a series of partnerships of basic and clinical scientists, academic clinicians and community clinic members, clinical researchers and participants in clinical trials, biomedical industry professionals, engineers, and physicians. NUCATS is comprised of a number of distinct but highly interactive centers that work together to transform how translational research is performed at Northwestern. These centers cover all aspects of biomedical research including clinical trials, community engagement, biomedical informatics, regulatory support, core resources, and pilot programs to promote both cutting-edge research and the development of radical new technologies. The five centers within NUCATS are the Center for Clinical Research, Center for Education and Career Development, Center for Translational Innovation, Community Engaged Research Center, and Biomedical Informatics Center.

Division of Adolescent Medicine:
The proposed research will be conducted within the Division of Adolescent Medicine at Lurie Children's Hospital, led by Dr. Garofalo. The Division of Adolescent Medicine employees a team pediatricians, clinical child and pediatric psychologists, licensed clinical social workers, researchers, and supporting staff to provide the highest standard of medical and mental health services to children and adolescents up to age 25. Additionally, the division expands evidence-based practice through research activities and provides community-based education on adolescent health issues.

Research activities within the Division of Adolescent Medicine are housed within The Center for Gender, Sexuality, and HIV Prevention. The Center for Gender, Sexuality and HIV Prevention, a Research Center of Excellence at Stanley Manne Children's Research Institute, directed by Dr. Garofalo with (b)(6) as associate

director, examines a broad range of multidisciplinary academic subjects including sexual health, gender, sexuality, HIV prevention and health disparities affecting adolescent and young adult populations at risk of acquiring HIV. The Center works to make the lives of high-risk adolescent populations healthier through clinical care, education and evaluation as well as professional training, research and public health advocacy. These populations include but are not limited to homeless, lesbian, gay, bisexual, transgender and questioning (LGBTQ) youth. The Center strives to partner with like-minded organizations to create an environment where clinicians, academics and scientists can collaborate to design projects with public health significance. Currently the Center is involved as primary awardee or subcontractor on 13 government-funded research projects and programs focusing on the Center's target populations.

Computer:
Lurie Children's maintains excellent computer support staff for general faculty services (i.e. internet access, purchasing, hardware support) and provides staff with full access to the computer resources. PCs are connected to secure Intranet, allowing for coordination of data entry and management. The PI and Co-I will have full access to computers and support staff for technical assistance.

Office:
The faculty listed have adequate office space at the Center for Gender, Sexuality, and HIV Prevention at Lurie Children's. The Center is located at 1440 North Dayton Street in Chicago and is co-located with the outpatient clinical care team in Adolescent Medicine as well as offices for the Pritzker Department of Child Psychiatry and Behavioral Health. The Potocsnak Family Division of Adolescent and Young Adult Medicine at the Dayton building offers a full range of services housed in a teen-friendly facility including, but not limited to adolescent and young adult primary care, behavioral health, family planning and the frontier programs in mental health in primary care, gender and sex development program. Additionally, services include confidential HIV/STI testing and outreach, community engagement and programming. The Division multidisciplinary model includes a strong focus on supporting underserved and marginalized young people as well as community engagement and collaboration.

Laboratory:
The Special Infectious Disease Laboratory (SIDL) at Lurie Children's was formed in 1987 to support HIV-related behavioral and clinical trials, including the ACTG/IMPAACT (formerly PACTG). Over the past 29 years our laboratory has supported more than 85 behavioral and clinical as well as more than 70 non-NIH clinical trials that included behavioral and therapeutic trials of various antimicrobial and antiviral agents as well as vaccine trials.

The SIDL has been CLIA Certified (14D0665386) for more than 24 years and is inspected biannually by the College of American Pathologists. The SIDL has a full time staff of 4 technologists and a quality assurance coordinator with more than 70 cumulative years of technical experience. Our clinical testing services include serological and molecular-based tests to determine HIV infection status including HIV DNA PCR and Rapid HIV screening. Molecular testing includes HIV DNA PCR and HIV RNA PCR (Abbott RealTime). The SIDL has more than 21 years of experience in HIV RNA PCR and DNA PCR. Flow cytometry (CD4/CD8 determinations and other panels) and culture-based testing have been performed in our laboratory since 1993. The SIDL has been IQA certified for PBMC processing and cryopreservation since 2008. The full staff of the SIDL is trained annually in all aspects of both domestic and international shipping and is certified by (b)(6) (trained in IATA Shipping through the NIH/DAIDS shipping training program) via our in-house certification program (which mirrors the CDC program). Both electronic shipment preparation and tracking software are available in the laboratory to manage and track specimen movement.

UNIVERSITY OF CALIFORNIA SAN FRANCISCO (UCSF) BENIOFF CHILDREN'S HOSPITALS

UCSF Benioff Children's Hospitals

The University of California, San Francisco (UCSF) is one of the premier medical research institutions in the world. UCSF is consistently ranked as one of the top five medical schools in the US. The 107-acre Parnassus campus houses the schools of Medicine, Dentistry, Pharmacy and Nursing, the Graduate Division, the UCSF Medical Center, and the Langley-Porter Neuropsychiatric Institute. Additional campuses include the Mt. Zion Cancer Center, the Laurel Heights Campus and the new 43 acre Mission Bay Campus, with >1.3 million ft^2. of research space. There are >1200 principal investigators at UCSF, including 4 Nobel laureates, 42 members of the National Academy of Sciences and 75 members of the Institute of Medicine. Thus, scientific excellence pervades the campus.

The UCSF Benioff Children's Hospital-San Francisco is located in the new Mission Bay Campus and accounts for about 25% of the total clinical activity at UCSF Medical Center. Opened in February 2015, the 183 bed children's hospital is part of a hospital complex dedicated to women's, children's and cancer care. UCSF Benioff Children's Hospital Mission Bay lies on a 14.5 acre plot directly adjacent to the 43 acre UCSF Mission Bay Campus. The Benioff Children's Hospital Mission Bay, assisted by a $100 million gift from (b)(6) (b)(6), includes state of the art facilities for translational research with faculty fully integrated into the Mission Bay research campus, ambulatory facilities along with space for faculty offices to accommodate the expansion of laboratory, clinical, and translational research within the Department of Pediatrics. With the administrative offices of the Clinical and Translational Sciences Institute (CTSI) located adjacent to Mission Bay, the Benioff Children's Hospital faculty and trainees are uniquely positioned to take maximum advantage of the UCSF tradition of research collaboration.

The recent transition of Oakland Children's Hospital to become UCSF Benioff Children's Hospital-Oakland has enabled us to extend our current study to the Oakland site, enabling increased racial and ethnic diversity to our clinical research programs (see detailed description of the UCSF Child and Adolescent Gender Center, below). For approximately 100 years, UCSF Benioff Children's Hospital-Oakland has been delivering exceptional medical care to children from all regions of California. This enterprise also incudes the Children's Hospital Oakland Research Institute, which is one of the top 10 NIH-funded pediatric research centers in the country. One of UCSF Benioff Children's Hospital-Oakland's greatest strengths lies in the diverse population that it serves. The patient population of UCSF Benioff Children's Hospital-Oakland reflects the multicultural and socioeconomic diversity of the Bay Area's six million residents. Over 40 different languages are spoken by families with youth entering schools in the city of Oakland.

The Clinical and Translational Sciences Institute (CTSI)

UCSF was one of the first twelve academic institutions selected to be part of the NIH's national clinical and translational science consortium, resulting in the creation of the Clinical and Translational Sciences Institute (CTSI). The consortium has a charter to transform clinical and translational research to ensure that the best health solutions get to patients as quickly as possible. The UCSF CTSI is a cross-campus institute. The four major goals of the CTSI are to: 1) enhance, support, and integrate existing training programs, thereby increasing the number and quality of programs, and providing trainees from diverse disciplines with the knowledge, skills, and motivation to make significant contributions to clinical and translational research; 2) enhance, support, and integrate existing infrastructure, thereby implementing changes required to foster the design and conduct of a diverse spectrum of high quality, original clinical investigation and translational research: 3) enhance career development of faculty and trainees involved in clinical investigation and translational research by providing mentoring, providing opportunities to catalyze original research, and changing the academic culture to appropriately reward original, multidisciplinary, collaborative work; and 4) create a "virtual home" for clinical and translational researchers, thereby nurturing communication, encouraging collaboration, fostering original ideas, and catalyzing the successful conduct of clinical investigation and translational research.

UCSF Benioff Children's Hospital Department of Pediatrics

For more than 100 years, the UCSF Department of Pediatrics has distinguished itself in educating the next generation of physicians, delivering excellent clinical care to young patients, and constantly improving treatment options through biomedical research. UCSF physicians deliver expert care to patients at UCSF

Benioff Children's Hospital-San Francisco, ranked among the nation's best children's hospitals by U.S. News & World Report. UCSF pediatric faculty also care for patients at UCSF Benioff Children's Hospital-Oakland, UCSF Medical Center at Mount Zion, San Francisco General Hospital, and at a number of outreach clinics throughout Northern California. Children and their families come from around the state, nation and the world to receive the benefit of our expertise. The clinical care provided in the Department of Pediatrics is nourished by pioneering basic and clinical research conducted by physician-scientists. Faculty members in the Department of Pediatrics receive millions of dollars annually in research funding that supports the rapid translation of laboratory discoveries into new treatments. The department is also rich in clinical research programs that inform the care of patients with common and rare disorders. The UCSF Department of Pediatrics also receives wide respect for its innovative residency and fellowship training opportunities. Its large, multi-site pediatric residency program pairs a diverse and often underserved patient population with the extraordinary clinical, educational and research resources of UCSF.

UCSF Child and Adolescent Gender Center (CAGC)

The UCSF Child and Adolescent Gender Center (CAGC) is one of the leading centers for the multidisciplinary care of transgender youth in the U.S. and serves as the Pediatric/Adolescent clinical arm of the widely recognized UCSF Center of Excellence for Transgender Health. Housed in the Division of Pediatric Endocrinology at the UCSF Benioff Children's Hospital, the CAGC offers patients and their families an integrated and coherent set of services—medical, mental health, educational, legal, and other forms of advocacy—across the span of childhood and young adulthood, empowering families to more effectively plan for the current and future needs of their gender diverse children. Through a unified network of multidisciplinary professionals, the CAGC serves to develop and provide best clinical practices, create greater acceptance of gender diversity in schools and other institutions, provide advocacy, influence public policy, and conduct research aimed at enhancing the healthy development and wellbeing of transgender children, adolescents, and young adults. Stephen Rosenthal, MD, Professor of Pediatrics and past Program Director for Pediatric Endocrinology, serves as co-founder and Medical Director of the UCSF CAGC. In collaboration with Dr. Rosenthal, the UCSF CAGC provides mental health support under the direction of Diane Ehrensaft, PhD, Associate Professor of Pediatrics, internationally known child psychologist/gender specialist and widely recognized author. In addition, the CAGC provides advocacy support through collaboration with Gender Spectrum, one of the leading national advocacy groups for transgender youth. The CAGC also provides nursing, social work, and legal support. The CAGC is the only such multi-disciplinary gender program in northern California, attracting patients not only from California, but nationally and internationally as well. **A steady increase in referrals has led to the opening of two satellite UCSF CAGC clinical sites in San Mateo, California, and in Oakland, California. Addition of the Oakland site, in particular, has brought increased racial and ethnic diversity to our CAGC clinical research programs.**

Drs. Rosenthal and Ehrensaft, Principal Investigator and Co-Investigator, respectively, are nationally and internationally recognized experts in the care of gender nonconforming and transgender youth. Both Drs. Rosenthal and Ehrensaft were recently appointed to the World Professional Association for Transgender Health (WPATH) Task Force for revision of the WPATH Standards of Care, and both previously served on the WPATH Consensus Committee for revisions of the International Classification of Disease (ICD)-11 pertaining to transgender youth and adults. Dr. Rosenthal is also Past President of the Pediatric Endocrine Society (PES), has served as Vice President of the Endocrine Society (ES), Clinical Scientist Position, and is currently a member of the Endocrine Society Board of Directors. He has authored multiple manuscripts on transgender youth, including a "State-of-the-art" invited review in *Pediatrics*, an invited review in the "Approach to the Patient" series for the *Journal of Clinical Endocrinology and Metabolism (JCEM)*, and is co-author on the revised Endocrine Society Clinical Practice Guideline for Gender-Dysphoric/Gender-Incongruent Persons, published in *JCEM* in 2017. Dr. Rosenthal has also served as Associate Editor for *Transgender Health*. He has been an invited speaker on transgender youth at annual meetings of PES and ES as well as at international meetings of WPATH, and has lectured on this subject at academic centers throughout the U.S. and in several countries in Europe, Asia, and South America. Dr. Rosenthal is also the recipient of the UCSF Chancellor Award for LGBT leadership in recognition of his work with transgender youth, is the recipient of the UCSF Family Advisory Council Caring Tree Award and the UCSF Haile T. Debas Academy of Medical Educators Excellence in Teaching Award, and was recently (2018) awarded the WPATH Harry Benjamin Lectureship "for significant contributions to the field of transgender health through research, healthcare provision, and medical education". Dr. Rosenthal has also had significant experience conducting multi-center trials. He has served as site PI for NIH/NICHD "Disorders of Sex Development: Platform for Basic and

Translational Research" (1R01HD068138-01A1), and is currently PI (multiple PI format) for NIH/NICHD "The Impact of Early Medical Treatment in Transgender Youth" (1R01HD082554) and co-Investigator for "Sex Hormone effect on Neurodevelopment: Controlled puberty in transgender adolescents" (1R01MH115349), and "Gender Nonconformity in Prepubescent Children: A Longitudinal Study" (1R01HD097122).

Dr. Ehrensaft has authored two books and over twenty journal articles or book chapters on the clinical needs and developmental trajectories of gender-nonconforming and youth, and has lectured nationally and internationally (Europe, South America, and Australia) on this topic, as well as having been featured in several documentaries (e.g. National Public Radio, BBC, CNN). Dr. Ehrensaft is currently serving as co-Investigator for NIH/NICHD "The Impact of Early Medical Treatment in Transgender Youth" (1R01HD082554) and as Principal Investigator (multiple PI format) for "Gender Nonconformity in Prepubescent Children: A Longitudinal Study" (1R01HD097122). As a reflection of its national and international impact, the UCSF CAGC was recently featured in a documentary on transgender youth produced by the British Broadcasting Corporation (BBC).

UCSF Transgender Center of Excellence

The UCSF Transgender Center of Excellence (CoE) was established in 2007 with the mission to increase access to comprehensive, effective, and affirming health care services for transgender and gender-variant communities. The CoE combines the unique strengths and resources of a nationally renowned training and capacity-building institution, the Pacific AIDS Education and Training Center (PAETC), and an internationally recognized leader in HIV prevention research, the Center for AIDS Prevention Studies (CAPS), both of which are housed at UCSF. The ultimate CoE goal is to improve the overall health and well-being of transgender individuals by developing and implementing programs in response to community-identified needs. The CoE has implemented several programs for the transgender community with support from the U.S. Centers for Disease Control and Prevention (CDC), the California Endowment, and the National Institutes of Health (NIH). These programs include Coalitions in Action for Transgender Community Health (CATCH): Project to increase community capacity to engage in HIV prevention activities; the Transitions Project, focused on training and assistance for programs seeking to implement HIV prevention interventions in transgender communities, particularly transgender communities of color; and the Transgender Evaluation and Technical Assistance Center (TETAC), focused on enhancing engagement and retention in quality HIV care for transgender women of color.

The UCSF Transgender CoE is linked with a range of clinical services which complement the educational, research, and capacity building missions of the CoE. The UCSF CAGC serves as the Pediatric/Adolescent clinical arm of the UCSF Transgender CoE. The multidisciplinary CAGC is complemented by transgender-focused clinical services in adult primary care, reproductive endocrinology, psychiatry, gynecology and gynecologic surgery, and urology and urologic surgery.

UCSF Library

The UCSF library, built in 1990, is both a traditional library, containing extensive collections of scientific books and journals relevant to the study of endocrinology, and is also a teaching and database management facility with The Interactive Learning Center and Center for Knowledge Management. The UCSF Digital Library (GALEN II) offers easy access to a broad collection of databases, reference resources, electronic journals and catalogues of local materials. Through the newly created California Digital Library, students, trainees, and faculty are able to view and request materials from the 10 UC campus libraries. The UCSF library has 900,000 volumes including 2,600 current subscriptions. In addition to the journals and books in the library, the Interactive Learning Centers maintain facilities for computing with PC and Macintosh computers, printers, software, documentation, consulting support, and connections to the internet, and electronic classrooms. The Multimedia Development Lab provides hardware, software, and consulting support for development of curriculum-integrated, educational materials. Education and Consulting Services offers curriculum-integrated instruction and seminars that assist students, fellows, and faculty in the use of databases, internet, and personal file management software. The Center for Knowledge Management develops knowledge bases and on-line tools for the health sciences, pursues applied research projects, and serves as a laboratory for graduate students interested in using new technologies to solve important health sciences information problems.

Offices

In the new configuration of Mission Hall at the new UCSF Mission Bay site, cubicles with computers and laser

printers are available to all faculty, as well as individual offices, as needed. This facility is directly across the street from the Pediatrics outpatient facility where the CAGC clinic in housed. In addition, The Department of Pediatrics at UCSF provides general office machines, faxes, photocopying, and office supplies.

CALLEN-LORDE COMMUNITY HEALTH CENTER

Callen-Lorde Community Health Center (CLCHC) is located across 3 clinical sites and 2 administrative sites in lower Manhattan and the Bronx. Its main clinical site is a 27,000-square foot, six-story building that is an ADA-compliant, fully licensed New York State Department of Health Article 28 Diagnostic and Treatment Center. In 2002, CLCHC was also designated a Federally Qualified Health Center (FQHC) by the U.S. Department of Health and Human Services' Bureau of Primary Health Care. The CLCHC is within walking distance of two subway stations and several bus stops. CLCHC's mission to o provide care to the LGBT communities and people living with HIV. **In 2018 CLCHC provided gender affirming services to over 5,000 transgender and gender nonconforming individuals, making this the largest clinic cohort of transgender people in North America.** The Health Outreach to Teens (HOTT) Program is the adolescent medicine program at CLCHC. Since 1989, The HOTT program has offered a vital link to health care and related services for LGBT and questioning youth. In 2015, the HOTT program had 1415 active patients between 13 and 24 years of age. **Approximately 450 of the HOTT clients identify as transmasculine (assigned female at birth).** This age group is racially and ethnically diverse; (b)(4); (b)(6) (b)(4); (b)(6) [redacted]. The majority of HIV-negative youth at CLCHC are at risk for HIV and STIs. 30-40% engages in exchange of sex for money or shelter. Approximately 70% of HOTT clients use one or more illicit substances, e.g. heroin, crystal methamphetamine, cocaine or marijuana. Psychosocial issues facing the target population include: homelessness or unstable housing; history of violence or abuse; mental illnesses (such as depression, suicidal ideation, feelings of isolation and inadequacy); alcohol/drug abuse; unsafe sex; and involvement with the criminal justice system.

Laboratory

There is a 250 sq ft laboratory on the main floor which is open Monday through Saturday staffed by 2 full-time phlebotomists. Callen-Lorde performs phlebotomy onsite and sends samples to external laboratories, including BioReference laboratories, Quest diagnostics, Monogram Biosciences and the Wadsworth Center, New York State Public Health Laboratory. In addition the 4 medical floors have satellite labs and ability to perform phlebotomy during routine clinical sessions. We conduct the following CLIA-waived and Provider-performed Microscopy. HIV testing – Alere Determine HIV-1/2 Ag/Ab, insti® hiv-1/hiv-2, Urine HCG, Contour Blood Glucose Procedure, Rapid Strep A Procedure, Fecal Occult Blood Procedure, Urinalysis and point of care rapid hepatitis C testing. Point-of-Care PPM Procedures performed by physicians include CLIA Provider Performed Microscopy and Vaginal Wet Prep and KOH Prep. The laboratory staff is trained and able to prepare specimens, including centrifugation and serum separation and preparation of specimens for transport to external laboratories. The staff follows strict protocols to maintain specimen integrity, which includes specimen and requisition identification, and the agency is in compliance with the regulations concerning the shipping and transport of specimens by ground for laboratory testing. Laboratory equipment at the site includes 2 centrifuges, two temperature monitored specimen storage refrigerators, a specimen freezer, storage capacity for the approximately 70 specimen tubes daily generated for the study and other study materials, label printers and an interface between the EHR and laboratory allowing accurate and timely printing of laboratory requests. The research department has a dedicated Stirling Ultracold Freezer Shuttle™ ULT-25NE that is capable of storing biological specimens at -86 degrees centigrade.

Clinical

The HOTT Program's multidisciplinary team targets a fluid, underserved and hard-to-reach population, ages 13-24 at high risk for HIV, sexually transmitted infections (STI) and unplanned pregnancy. The HOTT program is staffed by 3 physicians, 2 nurse practitioners, 1 registered nurse, 2 LPNs, 1 LCSW and 1 LMHC. There is a part-time psychiatrist who specializes in adolescent care and 5 case managers. HOTT provides a range of services

which include primary care, sexual and reproductive health services, family planning, mental health treatment (including psychiatry and individual counseling), dental care, prevention services for HIV/STI/unwanted pregnancy, HIV testing and counseling, case management, pharmacy vouchers, and other supportive services. These services are provided at both HOTT's youth-only modern medical suite at CLCHC and on its mobile medical unit (medical van), which travels throughout New York City. HIV positive and at-risk LGBT youth are best served in an environment with staff appropriately trained to deliver culturally competent health care. A key factor in CLCHC's success in retention of at risk and HIV positive youth has been the existence of a safe and welcoming space for LGBT youth. The HOTT Program is located on the second floor of the CLCHC with a dedicated clinical suite for adolescent services, a waiting room solely for young people, and separate registration area. The on-site medical suite provides a welcoming drop-in space for adolescents. The program has a dedicated entrance and stairwell accessible only to adolescent clients, allowing youth a unique, pleasant and private setting to congregate, even when not receiving medical services. The waiting area and the conference room are decorated with youth-friendly health posters and there is video player and television for viewing both educational and entertainment videos as well as books and literature. At CLCHC all staff receives ongoing cultural sensitivity training, specifically addressing the unique needs of our LGBT clients. Also important is the fact that many staff are members of the LGBT community, giving young clients access to positive adult LGBT role models in the community. This is especially important for those who may be distanced from their traditional families due to homophobia or transphobia. CLCHC's mobile medical unit allows street youth to confidentially access medical care in their own environment. We also provide metrocards for public transportation to facilitate compliance with appointments while helping the youth to coordinate other health care and ancillary appointments. Several members of the clinical, research and outreach team are Spanish speaking and CLCHC offers translation services in all languages as well as for the hearing impaired.

Animal

Not applicable

Offices

Dr. Radix has an office at the 19th street site equipped with a desk, several chairs, lockable filing cabinets and desk phone. They have access to fax machines, copiers, and full administrative support. There is a large group meeting room at the 19th street room which is linked to video and audio for virtual meetings. These facilities ensure that the investigator will have the necessary space in which to meet and communicate with other investigators as needed through Skype or phone meetings.

Computers

Dr. Radix occupies an office with a PC desktop computer (Hewlett Packard intel-based PC, running Windows 2010 Professional) with encryption software and hardwired high-speed internet connection. In addition Dr. Radix has HP Elitebook 2170p with VPN access to the Callen-Lorde network. The computers are equipped with Skype for Windows and other telecommunication software. The combination of these information technologies contributes to the potential for success by assuring efficient data handling and communication among members of the research team. There is also access to the internet through Callen-Lorde's secure wireless network.

Data Center

Callen-Lorde has onsite IT support (2 staff) at the 18th street location as well as a separate health informatics team (HIT) with 4 staff nearby at the 19th street location. The HIT Data Center has customized software for data management, statistical analysis, study design, internet access, and e-mail. The network is protected by a router, firewall and antivirus software. The database server is backed up continuously by a second server running in parallel. All network computers are backed up by a central tape backup system that is located off-site.

Institutional Support

Callen Lorde provides strong institutional support for investigators including staff education, development courses, resources for travel, and support for training; the center will provide logistical support such as administrative and grant management, including access to an administrative assistant.

Other

Dr. Asa Radix is on on the management team. They have collaborated with Dr Garofalo on other research projects. Dr. Radix has undergone the necessary human subjects trainings.

EQUIPMENT

Not applicable for this application.

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: Dr. First Name*: Johanna Middle Name L Last Name*: Olson-Kennedy Suffix: M.D.

Position/Title*: Associate Professor of Clinical Pediatrics
Organization Name*: CHILDREN'S HOSPITAL LOS ANGELES
Department:
Division:
Street1*: 4650 W Sunset Blvd
Street2: Mailstop 2
City*: Los Angeles
County:
State*: CA: California
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 90027-6062

Phone Number*: (b)(6) Fax Number:

E-Mail*: jolson@chla.usc.edu

Credential, e.g., agency login: (b)(6)

Project Role*: PD/PI Other Project Role Category:

Degree Type: MD,MS,MS,BS Degree Year: 1997,1993,2015,1992

Attach Biographical Sketch*: File Name: Olson-Kennedy_Biosketch.pdf

Attach Current & Pending Support: File Name:

Tracking Number: GRANT13040415

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: STEPHEN Middle Name M Last Name*: ROSENTHAL Suffix: M.D.

Position/Title*: Professor of Pediatrics
Organization Name*: University of California, San Francisco
Department: Pediatric Enocrinology
Division:
Street1*: 550 16th St, 4th Floor
Street2: Mission Hall, Box 0434
City*: SAN FRANCISCO
County:
State*: CA: California
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 94143-0434

Phone Number*: (b)(6) Fax Number:

E-Mail*: stephen.rosenthal@ucsf.edu

Credential, e.g., agency login: (b)(6)

Project Role*: PD/PI Other Project Role Category:

Degree Type: MD,BA Degree Year: 1976

Attach Biographical Sketch*: File Name: Rosenthal_Biosketch.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Yee-Ming Middle Name Last Name*: Chan Suffix: M.D.

Position/Title*: Assistant Professor of Pediatrics
Organization Name*: Boston Children's Hospital
Department: Pediatrics
Division: Endocrinology
Street1*: 300 Longwood Avenue
Street2: 6th Floor
City*: Boston
County:
State*: MA: Massachusetts
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 02115-5711

Phone Number*: (b)(6) Fax Number:

E-Mail*: Yee-Ming.Chan@childrens.harvard.edu

Credential, e.g., agency login: (b)(6)

Project Role*: PD/PI Other Project Role Category:

Degree Type: MD,PHD,BS Degree Year: 2002,2000,1993

Attach Biographical Sketch*: File Name: Chan_Biosketch.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Robert Middle Name Last Name*: Garofalo Suffix: M.D.

Position/Title*: Division Head - Adolescent Medicine
Organization Name*: LURIE CHILDREN'S HOSPITAL OF CHICAGO
Department:
Division:
Street1*: 225 E. CHICAGO AVE - BOX 161
Street2:
City*: CHICAGO
County:
State*: IL: Illinois
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 60611-2605

Phone Number*: (b)(6) Fax Number:

E-Mail*: rgarofalo@luriechildrens.org

Credential, e.g., agency login: (b)(6)

Project Role*: PD/PI Other Project Role Category:

Degree Type: MD,MPH,BS Degree Year: 1992,1999,1988

Attach Biographical Sketch*: File Name: Garofalo_Biosketch.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Marco Middle Name Armando Last Name*: Hidalgo Suffix: Ph.D

Position/Title*: Psychologist; Assistant Professor
Organization Name*: Children's Hospital Los Angeles
Department: Pediatrics
Division: Adolescent Medicine
Street1*: 4650 Sunset Blvd
Street2: MS#2
City*: Los Angeles
County:
State*: CA: California
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 90027-6062

Phone Number*: (b)(6) Fax Number:

E-Mail*: MAHIDALGO@CHLA.USC.EDU

Credential, e.g., agency login: (b)(6)

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PHD,MA,BA Degree Year: 2011,2007,2004

Attach Biographical Sketch*: File Name: Hidalgo_Biosketch.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Diane Middle Name Last Name*: Ehrensaft Suffix: Ph.D

Position/Title*: Adjunct Associate Professor of Pediatrics
Organization Name*: University of California, San Francisco
Department: Pediatrics
Division:
Street1*: 1825 4th St, 6th Floor
Street2: Ron Conway Family Gateway Medical Building
City*: San Francisco
County:
State*: CA: California
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 94143-2350

Phone Number*: (b)(6) Fax Number:

E-Mail*: diane.ehrensaft@ucsf.edu

Credential, e.g., agency login: (b)(6)

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year: 1974

Attach Biographical Sketch*: File Name: Ehrensaft_Biosketch.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: (b)(6) First Name*: (b)(6) Middle Name (b)(6) Last Name*: (b)(6) Suffix: (b)(6)

Position/Title*: Assistant Professor
Organization Name*: Boston Children's Hospital
Department: Pediatrics
Division: Endocrinology
Street1*: 300 Longwood Ave
Street2: 6th Floor
City*: Boston
County:
State*: MA: Massachusetts
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 02115-5711

Phone Number*: (b)(6) Fax Number:

E-Mail*: (b)(6)

Credential, e.g., agency login: (b)(6)

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: (b)(6) Degree Year: (b)(6)

Attach Biographical Sketch*: File Name: (b)(6)

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Diane Middle Name Last Name*: Chen Suffix: Ph.D

Position/Title*: Pediatric Psychologist
Organization Name*: Ann & Robert H. Lurie Children's Hospital
Department: Pediatrics & Psychiatry
Division: Adolescent Medicine
Street1*: 225 E Chicago Ave
Street2: Box 161B
City*: Chicago
County:
State*: IL: Illinois
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 60611-2605

Phone Number*: (b)(6) Fax Number:

E-Mail*: dichen@luriechildrens.org

Credential, e.g., agency login: (b)(6)

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PHD,MA,BA Degree Year: 2012,2008,2004

Attach Biographical Sketch*: File Name: Chen_Biosketch.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: (b)(First Name*: (b)(6) Middle Name (b)(6) Last Name*: (b)(6) Suffix: (b)(6)

Position/Title*: Associate Professor
Organization Name*: Children's Hospital Los Angeles
Department: Pediatrics
Division: Adolescent Medicine
Street1*: 4650 W Sunset Blvd
Street2: Mailstop 2
City*: Los Angeles
County:
State*: CA: California
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 90027-6062

Phone Number*: (b)(6) Fax Number:

E-Mail*: (b)(6)

Credential, e.g., agency login: (b)(6)

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: (b)(6) Degree Year:

Attach Biographical Sketch*: File Name: (b)(6)

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Carolyn Middle Name Fong Nap Last Name*: Wong Suffix: Ph.D

Position/Title*: Assistant Professor
Organization Name*: Children's Hospital Los Angeles
Department: Pediatrics
Division:
Street1*: 4650 W Sunset Blvd
Street2: Mailstop 2
City*: Los Angeles
County:
State*: CA: California
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 90027-6062

Phone Number*: 323-361-8427 Fax Number:

E-Mail*: cawong@chla.usc.edu

Credential, e.g., agency login: (b)(6)

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PHD Degree Year: 2005

Attach Biographical Sketch*: File Name: Wong_Biosketch.pdf

Attach Current & Pending Support: File Name:

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Asa Middle Name Elian Last Name*: Radix Suffix: M.D.

Position/Title*: Director of Research and Education
Organization Name*: Callen-Lorde Community Health Center
Department:
Division:
Street1*: 356 West 18th St
Street2:
City*: New York
County:
State*: NY: New York
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 10011-4401

Phone Number*: (b)(6) Fax Number:

E-Mail*: aradix@callen-lorde.org

Credential, e.g., agency login: (b)(6)

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: MD,PHD,MPH,MPHIL Degree Year: 1988,2020,1997,1995

Attach Biographical Sketch*: File Name: Radix_Biosketch.pdf

Attach Current & Pending Support: File Name:

OMB No. 0925-0001 and 0925-0002 (Rev. 06/19 Approved Through 03/31/2020)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES**.

NAME: Olson-Kennedy, Johanna L MD

eRA COMMONS USER NAME (credential, e.g., agency login): (b)(6)

POSITION TITLE: Associate Professor of Clinical Pediatrics

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of California San Diego	BA	1992	Animal Physiology
Chicago Medical School	MS	1993	Applied Physiology
Chicago Medical School	MD	1997	Medicine
Children's Hospital Orange County	Internship & Residency	2000	Pediatrics
Children's Hospital Los Angeles	Fellowship	2003	Adolescent Medicine
University of Southern California	MS	2015	Clinical, Biomedical and Translational Investigations

A. Personal Statement

The primary objective of this observational, longitudinal, multicenter renewal study is to **extend the initial 2-year follow-up period to evaluate longer-term physiological and psychological impact of puberty suppression initiated in early puberty on youth with gender dysphoria for up to an additional 4 years**. A second objective is to enhance the diversity and size of existing cohorts by enrolling additional youth of color (YOC) into both cohorts and enroll additional males assigned at birth specifically into the GAH cohort. A third objective is to add measurements of psychosocial variables required to answer new questions posed this renewal application. The proposed project aligns with the objectives outlined by the Institute of Medicine in "The Health of Lesbian, Gay, Bisexual, and Transgender People." Long-term follow-up on this ethnically diverse population is critical for generating the scientific evidence required to maximize treatment protocols and generate standards of care for the U.S.

The long-term goal of the proposed project is to establish a national research network dedicated to studies that have clinical and developmental relevance to the experience of gender dysphoria from early childhood to early adulthood. Over the last 14 years, I have developed research protocols, recruited and retained subjects and have initiated data analyses. I have been the recipient of two training grants to pursue research in the gender non-conforming and transgender youth populations – the first, a two year Clinical Research Career Development Award through the Saban Research Institute at CHLA and the second, a KL2 translational science award from USC ending in June 2014. I completed a Master's Degree in Clinical, Biomedical and Translational Investigations at USC and have thirteen first author papers about transgender youth. In 2015, I was awarded a large, multisite R01 grant sponsored by the NICHD to investigate the impact of puberty blockers and cross-sex hormones on mental health and physiologic parameters of transgender youth, the initial stage of this renewal proposal. I am the Medical Director of our Center for Transyouth Health and Development at CHLA. Over the past 14 years, I have expanded the services of the Center to include care and consultative services for gender non-conforming and transgender children and adolescents ages 4 to 24. Over the past 14 years, I have worked tirelessly to successfully quadruple the number of patients served by the Center, with

1,700 patients actively enrolled in the clinic at this time, making ours the largest transgender youth clinic in the U.S. Finally, I have made dozens of appearances across the country and on national television over the past several years to educate the community, parents, and providers about the needs of transgender youth.

B. Positions and Honors

Positions and Employment

2002-2003	Kaiser Permanente, Los Angeles, CA
2003-2005	University of California Los Angeles, Los Angeles, CA
2003-2006	Pediatric Practice of Zimble/Reinstein, Encino, CA
2004-2006	Northeast Valley Health Corporation, Los Angeles, CA
2006-2015	Assistant Professor of Clinical Pediatrics, University of Southern California, Los Angeles, CA
2008-2012	Adolescent Medicine Fellowship Program Director Children's Hospital Los Angeles, Los Angeles, CA
2011-	Medical Director of the Center for Transyouth Health and Development, Children's Hospital Los Angeles, Los Angeles, CA
2015-	Associate Professor of Clinical Pediatrics, University of Southern California, Los Angeles, CA

Other Experience and Professional Memberships

1997-	Member, American Academy of Pediatrics
2000-	Member, Society for Adolescent Health and Medicine
2010-2016	Board Member, Transyouth Family Allies
2010-	Member, World Professional Association of Transgender Health
2016-	Associate Editor, Transgender Health
2017-	NIH Peer Review Committee: Cognition and Perception, ad hoc reviewer

Honors

2009	Health Care Advocacy Champion – Democratic Advocates for Disability Issues.
2010	Clinical Research Academic Career Development Award -Saban Research Center TSRI Program: Community Health Outcomes and Intervention Project: "Treating transgender youth: the impact of a multidisciplinary care team approach".
2012	Extraordinary Service Award – Equality California
2014	Anne Marie Staas Ally Award - Stonewall Democratic Club
2014	Recognition Award for Outstanding, Compassionate and Innovative Service - SoCal Society for Adolescent Health and Medicine Regional Chapter
2015	Champion Award – The Champion Fund, Division of Adolescent and Young Adult Medicine, Children's Hospital Los Angeles

C. Contribution to Science

1. My primary clinical and research interest has been focused on transgender children and youth ages 25 and under. I have written and reviewed multiple manuscripts related to transgender adolescent specific care and developmental processes. Research regarding the transgender adolescent experience is developing and I have contributed to building knowledge most recently through my multisite R01 studying the impact of early care for transgender adolescents. Understanding clinical and mental health implications of early treatment for transgender children and adolescents is a critical step to advancing treatment and updating universal guidelines for the care of transgender children and youth.

    a. Olson-Kennedy J, Chan YM, Rosenthal S, et al. Creating the Trans Youth Research Network: A Collaborative Research Endeavor. *Transgend Health*. 2019;4(1):304–312. Published 2019 Nov 1. doi:10.1089/trgh.2019.0024
    b. Olson-Kennedy J, Chan YM, Garofalo R, et al. Impact of Early Medical Treatment for Transgender Youth: Protocol for the Longitudinal, Observational Trans Youth Care Study. JMIR Res Protoc. 2019;8(7):e14434. Published 2019 Jul 9. doi:10.2196/14434

c. Olson-Kennedy J, Warus J, Okonta V, et al. Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts. JAMA Pediatr 2018;172:431-6
d. Olson-Kennedy J, Okonta V, Clark LF, Belzer M. Physiologic Response to Gender-Affirming Hormones Among Transgender Youth. J Adolesc Health. 2018 Apr;62(4):397-401. doi: 10.1016/j.jadohealth.2017.08.005. Epub 2017 Oct 19. PubMed PMID: 29056436.

2. In addition to the contributions mentioned above, I have focused on mental health and transgender identity development. While we know transgender people experience mental health disparities related to stigma and discrimination, we are continually developing knowledge regarding mental health and developmental trajectories for children and adolescents. Understanding these developmental milestones and investigating experiences of gender dysphoria during childhood and adolescence adds to knowledge previously stemming from adult-focused research.

   a. Pang KC, Notini L, McDougall R, Gillum L, Savulescu J, Wilkinson D, **Olson-Kennedy J**, Telfer MM, Lantos JD, Long-term Puberty Suppression for a Nonbinary Teenager, Pediatrics, 2020 Feb;145(2). pii: e20191606. doi: 10.1542/peds.2019-1606
   b. Clark B, Virani A, Ehrensaft D, **Olson-Kennedy J**, (2019) Resisting the Post-Truth Era: Maintaining a Commitment to Science and Social Justice in Bioethics, The American Journal of Bioethics, 19:7, W1-W3
   c. **Olson-Kennedy J**, Hot Topics and Fresh Paradigms in Gender, Diversity, and Care, AMSTARs, 2018
   d. **Olson-Kennedy J**. Mental Health Disparities Among Transgender Youth Rethinking the Role of Professionals. *JAMA Pediatr*. 2016;170(5):423–424. doi:10.1001/jamapediatrics.2016.01

3. My earlier work has centered on medical treatment and adherence support for youth living with HIV. Youth living with HIV represent a distinct population with specific medical needs. The care and treatment of youth living with HIV require a specialized lens regarding the relationship between social support, stigma and access to care on medication adherence, health and mental health. These studies represent some of the early research on young people living with HIV, documenting the challenges associated with caring for young people who experience multiple systemic and complicated health and psychosocial histories.

   a. Puccio, JA, Belzer M, **Olson J,** Martinez M, Salata C, Tucker D, Tanaka D. The use of cell phone reminder calls for assisting HIV infected youth to adhere to highly active antiretroviral therapy: A pilot study. AIDS Patient Care and STDs. June 1, 2005, 20(6): 438-444. doi:10.1089/apc.2006.20.438. PMID: 16789857.
   b. Belzer M, Sanchez K, **Olson J**, Jacobs A, Tucker D. Advance supply of emergency contraception: A Randomized Trial in Adolescent Mothers. J Pediatr Adolesc Gynecol. 2005 Oct;18(5):347-54. PMID: 16202939.
   c. Belzer ME**, Olson J**. Adherence in adolescents: A review of the literature. Adolescent Medicine: State of the Art Reviews. Evaluation and Management of Adolescent Issues. Amer Acad of Peds 2008:1999-117.
   d. Belzer ME, Naar-King S, **Olson J**, Sarr M, Thornton S, Kahana SY, Gaur AH, Clark LF; Adolescent Medicine Trials Network for HIV/AIDS Interventions. The use of cell phone support for non-adherent HIV-infected youth and young adults: an initial randomized and controlled intervention trail. AIDS Behav. 2014 Apr;18(4):686-96. PMCID: PMC3962719.

Complete list of published work in My Bibliography:

https://www.ncbi.nlm.nih.gov/myncbi/1vUzyczJks5k7/bibliography/public

Ongoing Research Support

R01 HD097122 Hidalgo/Chen/Ehrensaft/Tishelman (MPI) 03/21/19-02/29/24
A Longitudinal Study of Gender Nonconformity in Prepubescent Children
This research aims to establish a national cohort of prepubertal transgender/gender- nonconforming (TGNC) children (and their parents), and longitudinally observe this cohort to expand the body of empirical knowledge

pertaining to gender development and cognition in TGNC children, their mental health symptomology and functioning over time, and how family-initiated social gender transition may predict or alleviate mental health symptoms and/or diagnoses.
Role: Co-Investigator

1R01HD082554 Olson-Kennedy (PI) 08/01/15-6/30/20
The Impact of Early Medical Treatment in Transgender Youth
This is a multicenter study which will be the first in the U.S. to evaluate the long-term outcomes of medical treatment for transgender youth. This study will provide essential, evidence-based information on the physiological and psychosocial impact, as well as safety, of hormone blockers and cross-sex hormones use in this population.
Role: Contact Principal Investigator (multi-PI)

Completed Research Support

1R01AI128796 Aldrovandi (PI) 02/24/17-01/31/20
Maturation, Infectibility and Trauma Contributes to HIV Susceptibility in Adolescents
This study explores the overarching hypothesis that fluctuations in sex steroid levels and mucosal trauma (sexual activity) are key determinants of mucosal immune activation and epithelial integrity, and that microbial communities are central to these processes. We will pursue this hypothesis by examining longitudinal changes in the anogenital microbiome as well as protein expression at these mucosal sites during sexual maturation (cisgender youth) and in hormonally-controlled sexual maturation (transgender youth). Associations between sex steroid levels, microbial community composition, mucosal trauma, and vaginal proteins will be determined and modeled.
Role: Co-Investigator

BIOGRAPHICAL SKETCH

NAME: Rosenthal, Stephen M. MD

eRA COMMONS USER NAME (credential, e.g., agency login): (b)(6)

POSITION TITLE: Professor of Pediatrics

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Yale University, CT	B.A.	05/1972	Psychology
Columbia University, College of Physicians & Surgeons, NY	M.D.	05/1976	Medicine
Presbyterian Hospital, Columbia University, NY		06/1979	Intern/Resident, Pediatrics
University of California, San Francisco		06/1982	Fellow, Pediatric Endocrinology

A. Personal Statement

Since joining the UCSF faculty in 1982, I have mentored numerous trainees in our Pediatric Endocrine NIH-T32 Fellowship program, and have served as Program Director, Director of the Pediatric Endocrine Clinics, and as Co-Director of the Disorders (Differences) of Sex Development (DSD) Clinic. I currently serve as co-founder and Medical Director of the UCSF Child and Adolescent Gender Center (CAGC). The UCSF CAGC serves as the Pediatric/Adolescent clinical arm of the widely recognized UCSF Center of Excellence for Transgender Health. The CAGC provides multi-disciplinary care to gender non-conforming/transgender youth and adolescents, attracting patients not only from northern California, but from as far away as Alaska, Florida, and Egypt. In recognition of my experience providing care and developing protocols for transgender youth, I was appointed as the official representative of the Pediatric Endocrine Society (PES) to the Endocrine Society (ES)'s Clinical Practice Guidelines Revision Task Force for the Care of Transgender Individuals, and was appointed to the World Professional Association for Transgender Health (WPATH) Consensus committee for revisions of the International Classification of Disease (ICD)-11 pertaining to transgender youth and adults. I am also Past President of the Pediatric Endocrine Society, have served as Vice President of the Endocrine Society, Clinical Scientist Position, and am a member of the Endocrine Society Board of Directors. I have authored multiple manuscripts on transgender youth, including a "State-of-the-art" invited review in *Pediatrics*, an invited review in the "Approach to the Patient" series for the *Journal of Clinical Endocrinology and Metabolism (JCEM)*, and am co-author on the revised Endocrine Society Clinical Practice Guideline for Gender-Dysphoric/Gender-Incongruent Persons, published in *JCEM* in 2017. I have also served as Associate Editor for *Transgender Health*. I have been an invited speaker on transgender youth at annual meetings of PES and ES as well as at international meetings of WPATH, and have lectured on this subject at academic centers throughout the U.S. and in several countries in Europe, Asia, and South America. I am also the recipient of the UCSF Chancellor Award for LGBT leadership in recognition of my work with transgender youth and was recently (2018) awarded the WPATH Harry Benjamin Lectureship "for significant contributions to the field of transgender health through research, healthcare provision, and medical education". I have had significant experience conducting multi-center trials. I have served as site PI for NIH/NICHD "Disorders of Sex Development: Platform for Basic and Translational Research" (1R01HD068138-01A1), and am currently PI (multiple PI format) for NIH/NICHD "The Impact of Early Medical Treatment in Transgender Youth" (1R01HD082554) and co-Investigator for "Sex Hormone effect on Neurodevelopment: Controlled puberty in transgender adolescents" (1R01MH115349), and "Gender Nonconformity in Prepubescent Children: A Longitudinal Study" (1R01HD097122).

B. Positions and Honors

Positions and Employment

1982-83	Clinical Instructor in Pediatrics, University of California San Francisco, CA
1983-92	Assistant Professor of Pediatrics, University of California San Francisco, CA
1992-98	Associate Professor of Pediatrics, University of California San Francisco, CA
1998-	Professor of Pediatrics, University of California San Francisco, CA
2006-15	Director, Pediatric Endocrine Clinics, University of California San Francisco, CA
2008-11	Associate Program Director, Pediatric Endocrinology, University of California San Francisco, CA
2011-15	Program Director, Pediatric Endocrinology, University of California San Francisco, CA
2011-18	Co-Director, Disorders of Sex Development Clinic, University of California San Francisco, CA
2011-	Medical Director, Child and Adolescent Gender Center, University of California San Francisco, CA

Other Experience and Professional Memberships

1991-	Elected to Society for Pediatric Research
2000-05	Appointed to Drug and Therapeutics Committee, Lawson Wilkins Pediatric Endocrine Society
2000-05	Appointed to Special Programs Committee, The Endocrine Society
2002-04	Chair, Drug and Therapeutics Committee, Lawson Wilkins Pediatric Endocrine Society
2005-08	Appointed to Meetings and Educational Programs Committee of The Endocrine Society
2007-13	Appointed to Ethics Committee, Pediatric Endocrine Society
2008-11	Appointed to Annual Meeting Steering Committee, The Endocrine Society
2010-13	Elected to Board of Directors, Pediatric Endocrine Society
2012-15	Appointed to the Clinical Endocrine Education Committee, The Endocrine Society
2013	Appointed to the World Professional Association for Transgender Health Consensus Committee for ICD-11 revisions pertaining to transgender youth and adults
2014-17	Appointed as the Pediatric Endocrine Society's official representative to the Endocrine Society's Clinical Practice Guidelines Revision Task Force for the Care of Transgender Individuals
2015-17	Appointed Associate Editor, *Transgender Health*
2015-16	President-elect, Pediatric Endocrine Society
2016-17	President, Pediatric Endocrine Society
2017-18	Immediate Past President, Pediatric Endocrine Society
2018-19	Vice President, Endocrine Society, Clinical Scientist Position
2019-	Director, Endocrine Society

Honors

2012	UCSF Family Advisory Council Caring Tree Award
2013	UCSF Chancellor Award for Gay, Lesbian, Bisexual, and Transgender Leadership
2014	UCSF Haile T. Debas Academy of Medical Educators Excellence in Teaching Award
2018	Harry Benjamin Lectureship, World Professional Association for Transgender Health, for significant contributions to the field of transgender health through research, healthcare provision and medical education

C. Contribution to Science

Over the past forty years, my career has focused on four principal areas of scientific investigation: 1. Gender non-conforming/transgender youth and youth with Disorders/ Differences of Sex Development (DSD); 2. Insulin-like Growth Factors (IGFs) and skeletal muscle differentiation; 3. Characterization of a novel disorder of water balance: Nephrogenic Syndrome of Inappropriate Antidiuresis; and 4. Preservation of beta cell function in new onset Type 1 Diabetes mellitus.

1. Gender non-conforming/transgender youth and youth with Disorders/Differences of Sex Development (DSD)

I led efforts to create the UCSF Child and Adolescent Gender Center (CAGC) and serve as its Medical Director. The UCSF CAGC serves as the Pediatric/Adolescent clinical and research arm of the widely recognized UCSF Center of Excellence for Transgender Health. The CAGC provides multi-disciplinary care

to gender non-conforming/transgender youth and adolescents, and serves patients/families from northern California and beyond. The CAGC serves as a platform for research focused on optimization of care for gender-nonconforming/transgender youth. I am PI (multiple PI format) for NIH/NICHD "The Impact of Early Medical Treatment in Transgender Youth" (1R01HD082554-01A1) co-I on two additional NIH grants focused on care of gender-nonconforming/ transgender youth. I have also served as co-Director of the UCSF DSD Clinic and as site PI for NIH/NICHD "Disorders of Sex Development: Platform for Basic and Translational Research (1R01HD068138-01A1)". Publications highlighting this work include:

a. **Rosenthal SM.** Approach to the Patient: Transgender Youth: Endocrine Considerations. *Journal of Clinical Endocrinology and Metabolism* 99:4379-4389, 2014. PMID: 25140398

b. Olson-Kennedy J, Cohen-Kettenis PT, Kreukels BP, Meyer-Bahlburg HF, Garofalo R, Meyer W, **Rosenthal SM**. Research priorities for gender nonconforming/transgender youth: Gender identity development and biopsychosocial outcomes. *Current Opinion in Endocrinology Diabetes and Obesity* 23:172-179, 2016. PMID: 26825472. PMCID: PMC4807860

c. Hembree WC, Cohen-Kettenis PT, Gooren L, Hannema SE, Meyer WJ, Murad MH, **Rosenthal SM**, Safer JD, Tangpricha V, T'Sjoen GG. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *Journal of Clinical Endocrinology and Metabolism* 2017 Sep 13. doi: 10.1210/jc.2017-01658. [Epub ahead of print]. PMID: 28945902

d. Olson-Kennedy J, Chan Y-M, Garofalo R, Spack N, Chen D, Clark L, Ehrensaft D, Hidalgo M, Tishelman A, **Rosenthal S**. Impact of early medical treatment for transgender youth: Protocol for the longitudinal, observational Trans Youth Care study. *JMIR Research Protocols*, 8(7):e14434, 2019. PMID: 31290407

2. Insulin-like Growth Factors (IGFs) and skeletal muscle differentiation

I previously directed a basic science laboratory focused on the effects of insulin-like growth factors (IGFs) on skeletal muscle differentiation. In particular, our focus was on identifying target genes of IGF action that influence the decision of a skeletal myoblast to either remain in the cell cycle and proliferate, or leave the cell cycle and terminally differentiate. Our laboratory was the first to demonstrate time-dependent, opposing effects of IGFs on retinoblastoma protein phosphorylation and on myogenin gene expression, key factors which influence myoblast proliferation and differentiation. Publications highlighting this work include:

a. **Rosenthal SM**, Cheng ZQ. Opposing early and late effects of insulin-like growth factor I on differentiation and the cell cycle regulatory retinoblastoma protein in skeletal myoblasts. *Proc Natl Acad Sci USA 92*:103017-10311, 1995. PMID: 7479773

b. Adi S, Cheng ZQ, Zhang PL, Wu NY, Mellon SH, **Rosenthal SM**. Opposing early inhibitory and late stimulatory effects of insulin-like growth factor-I on myogenin gene transcription. *Journal of Cellular Biochemistry* 78:617-626, 2000. PMID: 10861859

c. Adi S, Bin-Abbas B, Wu NY, **Rosenthal SM**. Early stimulation and late inhibition of extracellular signal-regulated kinase 1/2 phosphorylation by IGF-I: a potential mechanism mediating the switch in IGF-I action on skeletal muscle cell differentiation. *Endocrinology* 143:511-516, 2002. PMID: 11796505

d. Tiffin N, Adi S, Stokoe D, Wu NY, **Rosenthal SM**. Akt phosphorylation is not sufficient for insulin-like growth factor-stimulated myogenin expression but must be accompanied by down-regulation of mitogen-activated protein kinase/extracellular signal-regulated kinase phosphorylation. *Endocrinology* 145:4991-4996, 2004. PMID: 15489316

3. Characterization of a novel disorder of water balance: Nephrogenic Syndrome of Inappropriate Antidiuresis (NSIAD)

I co-discovered and co-characterized the initial patients with NSIAD resulting form activating mutations of the V2-vasopressin receptor. Our group also characterized the clinical course and therapy for NSIAD. This work has led to a series of other studies form our group and from other laboratories around the world to better understand the basic science and clinical issues associated with this disorder. Publications highlighting this work include:

a. Feldman BJ*, **Rosenthal SM***, Vargas GA, Fenwick RG, Huang EA, Matsuda-Abedini M, Lustig RH, Mathias RS, Portale AA, Miller WL, Gitelman SE. Nephrogenic syndrome of inappropriate antidiuresis. *New England Journal of Medicine* 352:1884-1890, 2005. ***denotes co-first author.** PMID: 15872203. PMCID: PMC5340184

b. Huang EA, Feldman BJ, Schwartz ID, Geller DH, **Rosenthal SM**, Gitelman SE. Oral urea for the treatment of chronic syndrome of inappropriate antidiuresis in children. *Journal of Pediatrics* 148:128-131, 2006. PMID: 16423613

c. Rochdi MD, Vargas GA, Carpentier E, Oligny-Longpré G, Chen S, Kovoor A, Gitelman SE, **Rosenthal SM**, von Zastrow M, Bouvier M. Functional characterization of vasopressin type 2 receptor substitutions (R137H/C/L) leading to nephrogenic diabetes insipidus and nephrogenic syndrome of inappropriate antidiuresis: implications for treatments. *Molecular Pharmacology* 77:836-845, 2010. PMID: 20159941. PMCID: PMC2872969

d. Cheung CC, Cadnapaphornchai MA, Ranadive SA, Gitelman SE, **Rosenthal SM**. Persistent elevation of urine aquaporin-2 during water loading in a child with nephrogenic syndrome of inappropriate antidiuresis (NSIAD) caused by a R137L mutation in the V2 vasopressin receptor. *International Journal of Pediatric Endocrinology* 3:1-6, 2012. PMID: 22325688. PMCID: PMC3299583

4. Preservation of beta cell function in new onset Type 1 Diabetes mellitus

I have served as site co-Principal Investigator on a number of NIH and Immune Tolerance Network-funded multi-center studies focused on preservation of beta cell function in patients with new onset Type 1 Diabetes mellitus. These studies have shown that a humanized anti-CD3 monoclonal antibody as well as a combination of anti-thymocyte globulin and G-CSF may be effective strategies to delay beta cell loss. Publications highlighting this work include:

a. Herold KC, Gitelman SE, Willi SM, Gottlieb PA, Waldron-Lynch F, Devine L, Sherr J, **Rosenthal SM**, Adi S, Jalaludin MY, Michels AW, Dziura J, Bluestone JA. Teplizumab treatment may improve C-peptide responses in participants with type 1 diabetes after the new-onset period: a randomised controlled trial. *Diabetologia* 56:391-400, 2013.
PMID: 23086558. PMCID: PMC3537871

b. Haller MJ, Gitelman SE, Gottlieb PA, Michels AW, **Rosenthal SM**, Shuster JJ, Zou B, Brusko TM, Hulme MA, Wasserfall CH, Mathews CE, Atkinson MA, Schatz DA. Anti-thymocyte globulin/G-CSF treatment preserves β cell function in patients with established type 1 diabetes.
Journal of Clinical investigation 125:448-455, 2015. PMID: 25500887. PMCID: PMC4382237

Complete List of Published Work in My Bibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/stephen.rosenthal.1/bibliography/47995154/public/?sort=date&direction=ascending.

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

R01HD082554 Rosenthal (PI), (Multiple PI format) 08/01/2015-06/30/2020
NIH/NICHD
The Impact of Early Medical Treatment in Transgender Youth
This is a multicenter study which will be the first in the U.S. to evaluate the long-term outcomes of medical treatment for transgender youth. This study will provide essential, evidence-based information on the physiological and psychosocial impact, as well as safety, of hormone blockers and cross-sex hormones use in this population.
Role: PI

R01MH115349 Hong (PI) 07/01/2018 – 06/30/2023
NIH/NIMH
Sex Hormone effect on Neurodevelopment: Controlled puberty in transgender adolescents
This will be the first study of its kind to directly investigate longitudinal brain anatomy in young adolescents with gender dysphoria (GD). The study will utilize an innovative, cross-disciplinary approach that takes advantage of sophisticated imaging modalities to elucidate the interaction between sex hormone therapies and brain anatomy and connectivity in youth. Results from this interdisciplinary proposal will directly impact clinical care for individuals with GD and provide a much-needed empirical foundation for understanding the longitudinal impact of treatments that are already being used in clinical settings.
Role: Co-I

R01HD097122 Ehrensaft (PI) 03/21/2019 – 02/29/2024
NIH/NICHD
Gender Nonconformity in Prepubescent Children: A Longitudinal Study
This project is a prospective longitudinal observational study of pre-pubertal children who are gender-nonconforming and their care. It is a four-site study involving U.S.-based university affiliated pediatric gender clinics. With a targeted N of 320 subjects, the objective of the proposed research is to provide evidence-based data to inform clinical care for prepubescent transgender and gender-nonconforming children (TGNC).
Role: Co-I

Completed Research Support

Internal Award Rosenthal (PI) 06/01/2018 -05/31/2019
NIH/CTSI
Bone Density, Structure, and Estimated Strength in Transgender Youth Receiving Pubertal Suppression in Early Puberty
Minimal data exist on the skeletal effects of puberty suppression in early pubertal transgender youth. This longitudinal cohort study assessed bone mineral density by dual-energy x-ray absorptiometry and bone microarchitecture and strength by high-resolution peripheral quantitative computed tomography, as well as bone turnover markers, body composition, vitamin D status, weight-bearing exercise, and dietary calcium intake. These data will lead to longer-term studies and investigations of interventions to mitigate the expected lag in skeletal development during pubertal suppression. Ultimately, this research should positively contribute to the clinical care of transgender youth. This funding supported the above-noted studies carried out by postdoctoral fellow, Janet Y. Lee, MD, MPH.
Role: PI

OMB No. 0925-0001 and 0925-0002 (Rev. 09/17 Approved Through 03/31/2020)

BIOGRAPHICAL SKETCH

NAME: Yee-Ming Chan, M.D., Ph.D.

eRA COMMONS USER NAME: (b)(6)

POSITION TITLE: Assistant Professor of Pediatrics, Harvard Medical School; Associate Physician in Pediatrics and Director, Pediatric Reproductive Hormone Program, Boston Children's Hospital

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Yale University, New Haven, CT	B.S.	5/1993	Biology
University of California, San Francisco, CA	Ph.D.	12/2000	Genetics
University of California, San Francisco, CA	M.D.	6/2002	
University of California, San Francisco, CA	Internship	6/2003	Pediatrics
University of California, San Francisco, CA	Residency	6/2005	Pediatrics
Boston Children's Hospital (BCH), MA	Clinical Fellowship	6/2008	Pediatric Endocrinology
Massachusetts General Hospital, Boston, MA	Research Fellowship	6/2012	Reproductive Endocrinology

A. Personal Statement

I am a pediatric endocrinologist and translational researcher with an interest in puberty and the reproductive endocrine system. I am Director of the Pediatric Reproductive Hormone Program at Boston Children's Hospital, which provides care for patients with pubertal disorders, patients with disorders of sex development, and transgender and gender-diverse youth, and conducts research in these areas. In addition to my clinical expertise in pediatric reproductive endocrinology, I have broad scientific training that spans basic science, human genetics, and clinical research.

The goal of both my own research program and the Pediatric Reproductive Hormone Program more broadly is to make discoveries that will have an impact on clinical care in addition to expanding our knowledge of human reproductive endocrine biology. Our research approaches include retrospective chart reviews, prospective phenotyping studies, human genetic analyses, and clinical trials of novel diagnostic methods. As co-PI for the Transgender Youth Consortium (TYC) Study and site PI for the BCH site, I have overseen study activities at BCH and have supervised a clinical pediatric endocrinology fellow in the analysis of physiological data from the study. With the research infrastructure for this study firmly in place at the BCH site, we are well positioned to extend the TYC Study to address key questions as our study cohorts transition from childhood to adolescence to adulthood.

1. Zhu J, Choa RE-Y, Guo MH, Plummer L, Buck C, Palmert MR, Hirschhorn JN, Seminara SB,* **Chan Y-M**.* A shared genetic basis for self-limited delayed puberty and idiopathic hypogonadotropic hypogonadism. *J Clin Endocrinol Metab* 2015;100:E646-654. PMID: 25636053. PMCID: PMC4399304.
2. Swartz JM, Ciarlo R, Denhoff E, Abrha A, Diamond DA, Hirschhorn JN, **Chan Y-M**. Variation in the clinical and genetic evaluation of undervirilized boys with bifid scrotum and hypospadias. 2017;13:293.e1-293.e6. PMID: 28215832. PMCID: PMC5483185.

3. **Chan Y-M**, Lippincott MF, Sales Barroso P, Alleyn C, Brodsky J, Granados H, Roberts SA, Sandler C, Srivatsa A, Seminara SB. Using kisspeptin to predict pubertal outcomes for youth with pubertal delay. J Clin Endocrinol Metab, accepted.
4. Olson-Kennedy J, **Chan Y-M**, Rosenthal S, Hidalgo M, Chen D, Clark L, Ehrensaft D, Tishelman A, Garofalo R. Creating the Trans Youth Research Network: a collaborative research endeavor. Transgender Health 2019;4:304-312. PMID: 31701011. PMCID: PMC6830532.

B. Positions and Honors

Positions

2008-2014	Instructor in Pediatrics, Harvard Medical School, Boston, MA
2008-2014	Assistant in Medicine, Division of Endocrinology, Department of Medicine, Boston Children's Hospital, Boston, MA
2014-	Assistant Professor of Pediatrics, Harvard Medical School, Boston, MA
2014-	Associate in Medicine, Division of Endocrinology, Department of Medicine, Boston Children's Hospital, Boston, MA. Division Chief: Joel N. Hirschhorn, M.D.
2014-	Clinical Associate in Pediatrics, Massachusetts General Hospital, Boston, MA

Honors

2007	Endocrine Society Students and Fellows Day Travel Award
2007, 2008	Endocrine Society Genentech Travel Award
2007-2010	National Institutes of Health Pediatric Loan Repayment Program
2010	ENDO 2010 Outstanding Abstract Award
2012	Poster of Distinction, MGH Clinical Research Day
2013	Poster of Distinction, MGH Scientific Advisory Committee Annual Symposium
2015	Robert J. Masland Jr. Teaching Award (HMS/BCH)
2017	Elected to Society of Pediatric Research
2018	BCH Pediatric Endocrinology Fellowship Teaching Award

C. Contribution to Science

1. I have identified genetic mutations that cause permanent reproductive endocrine dysfunction (idiopathic hypogonadotropic hypogonadism, IHH) through candidate-gene and whole-exome approaches. I have also used mouse models to explore the biology of IHH genes.
    a. **Chan Y-M**, de Guillebon A, Lang-Muritano M, Plummer L, Cerrato F, Tsiaras S, Gaspert A, Lavoie H, Wu C-H, Crowley WF, Amory JK, Pitteloud N, Seminara SB. *GNRH1* mutations in patients with idiopathic hypogonadotropic hypogonadism. Proc Natl Acad Sci USA 2009;106:11703-11708. PMID: 19567835. PMCID: PMC2710623.
    b. **Chan Y-M**, Broder-Fingert S, Seminara SB. Kisspeptin/Gpr54-independent GnRH secretion: evidence from *Kiss1* and *Gpr54* mutant mice. J Neuroendocrinol 2009; 21:1015-1023. PMID: 19840236. PMCID: PMC2789182.
    c. Margolin DH,* Kousi M,* **Chan Y-M,*** Lim ET, Schmahmann JD, Hadjivassiliou M, Hall JE, Adam I, Dwyer A, Plummer L, Aldrin SV, O'Rourke J, Kirby A, Lage K, Milunsky A, Milunsky JM, Chan J, Hedley-Whyte ET, Daly MJ, Katsanis N, Seminara SB. Ataxia, dementia, and hypogonadotropism caused by disordered ubiquitination. N Engl J Med 2013;368:1992-2003. PMID: 23656588. PMCID: PMC3738065.
    d. True C, Alam SN, Cox K, **Chan Y-M**, Seminara SB. Neurokinin B is critical for normal timing of sexual maturation but dispensable for adult reproductive function in female mice. Endocrinology 2015;156:1386-1397 PMID: 25574869. PMCID: PMC4399316.

2. To bring these findings back to the human, I have conducted a series of studies administering kisspeptin to human subjects. These protocols have revealed previously unappreciated effects of kisspeptin on the timing of GnRH secretory pulses as well as modulation of the effects of kisspeptin both by physiologic changes across the menstrual cycle and by pathophysiologic conditions such as IHH. Most recently, we have used kisspeptin as a tool to diagnose IHH in children presenting with delayed puberty.

a. **Chan Y-M**, Butler JP, Pinnell NE, Pralong FP, Crowley SF Jr, Ren C, Chan KK, Seminara SB. 2011. Kisspeptin resets the hypothalamic GnRH clock in men. J Clin Endocrinol Metab 96: E908-915. PMID: 21470997. PMCID: PMC3100758.
b. **Chan Y-M**, Butler JP, Sidhoum VF, Pinnell NE, Seminara SB. 2012 Kisspeptin administration to women: a window into endogenous kisspeptin secretion and GnRH responsiveness across the menstrual cycle. J Clin Endocrinol Metab 97:E1458-1467. PMID: 22577171. PMCID: PMC3410261
c. **Chan Y-M**, Lippincott MF, Kusa TO, Seminara SB. Divergent responses to kisspeptin in children with delayed puberty. JCI Insight 2018;3:e99109. PMID: 29669934
d. Lippincott MF, León S, **Chan Y-M**, Fergani C, Talbi R, Farooqi IS, Jones CM, Arlt W, Stewart SE, Cole TR, Terasawa E, Hall JE, Shaw ND, Navarro VM, Seminara SB. Hypothalamic reproductive endocrine pulse generator activity independent of neurokinin B and dynorphin signaling. J Clin Endocrinol Metab. 2019;104:4304-4318. PMID: 31132118. PMCID: PMC6736049.

3. I am now focusing on delayed puberty, and I have used whole-exome sequencing to demonstrate that a subset of genes implicated in IHH also contribute to delayed puberty. I have also helped develop and refine methods for exome-wide burden testing to identify new delayed puberty genes. I am also exploring clinical characteristics of patients with delayed puberty using both retrospective and prospective approaches.
   a. Zhu J, Choa RE-Y, Guo MH, Plummer L, Buck C, Palmert MR, Hirschhorn JN, Seminara SB,* Chan Y-M.* A shared genetic basis for self-limited delayed puberty and idiopathic hypogonadotropic hypogonadism. J Clin Endocrinol Metab 2015;100:E646-654. PMID: 25636053. PMCID: PMC4399304.
   b. Guo MH, Dauber A, Lippincott MF, **Chan Y-M**, Salem R, Hirschhorn JN. Determinants of power in gene-based burden testing for monogenic disorders. Am J Hum Genet 2016; 99:527-539. PMID: 27545677. PMCID: PMC5011058.
   c. Guo MH, Plummer L, **Chan Y-M**, Hirschhorn J, Lippincott M. Burden testing of rare variants identified through exome sequencing using publicly available control data. Am J Hum Genet 2018;103:522-534. PMID: 30269813. PMCID: PMC6174288.
   d. Zhu J, Feldman HA, Eugster EA, Fechner PY, Nahata L, Thornton PS, **Chan Y-M**. Practice variation in the management of girls and boys with delayed puberty. Endocr Pract 2019 Dec 20. doi: 10.4158/EP-2019-0344. [Epub ahead of print]. PMID: 31859552

4. I am also studying the genetics of disorders of sex development and have identified a key role for *NR5A1* (*SF1*) in both testicular and ovarian development. I am also studying the role of genetic testing in the clinical evaluation of DSD patients and participating in a study of outcomes of surgery for these patients.
   a. Swartz JM, Ciarlo R, Guo MH, Abrha A, Weaver B, Diamond DA, **Chan Y-M**, Hirschhorn JN. A 46,XX ovotesticular disorder of sex development likely caused by a *steroidogenic factor-1* (*NR5A1*) variant. Horm Res Paediatr 2017;87:191-195. PMID: 27855412. PMCID: PMC5388569.
   b. Heksch RA, Matheson MA, Tishelman AC, Swartz JM, Jayanthi VR, Diamond DA, Harrison CJ, **Chan Y-M**, Nahata L. Testicular regression syndrome: practice variation in diagnosis and management. Endocr Pract. 2019;25:779-786. PMID: 31013155.
   c. Perez MN, Delozier AM, Aston CE, Austin P, Baskin L, **Chan Y-M**, Cheng EY, Diamond DA, Fried A, Greenfield S, Kolon T, Kropp B, Lakshmanan Y, Meyer S, Meyer T, Nokoff N, Palmer B, Paradis A, Poppas D, Scott Reyes KJ, Swartz JM, Tishelman A, Wisniewski AB, Wolfe-Christensen C, Yerkes E, Mullins LL. Predictors of psychosocial distress in parents of young children with disorders of sex development. J Urol 2019;202:1046-1051. PMID: 31268850. PMCID: PMC6946548.
   d. Crerand CE, Kapa HM, Litteral JL, Nahata L, Combs B, Indyk JA, Jayanthi VR, **Chan Y-M**, Tishelman AC, Hansen-Moore J. Parent perceptions of psychosocial care for children with differences of sex development. J Pediatr Urol. 2019 Jul 4 [Epub ahead of print] PMID: 31353277.

5. I am one of four co-PI's for the Transgender Youth Consortium (TYC) Study, a project involving Boston Children's Hospital, Benioff Children's Hospital at UCSF, Children's Hospital Los Angeles, and Lurie Children's Hospital. The TYC study is examining physiologic and psychosocial outcomes of hormonal treatment for transgender youth: pubertal blockade with GnRH agonists in early pubertal transgender children and gender-affirming sex steroids in older transgender adolescents.
   a. Polderman TJC, Kreukels BPC, Irwig MS, Beach L, **Chan Y-M**, Derks EM, Esteva I, Ehrenfeld J, Den Heijer M, Posthuma D, Raynor L, Tishelman A, Davis LK. The biological contributions to

gender identity and gender diversity: bringing data to the table. Behav Genet 2018;48:95-108. PMID: 29460079.

b. Millington K, Liu E, **Chan Y-M**. The utility of potassium monitoring in gender-diverse adolescents taking spironolactone. J Endocr Soc 2019;3:1031-1038. PMID: 31065620. PMCID: PMC6497918.

c. Olson-Kennedy J, **Chan Y-M**, Garofalo R, Spack N, Chen D, Clark L, Ehrensaft D, Hidalgo M, Tishelman A, Rosenthal S. Impact of early medical treatment for transgender youth: protocol for the longitudinal, observational Trans Youth Care Study. JMIR Res Protoc 2019;8:e14434. PMID: 31290407. PMCID: PMC5875384.

Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/myncbi/browse/collection/50569153/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support

R01 HD082554 Olson, Garofalo, Rosenthal, **Chan** (co-PIs) 8/1/2015-6/30/2020
The Impact of Early Medical Treatment in Transgender Youth
The goal of this research project is to conduct a multi-site observational study examining the physiological and psychosocial outcomes of existing medical treatment protocols for gender dysphoria in early pubertal and late pubertal transgender youth.

R01 HD089521 Hirschhorn and Holm (co-PIs) 7/1/2016-6/30/2021
Exome Sequencing in Disorders of Sex Development: Impact on Patients and Families
This project uses whole-exome sequencing to identify causes of disorders of sex development and assesses the impact of returning genetic results on patients and families.
Role: Co-Investigator

R01 HD090071 and HD090071-S1 **Chan** (PI) 4/11/2017-3/31/2022
Delayed Puberty: Causes and Consequences, Genotypes and Phenotypes
This project is examining clinical characteristics of individuals presenting with delayed puberty, evaluating adults with a history of delayed puberty, and determining the roles of rare and common variants in causing delayed puberty through an international consortium of investigators.

R01 HD074579 Mullins (PI) 5/1/2018-4/30/2023
Long-Term Outcomes of Interventions for Reproductive Dysfunction
The goals of this project are to assess physician and parent perceptions of outcomes of genital surgery in children with ambiguous genitalia, and to examine the impact on parental stress.
Role: Co-Investigator, Site PI

R01 HD097122 Tishelman, Chen, Ehrensaft, Hildalgo (co-PIs) 3/21/2019-2/29/2024
A Longitudinal Study of Gender Nonconformity in Prepubescent Children
This study will establish a national cohort of prepubertal transgender/gender non-conforming children to examine mental health outcomes and the effects of social gender transition.
Role: Co-Investigator

OMB No. 0925-0001 and 0925-0002 (Rev. 09/17 Approved Through 03/31/2020)

BIOGRAPHICAL SKETCH

NAME: Robert Garofalo MD, MPH

eRA COMMONS USER NAME (credential, e.g., agency login): (b)(6)

POSITION TITLE: Division Head- Adolescent Medicine, Lurie Children's Hospital of Chicago; Professor of Pediatrics-Northwestern University

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE	Completion Date MM/YYYY	FIELD OF STUDY
Duke University; Durham, NC	BS	05/88	Biological Psychology
New York University School of Medicine; NY, NY	MD	06/92	Medicine
Harvard University School of Public Health; Boston, MA	MPH	06/99	Family and Community Health
Postdoctoral Training			
Children's Hospital of Philadelphia; Phila, PA	Intern	07/92-06/93	Pediatrics
Children's Hospital of Philadelphia; Phila, PA	Resident	07/93-06/95	Pediatrics
Children's Hospital; Boston, MA	Fellow	07/95-06/97	Pediatric Advocacy
Children's Hospital; Boston, MA	Fellow	07/00-06/01	Adolescent Medicine

A. Personal Statement

The proposed renewal for the study, *"The Impact of Early Medical Treatment in Transgender Youth,"* will extend the initial 2-year follow-up period to evaluate longer-term physiological and psychological outcomes of pubertal suppression and gender-affirming hormone treatment in the only federally-funded cohort of transgender and gender-nonconforming (TGNC) adolescents in the United States. As a pediatrician I believe the work proposed in this application is critically needed in the field to help inform evidence –based practices which is currently lacking as we advise and counsel parents and families. My background in both clinical care and research as it relates to transgender health is well-suited to serve as MPI for the proposed research. My research career has focused on the collection of basic data on marginalized populations and the translation of this data into intervention development. I have extensive experience engaging transgender women and young MSM age 16-24, in longitudinal and STI/HIV prevention research. I have extensive experience being the PI of clinical and translational research projects funded by the NIH. I have been PI or Co-PI on 13 NIH grants (including R01HD082554, the study this competitive renewal proposes to extend), 2 CDC research grants, and Co-Investigator on 16additional NIH grants. Across these projects I have developed the skills to lead interdisciplinary and multi-site clinical research teams. I have >150 peer-reviewed manuscripts many of which are related to transgender populations and germane to the proposed research. I believe the work being proposed herein is the most innovative and important research with regard to public health impact and clinical significance in my entire career.

I am the Director of Lurie Children's Center for Gender, Sexuality and HIV Prevention as well as the Co-Director of our Program in Gender and Sex Development. I also serve as the hospital's Division Head of Adolescent and Young Adult Medicine. I have over 15 years' experience doing clinical work with the proposed populations of youth and adolescents. I have led the formation of a multidisciplinary clinical and research team at our institution as they relate to gender non-conforming children and adolescents. I served on the Institute of Medicine Committee on "The Health of Lesbian, Gay, Bisexual and Transgender People" where my expertise in youth, transgender health and HIV were focal points of my involvement. It is the findings from this

Committee that in large part motivate and contextualize the proposed research. I am the Editor-in-Chief of the journal *Transgender Health*. As MPI, I will oversee the scientific integrity, daily operations, and implementation of study aims at Lurie Children's, and collaborate with our team of investigators on dissemination of findings.

a. (b)(4)

b. Chodzen, G., Hidalgo, M. A., Chen, D., & **Garofalo, R**. (2018). Minority Stress Factors Associated With Depression and Anxiety Among Transgender and Gender-Nonconforming Youth. *J AdolescHealth*. doi:10.1016/j.jadohealth.2018.07.006

c. Hidalgo, M.A., Chen, D., **Garofalo, R**., and Forbes, C. (2017) Perceived parental attitudes of gender expansiveness: Development and preliminary factor structure of a self-report youth questionnaire. Transgender Health, 2.1, 180-187. DOI: 10.1089/trgh.2017.0036

B. Positions and Honors

Instructor in Pediatrics, Harvard Medical School

1997	Health Policy Fellow: Office of Senator Edward M. Kennedy. Washington, DC.
1997-01	Assistant in Medicine/Attending Physician, Division of General Pediatrics Children's Hospital/Harvard Medical School, Boston, MA
1997-01	Director of Adolescent Medicine. JRI/Sidney Borum Community Health Center. Boston, MA.
2001-	Attending Physician, Division of General Academic Pediatrics/Infectious Diseases Lurie Children's Hospital (formerly Children's Memorial Hospital)/Northwestern University Medical School, Chicago, IL
2001-11	Program Director/Principal Investigator: PATH Youth Network. HRSA/Ryan White Title IV-funded collaboration for Adolescent HIV: Children's Memorial Hospital and Howard Brown Health Center, Chicago, IL.
2001-	Director of Adolescent HIV Services, Lurie Children's Hospital, Chicago, IL
2002-05	Director of Youth Services; Howard Brown Health Center, Chicago, IL
2006-11	Deputy Director/Director of Youth Services; Howard Brown Health Center, Chicago, IL
2008-	Associate Professor of Pediatrics and Preventive Medicine; Northwestern University Feinberg School of Medicine. Chicago, IL
2014-	Professor in Pediatrics and Preventive Medicine Northwestern University's Feinberg School of Medicine, Chicago, IL

Honors

1988	Magna Cum Laude – Duke University. Durham, NC
1992	Alpha Omega Alpha (AOA) – New York University School of Medicine. NY, NY
1992	AOA Achievement Award – New York University School of Medicine. NY, NY
2000	Employee of the Year – Justice Resource Institute (JRI). Boston, MA
2001	Community Service Award – Beth Israel Deaconess Medical Center. Boston, MA
2005	Friend for Life Award – Howard Brown Health Center. Chicago, IL
2007	GLMA Achievement Award – Gay and Lesbian Medical Association
2011	City of Chicago LGBT Hall of Fame Inductee

C. Contribution to Science

1. Over the past 10 years, I have worked to develop several HIV prevention interventions for populations at high risk of HIV infection, including TW and MSM. My published work in this area dates back to 2004 with research and projects funded by the CDC, SAMHSA and NIH. I led or co-led all aspects of the work described in these publications, which are among the first to document efficacy for HIV prevention interventions focused on these populations. This includes the development of the hypothesis, mobilizing the community (e.g. the research used a community participatory research approach), writing of the research protocol, writing the grant and securing funding, training all staff on study procedures, and overseeing the writing of the intervention curricula as well as overseeing all data collection and analysis activities.
    a. Kuhns, L. M., Hotton, A. L., Perloff, J., Paul, J., Parker, C., Muldoon, A. L., Johnson, A.K., **Garofalo, R**. (2019). Evaluation of Translife Care: An Intervention to Address Social Determinants of Engagement in HIV Care Among Transgender Women of Color. *AIDS Behav*.

b. **Garofalo R,** Kuhns LM, Reisner SL, Biello K, Mimiaga MJ. Efficacy of an Empowerment-Based, Group-Delivered HIV Prevention Intervention for Young Transgender Women: The Project LifeSkills Randomized Clinical Trial. *JAMA pediatrics*. Aug 13 2018. (epub ahead of print)
c. **Garofalo, R**, Johnson, AK, Kuhns, LM, Cotton, C, Joseph, H, Margolis, A (2012). Life skills: Evaluation of a theory-driven behavioral HIV prevention intervention for young transgender women. *Journal of Urban Health*. 2012. 89(3):419-431.
d. Hidalgo MA, Kuhns LM, Hotton AL, Johnson AK, Mustanski B, **Garofalo R**. The MyPEEPS Randomized Controlled Trial: A Pilot of Preliminary Efficacy, Feasibility, and Acceptability of a Group-Level, HIV Risk Reduction Intervention for Young Men Who Have Sex with Men. (2014) *Archives of sexual behavior*. Aug 19 2014. PMC Journal – In process.

2. My previous work has helped to identify the factors associated with HIV infection among TW, which formed the basis for the intervention work highlighted above. These publications are part of a large set of peer-reviewed publications resulting from my initial grants from NIH (within the Adolescent Trials Network) and the CDC (focused on TW). Each publication was among the first to examine the social context of HIV risk among TW.
   a. Mimiaga, M. J., Hughto, J. M. W., Biello, K. B., Santostefano, C. M., Kuhns, L. M., Reisner, S. L., & **Garofalo, R**. (2019). Longitudinal analysis of syndemic psychosocial problems predicting HIV risk behavior among a multicity prospective cohort of sexually active young transgender women in the United States. *J Acquir Immune Defic Syndr*
   b. **Garofalo R**, Deleon J, Osmer E, Doll M, Harper G. Overlooked, misunderstood and at-risk: Exploring the lives and HIV risk of ethnic minority male-to-female transgender youth. *Journal of Adolescent Health*. 2006;38:230-236.
   c. **Garofalo R**, Osmer E, Sullivan C, Doll M, Harper G. Environmental, psychosocial, and individual correlates of HIV risk in ethnic minority male-to-female transgender youth. *Journal of HIV/AIDS Prevention in Children & Youth* 2006;7(2):89-104.

3. My recent work has focused on the development of practical and sustainable interventions, including technology-based interventions to improve the health of HIV positive youth. We recently demonstrated the feasibility, acceptability and preliminary efficacy of SMS text messages to improve adherence to HIV medications among HIV+ youth. The results of this text messaging study are the foundation for future work in this area including a recently concluded NIDA-funded R34 which extends this pilot work to a more rigorous RCT design. The primary outcome paper for this SMS text intervention was recently published in *AIDS & Behavior*.
   a. (b)(4)
   b. **Garofalo, R**, Kuhns, LM, Hotton, A, Johnson, A, Muldoon, A, Rice, D. A randomized controlled trial of personalized text message reminders to promote medication adherence among HIV-positive adolescents and young adults. *AIDS & Behavior*. 2015. Sept 11 [epublished ahead of print]
   c. Dowshen, N, Kuhns, LM, Gray, C, Lee, S, **Garofalo, R**. Feasibility of interactive text message response (ITR) as a novel, real-time measure of adherence to antiretroviral therapy for HIV+ youth. *AIDS & Behavior*. 2013. Jul;17(6):2237-43

4. Recent work has included assessment of feasibility, acceptability and initial efficacy of pre-exposure prophylaxis as a biobehavioral HIV prevention strategy, which demonstrates my knowledge and work in this area, an emerging focus of my current research portfolio.
   a. Restar, A. J., **Kuhns, L.,** Reisner, S. L., Ogunbajo, A., **Garofalo, R**., & Mimiaga, M. J. (2018). Acceptability of Antiretroviral Pre-exposure Prophylaxis from a Cohort of Sexually Experienced Young Transgender Women in Two U.S. Cities. *AIDS Behav*.
   b. Mustanski B, Johnson AK, **Garofalo R**., Ryan D., & Birkett M. Perceived likelihood of using HIV pre-exposure prophylaxis medications among young men who have sex with men. *AIDS and Behavior*. 2013. Jul;17(6) 2173-2179. PMID:232128980
   c. Hosek S, Siberry G, Bell M, Lally M, Kapogiannis B, Green K, Fernandez I, Rutledge B, Martinez J, **Garofalo R**, Wilson C, and the Adolescent Trials Network for HIV/AIDS interventions (ATN). The

acceptability and feasibility of an HIV pre-exposure prophylaxis trial with young men who have sex with men (YMSM). *JAIDS*. 2013. Apr; 62(4): 447-456

d. Kuhns, LM, Reisner, S, Mimiaga, M, Gayles, T, Shelendich, M, **Garofalo, R.** Correlates of PrEP indication in a multi-site cohort of young HIV-uninfected transgender women. *AIDS Behavior*. 2015. Sept 3 [epublished ahead of print].

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1r92xwjc9Olk3/bibliography/42345140/public/?sort=date&direction=ascending

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

R01HD097122 (Chen/Hidalgo/Tishelman/Ehrensaft) 04/1/19-03/31/24 NICHD
A Longitudinal Study of Gender Nonconformity in Prepubescent Children
The goals of the study are to establish the first longitudinal cohort of prepubertal transgender and gender nonconforming children (TGNC) (i.e., Tanner stage I) and their caregivers in the United States to provide evidence to inform clinical care for prepubertal TGNC children. Role: Co-Investigator

R01MH116721 (Dworkin/Garofalo) 02/11/19-11/30/23 NIMH
A mobile phone intervention using a relational human talking Avatar to promote multiple stages of the HIV Care Continuum in African American MSM Role: Co-Investigator

UG3HD096920 (B. Taiwo/R. Garofalo) 09/01/18-08/31/23 NICHD
Intensive Combination Approach to Rollback the Epidemic (iCARE) in Nigerian Adolescents
This project tests two combination prevention interventions among youths aged 15 to 24 years in a multistage UG3/UH3 in three cities in Nigeria. Role: Principal Investigator (MPI agreement)

R01MH113467 (R. Schnall/R. Garofalo) 09/01/18-08/31/23 NIH
mLab for Improving Uptake of rapid HIV self-testing and Linking Youth to Care
Theoretically-guided by the Health Information Technology Usability Evaluation Model, the proposed project will refine and test a next-generation diagnostic intervention delivered on a mobile platform to improve HIV testing and linkage-to-care outcomes among youth living with and at-risk for HIV. Role: Principal Investigator (MPI agreement)

1R01NR017098-01 (R. Garofalo/M. Mimiaga) 09/26/16-06/30/21 NINR
Adaptive intervention strategies trial for strengthening adherence to antiretroviral HIV treatment among youth
The goal of this project is to test the efficacy of a stepped-care "adaptive" ART adherence intervention ("Positive STEPS") for HIV infected adolescents, ages 16 to 24. Stepped-care is an efficiency healthcare delivery model in which the least resource intensive part of an intervention is delivered first, and only those who do not improve then receive the high intensity, more resource intensive part of an intervention. Role: Co-Investigator

1U01MD011279-01 (R. Schnall/R. Garofalo/L. Kuhns) 09/01/16-04/30/21 NIH
A Pragmatic Clinical Trial of of MyPEEPS Mobile to Improve HIV prevention behaviors in Diverse Adolescent MSM
Using a participatory approach, our study will incorporate user-centered design in the translation of the MyPEEPS intervention onto a mobile platform. MyPEEPS was tested with older adolescents (16-18 year olds) and prior to the availability of non-occupational post-exposure prophylaxis (nPEP) and pre-exposure prophylaxis (PrEP); therefore, in addition to the mobile adaptation, we will update the intervention content. Role: Co-Investigator

1U01PS005140-01 (L. Kuhns/J. Perloff/R. Garofalo) 09/30/16-09/29/20 CDC
Evaluation of TransLife Center: A Locally-Developed Combination Prevention Intervention for Transgender Women at High Risk of HIV Infection
The study will address the current gap in transgender-specific combination HIV prevention interventions by testing a promising and potentially effective, culturally specific, and highly accessible intervention to reduce

disparities in TW by directly targeting the social determinants of HIV infection in this extremely high risk group. Role: Co-Investigator

R01DA041071-01 (R. Garofalo/N. Karnik) 09/15/15-07/31/20 NIDA
Employing eSBI in a Community-based HIV Testing Environment for At-risk Youth
The purpose of this study is to test a structural change to the Seek, Test, Treat and Retain (STTR) model by integrating substance use screening and brief intervention into the traditional community- based HIV testing environment for young MSM and transgender women. Role: Principal Investigator (MPI Agreement)

R01-HD082554-01A1 (J. Olson/R. Garofalo/S. Rosenthal/Y. Chan) 08/01/15-06/30/20 NICHD
The Impact of Early Medical Treatment in Transgender Youth
This project fills gaps in knowledge, provides empirical evidence to inform clinical care, and is the first study of its kind evaluating longitudinal outcomes of medical interventions for transgender youth in the US. Four university-affiliated gender clinics across the United States partnered to conduct a multi-site observational study of two developmental cohorts examining the safety of hormonal interventions and the physiological and psychosocial outcomes associated with these treatments. Role: Principal Investigator (MPI agreement)

RFA-DA-19-008 UG1 (Karnik/Garofalo) 06/15/2019-02/29/2024 NIDA
National Institute for Drug Abuse/NIH The National Drug Abuse Treatment Clinical Trials Network
Great Lakes Node of the Drug Abuse Clinical Trials Network
This project will establish the Great Lakes Node of the Drug Abuse Clinical Trials Network. The creation of this node will help facilitate research on substance and opioid misuse which are key components of NIH and federal government strategy to reduce the mortality and morbidity associated with the current opioid and substance epidemics. This node will support clinical trials relevant to the epidemics and also advance research in novel models of care, data analytics, mobile interventions and training. Role: Co-Investigator

Completed Research Support:

R01HD075655 (R.Stephenson/M. Mimiaga/R.Garofalo) 04/01/13-12/31/18 NICHD
CVCTPlus: A Couples-Based Approach to Linkage to Care and ARV Adherence
From a sample of 3,360 MSM in Atlanta, Boston, and Chicago, 250 HIV-serodiscordant couples will be randomized to either Individual or Couples HIV Counseling and Testing, and then followed prospectively for two years. Couples randomized to couples-based counseling and testing will also receive a dyadic adherence intervention, with the research aimed to determine if couples testing together impacts linkage to HIV care, retention in HIV care, ART adherence and viral suppression. Role: Principal Investigator

R01MH100021 (K.Fujimoto/J.Schneider) 07/01/13-06/30/18 NIMH
YMAP: Young Men's Affiliation Project of HIV Risk & Prevention Venue
Younger men who have sex with men (YMSM) are at increased risk of HIV and STIs in the United States. The goal of the proposed longitudinal network study is to investigate the complex interactions between YMSM and both preventive health venues and risk venues to gain a deep understanding of the sometimes conflicting influences and complex interactions that may also provide risk and protection in the same venue. Using two mode "affiliation" social network analysis, the proposed study has potential to advance and expand the utility of social network analysis for understanding and addressing public health issues, which will provide new directions in developing venue-based network interventions and modify individual level interventions targeting those most at risk of HIV/STI infection. Role: Co-Investigator

OMB No. 0925-0001 and 0925-0002 (Rev. 09/17 Approved Through 03/31/2020)

BIOGRAPHICAL SKETCH

NAME: Marco Armando Hidalgo

eRA COMMONS USER NAME (credential, e.g., agency login): (b)(6)

POSITION TITLE: Assistant Professor of Clinical Pediatrics/Attending Faculty Psychologist

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
Universiteit van Amsterdam; Amsterdam, NL	Certificate	06/2002	Gender & Sexuality Studies
San Francisco State University; San Francisco, CA	BA	05/2004	Psychology
DePaul University; Chicago, IL	MA	06/2007	Clinical Psychology
DePaul University; Chicago, IL	PhD	08/2011	Clinical Psychology
Cambridge Health Alliance/Harvard Medical School; Boston, MA	Fellow	08/2012	Clinical Psychology

A. Personal Statement

Research examining physiological and psychosocial health outcomes among transgender individuals who initiate medical treatment for gender dysphoria has historically focused on adulthood. Outside of our current study (i.e., R01HD082554), no known US studies have examined similar outcomes among transgender/gender-diverse (TGD) youth with gender dysphoria. This proposed research will significantly impact the growing field of TGD health by examining longer-term health outcomes among TGD individuals who initiated medical treatment for gender dysphoria in adolescence. We aim to extend and to further the original research aims of R01HD082554 to examine *longer-term* health (physiological, psychosocial) and safety outcomes for an additional 5 years. We also propose to expand the study sample by enrolling an ethnic/racial minority subgroup of TGD adolescents to better reflect an increasingly diverse racial/ethnic clinical population presenting for care at each of our network's four clinics.

As a clinical-child and adolescent psychologist who specializes in mental health care among TGD children, adolescents and young adults, I can attest to the current need for longitudinal research examining health outcomes of TGD individuals who begin treatment for gender dysphoria during adolescence. The outcomes of the proposed study will provide my patients (and their caregivers/parents), as well as colleagues and trainees, with a greater and more comprehensive understanding of the safety and health risks associated with medical treatments for gender dysphoria (e.g., puberty suppression, gender-affirming hormone therapy). The salience of this research is further underscored by the many letters of support accompanying this resubmitted proposal, sent from individuals representing TGD-serving health organizations, hospital programs, and advocacy groups.

I am well-suited to continue as Co-Investigator (Co-I) on this team because of my contribution to the scientific aims and methods of the original study from which we are intending to extend our work (i.e., R01HD082554). In addition, I have exclusive and extensive experience conducting complex, multisite and longitudinal/repeated measures research among sexual and gender minority children, adolescents and young adults.

I am **Contact PI of an NICHD-funded study** (R01HD097122). This study is the first of its kind to establish a US national cohort of prepubertal TGD children. The primary objective of this longitudinal, multisite, observational study is to provide empirical evidence to inform clinical care by characterizing developmental patterns of gender identity and gender-role behavior, mental health outcomes at baseline and over time, and the impact of social gender transition (when present) in a cohort of prepubertal TGD children. The study PIs are comprised of clinical

psychologists at the leading gender programs in the US who are also Co-Investigators on the proposed study (i.e., Chen of Lurie Children's, (b)(6) of Boston Children's and Ehrensaft of UCSF.

I am also currently serving as **Co-I on 4 NIH-funded studies** all conducted among sexual and/or gender minority youth and focused on topics ranging from longitudinal observation of safety and health outcomes of medical care to development and efficacy testing of HIV prevention intervention. Aside from these studies, I was also PI of a NIAID-funded early career award (P30AI050409)—facilitated by the Emory University Center for AIDS Research— that examined HIV pre-exposure prophylaxis (PrEP) uptake in Latina transgender adolescents/young adults and Latino MSM. Since 2005, I have served either in study leadership or as an investigator on multi-site, NIH-funded health behavior research among sexual and gender minority adolescents and young adults. The breadth of my experiences have been on study designs that ranged from cross-sectional, to randomized controlled trials (RCTs), and longitudinal studies requiring multiple follow-up visits.

As a practitioner, I have extensive experience treating mental health problems (including gender dysphoria) in TGD children. I have conducted diagnostic assessment and treatment of TGD youth in multidisciplinary clinical settings since 2006. In 2013, I co-established Lurie Children's Gender and Sex Development Program (GSDP), and served as its Co-director of Behavioral Health Services from 2013-2017. In a relatively short amount of time, GSDP developed a national reputation for excellence in research and clinical care of TGD youth. In January 2018, I relocated as faculty of Lurie Children's/Northwestern University Feinberg School of Medicine to join the faculty of Children's Hospital Los Angeles (CHLA)/Keck School of Medicine of University of Southern California (USC). I relocated to become Director of Mental Health Services within the Center for Transyouth Health and Development—the country's largest multidisciplinary gender program directed by Dr. Johanna Olson-Kennedy (Contact PI) and serving approximately 1,700 TGD youth. I have experience developing, implementing and monitoring baseline and follow-up evaluations that inform evidence-based care in both of these clinical settings focused on TGD youth and their families. My previous role at GSDP is also advantageous due to a history of and ongoing scholarly/clinical collaboration with Drs. Chen (Co-I) and Garofalo (MPI).

In addition to my scholarly and clinical experience, I have a growing record of national professional leadership in the field of TGD mental health. I am the founder and chair of national and regional groups dedicated to increasing clinical training and consultation of mental health professionals and trainees working with TGD youth. Dr. Chen (Co-I, Lurie Children's) and I are founding co-chairs of the Gender Variance Special Interest Group (GV-SIG) of the American Psychological Association's Society for Clinical Child and Adolescent Psychology. I am also the founding chair of a Midwestern regional consultation group consisting of 70 mental health clinicians dedicated to increasing clinical acumen related to TGD youth.

My role as Co-I will include various responsibilities. Chiefly, and across all sites, I will communicate regularly with the PIs, Co-Is and site staff to ensure the study meets its aims, while also ensuring the ethical treatment of human subjects, and confidentiality and security of data. I will also supervise staff at my site, and co-develop and oversee systematic quality-assurance practices of data collected from each site. As we reach milestones in data collection (e.g., full enrollment of baseline, 6 mos, 12 mos, etc.) I will participate in the dissemination of our findings through academic journals with both scholarly and clinical impact. Please refer to the MPI plan for detailed information regarding the roles of each PI and Co-I.

B. Positions and Honors

Positions and Employment

2004-2006	Project Director, (PIs: GW Harper and MI Fernandez) Adolescent Community Health Research Group, DePaul University, Chicago, IL
2006-2008	National Student Representative, Executive Committee, Society for Community Research and Action (Div. 27), American Psychological Association
2007-2008	Instructor, Department of Psychology, DePaul University, Chicago, IL
2008-2010	Project Director (PI: Garofalo) Howard Brown Health Center/Lurie Children's, Chicago, IL
2010-2011	Predoctoral Intern in Clinical Psychology, Alexian Bros Behavioral Health Hospital, Hoffman Estates, IL
2011-2012	Clinical Fellow of Psychology in Psychiatry, Harvard Medical School, Boston, MA
2012-2017	Medical Psychologist, Division of Adolescent Medicine, Lurie Children's Hospital, Chicago, IL

2014-2017	Assistant Professor, Departments of Psychiatry & Behavioral Sciences, and Pediatrics, Northwestern University, Feinberg School of Medicine, Chicago, IL
2015-Present	Founding Chair, Gender Variance Special Interest Group, Society for Clinical Child and Adolescent Psychology (Div. 53), American Psychological Association
2018-Present	Clinical Psychologist, Division of Adolescent and Young Adult Medicine, Children's Hospital Los Angeles, Los Angeles, CA
2018-Present	Assistant Professor, Department of Pediatrics, Keck School of Medicine of the University of Southern California, Los Angeles, CA

Honors

2002-2004	National Institute of Mental Health Career Opportunities in Research (NIMH-COR) Scholar – San Francisco State University. San Francisco, CA
2004	Magna Cum Laude – San Francisco State University. San Francisco, CA
2009	Recipient, 30 Under 30 Award, Windy City Media Group, Chicago, IL
2010	Recipient, Scrivner Memorial Research Grant ($5,000) – American Psychological Foundation
2013	Finalist, Robert H. DuRant Award for Statistical Rigor and Innovation in Adolescent Health Research – Society for Adolescent Health and Medicine 2014, Austin, TX
2017	Recognition for Excellence in Teaching (Child/Adolescent gender and sexual identity development) – Northwestern University, Feinberg School of Medicine, Chicago, IL

C. Contributions to Science

1. A growing body of my research is consistent with my career-long interests of **examining gender identity in populations accessing mental health treatment in multidisciplinary settings** (a-d). Publications in these areas have stemmed from my background in interpersonal trauma as well as evidence-based clinical care, psychometric measure development, and burgeoning research among TGD individuals (and parents) engaged in multidisciplinary care settings. I developed these manuscripts along with a team of scientist-practitioners across disciplines (e.g., psychology, psychiatry, general pediatrics, and endocrinology). One publication (i.e., item b below) was co-authored by psychologists and physicians from all four academic institutions affiliated with this submission, most of whom are also collaborators on a multisite observational study of psychosocial outcomes in transgender youth, aged 12-21 (R01HD082554).
    a. **Hidalgo MA**, Chen D, Garofalo R, Forbes C. Perceived parental attitudes of gender expansiveness: Development and preliminary factor structure of a self-report youth questionnaire. Transgender Health. 2017 2(1): 180-187. PMCID: PMC5685204
    b. **Hidalgo MA**, Ehrensaft D, Tishelman AC, Clark LF, Garofalo R, Rosenthal SM, Spack NP, Olson J. The gender affirmative model: What we know and what we aim to learn. Human Development. 2013;56(5):285-290.
    c. **Hidalgo MA**, Petras H, Chen D, Chodzen G. The Gender Minority Stress and Resilience Measure: Psychometric Validity of an Adolescent Extension. *Clinical Practice in Pediatric Psychology, 7*(3):278-290, Sept 2019. PMC not yet available.
    d. **Hidalgo MA**, Chen D. Experiences of gender minority stress in cisgender parents of transgender/gender-expansive prepubertal children: A qualitative study. Journal of Family Issues. 2019;40(7):865-886. PMID: Not yet assigned

2. In addition to my contributions to science regarding TGD youth, a significant portion of my 25 publications has focused on investigating the **influence of individual-level and social-ecological factors on mental health and health behavior** among ethnically-diverse young transgender women (YTW) and young men who have sex with men (YMSM). These populations are of particular interest because they are disproportionately afflicted with psychopathology and infected with HIV. Within this domain of my research, co-authors and I have examined individual-level factors such as **gender role expression** (a & c), and socio-ecological factors such as the influence of partner violence and religiosity on sexual risk behavior. I have also conducted more applied research, mostly notably directing a RCT to examine preliminary efficacy of a group-based HIV prevention intervention for ethnic/racial-minority YMSM aged 16-20 (b). Dr. Garofalo (Co-I) and I are currently testing efficacy of an adaptation of this intervention to a mobile platform (i.e., U01 MD011279).

a. **Hidalgo**, **MA**, Kuhns, LM, Kwon S, Mustanski, B, Garofalo, R. The impact of childhood gender expression on childhood sexual abuse and psychopathology among young men who have sex with men. Child Abuse Neglect, 2015; 46:103-112. PMCID: PMC4527874
b. **Hidalgo MA**, Kuhns LM, Hotton AL, Johnson AK, Mustanski B, Garofalo R. The MyPEEPS randomized controlled trial: A pilot of preliminary efficacy, feasibility, and acceptability of a group-level, HIV risk reduction intervention for young men who have sex with men. Archives of sexual behavior. 2015 Feb 1;44(2):475-85. PMCID: PMC4559339
c. Wilson BM, Harper G, **Hidalgo MA**, Jamil O, Torres R, Isabel Fernandez M. Negotiating Dominant Masculinity Ideology: Strategies Used by Gay, Bisexual and Questioning Male Adolescents. Amer J Community Psychology. 2010;45(1-2):169-185. PMCID: PMC2906685
d. (b)(4)

3. Another important domain to highlight, are the subset of publications that reflects my experience engaging disenfranchised minority populations in research that is both quantitative and qualitative in nature.
   a. **Hidalgo, MA**, Suarez N, Garofalo R, Hoehnle S, Thai J, Mimiaga MJ, Brown E, Sullivan P, Bratcher A, Wimbly T, Stephenson R. Clinically Significant Depressive Symptoms among a Diverse Sample of Same-Sex Male Couples in Atlanta, Boston, and Chicago: An Analysis of Individual- and Dyadic-level Factors. *Journal of Gay and Lesbian Mental Health,* 22(4): 327-347, 2018. PMC not yet assigned.
   b. (b)(4)
   c. Stephenson R, Suarez NA, Garofalo R, **Hidalgo MA**, Hoehnle S, Thai J, Mimiaga MJ, Brown E, Bratcher A, Wimbly T, Sullivan P. Project Stronger Together: Protocol to test a dyadic intervention to improve engagement in HIV care among sero-discordant male couples in three US cities. JMIR Res Protoc, 2017; 6(8): e170. PMCID: PMC28860107
   d. **Hidalgo MA**, Cotten C, Johnson AK, Garofalo R. 'Yes, I am more than just that.': Gay/bisexual young men residing in the United States discuss the influence of minority stress on their sexual risk behavior prior to HIV infection. International Journal of Sexual Health, 2013; 25(4): 291-304.

Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/myncbi/browse/collection/48488502/?sort=date&direction=descending

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

R01 HD097122 Hidalgo/Chen/Ehrensaft/Tishelman (MPI) 03/21/19-02/29/24
A Longitudinal Study of Gender Nonconformity in Prepubescent Children.
This research aims to establish a national cohort of prepubertal transgender/gender- nonconforming (TGNC) children (and their parents), and longitudinally observe this cohort to expand the body of empirical knowledge pertaining to gender development and cognition in TGNC children, their mental health symptomology and functioning over time, and how family-initiated social gender transition may predict or alleviate mental health symptoms and/or diagnoses. Role: Principal Investigator

1 UN 87PS004362-01-00 Humphreys (PD) 08/01/18-07/31/23
Promoting Safe and Supportive Environments for Local Educational Agencies providing school-based HIV/STD Prevention – Component 3C
The goal of this project is to provide technical assistance to CDC-funded local educational agencies around positive youth development and safe environments in which to provide HIV/STD prevention programing and educational resources. Role: Co-Investigator

1 U01 MD 011279-01 Schnall/Garofalo/Kuhns (MPI) 09/01/16-08/31/21
A Pragmatic Clinical Trial of MyPEEPS Mobile to Improve HIV Prevention Behaviors in Diverse Adolescent MSM

Using a participatory approach, our study will incorporate user-centered design in the translation of the MyPEEPS intervention onto a mobile platform. MyPEEPS was tested with older adolescents (16-18 year olds) and prior to the availability of non-occupational post-exposure prophylaxis (nPEP) and pre-exposure prophylaxis (PrEP); therefore, in addition to the mobile adaptation, we will update the intervention content. Role: Co-Investigator

1 R34 DA 044106-01A1 Kipke (PI) 08/15/18-07/31/21
Y2Prevent: Preventing Drug Use and HIV through Empowerment, Social Support and Mentorship.
The major goal of this research is to further refine and pilot test an intervention called Young Men's Adult Identity Mentoring (YM-AIM), an adaptation of CDC's Diffusion of Effective Behavioral Intervention entitled Project AIM. The goal of YM-AIM is to help AAYMSM develop a healthy vision for their future (or "possible future self"). This study will further strengthen and refine YM-AIM by adding a youth mentoring/support component, called Youth Initiated Mentoring (YIM). Role: Co-Investigator

5U01 DA 036926-04 Kipke (PI) 08/15/15-07/31/20
Young Men of Color Who Have Sex with Men Cohort Study.
The major goals of this research are to conduct longitudinal research with a large and diverse cohort of 450 YMSM of color in order to prevent new HIV infections, reduce transmission, and reduce HIV/AIDS-related disparities by focusing on successful engagement in care. Role: Co-Investigator

R01 HD 082554-01A1 Olson/Garofalo/Rosenthal/Chan (MPI) 08/01/15-06/30/20
The Impact of Early Medical Treatment in Transgender Youth
This proposed research will fill gaps in knowledge, provide empirical evidence to inform clinical care, and would be the first study of its kind evaluating longitudinal outcomes of medical interventions for transgender youth in the US. Four university-affiliated gender clinics across the United States will partner to conduct a multi-site observational study of two developmental cohorts examining the safety of hormonal interventions and the physiological and psychosocial outcomes associated with these treatments. Role: Co-Investigator

Completed Research Support

1R56 MH 113684-01A1 Mimiaga (PI) 09/21/18-09/20/20
Mobile Adaptation and Testing of a Uniquely Targeted HIV Intervention for Young Transgender Women.
The goals of this proposed study are to adapt "LifeSkills"- an efficacious and uniquely targeted group- based HIV prevention intervention for young transgender women (YTW) ages 16-29, at risk for HIV transmission or acquisition- to a mobile platform; and once adapted, to conduct a full-scale randomized controlled trial (RCT) to determine its efficacy in decreasing HIV risk behavior. Role: Co-Investigator

R01 HD 075655 Stephenson/Mimiaga/Garofalo (MPI) 04/01/13-03/31/18
CVCTPlus: A Couples-Based Approach to Linkage to Care and ARV Adherence
From a sample of 3,360 MSM in Atlanta, Boston, and Chicago, 250 HIV-serodiscordant couples will be randomized to either Individual or Couples HIV Counseling and Testing, and then followed prospectively for two years. Couples randomized to couples-based counseling and testing will also receive a dyadic adherence intervention, with the research aimed to determine if couples testing together impacts linkage to HIV care, retention in HIV care, ART adherence and viral suppression. Role: Co-Investigator

(b)(4) Hidalgo (PI) 08/01/15-07/31/17
PrEP engagement among Latino men who have sex with men and Latina transgender women in Chicago
(P30AI050409 facilitated by Emory University; Del Rio). In an effort to decrease HIV-related health disparities among two highly vulnerable Latino subgroups of people aged 18-29 – men who have sex with men (LMSM) and transgender women who have sex with men (LTW) – this projected, **supported by an NIH early career award mechanism**, assessed among these subgroups personal and social factors that influenced sexual risk behavior, interpersonal relationships, and individual uptake and adherence to pre-exposure prophylaxis. Role: Principal Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Diane Ehrensaft

eRA COMMONS USER NAME (credential, e.g., agency login): (b)(6)

POSITION TITLE: Adjunct Associate Professor of Pediatrics

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Michigan	B.A.	05/1968	Psychology
University of Michigan	Ph.D.	05/1974.	Developmental Psychology
Children's Hospital Oakland		07/1980	Clinical Psychology
Children's Hospital San Francisco		07/1981	Clinical Psychology

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A. Personal Statement

I am a developmental and clinical psychologist who has been engaged in gender studies since entering graduate school in 1968, culminating in my doctoral dissertation, Sex Role Socialization in Preschool Age Children. Since that time I have devoted my career to studying, do research, and engaging in clinical practice centered around both the gender development in children and the gender relations among parenting couples. In the past decade and a half, that work has zeroed in on the development and emotional needs of gender-nonconforming children, focusing on children and adolescents who do not abide by the norms of the culture regarding their gender or indicate that their gender is discrepant from what others have thought it to be based on the sex assigned on their birth certificate. In 2009 a group of professionals came together to pool our efforts to meet the rapidly growing and therefore rapidly expanding needs of these children and their families, culminating in the formation of the Child and Adolescent Gender Center, of which I am a founding member and presently the Director of Mental Health. Within this community-university partnership we established our interdisciplinary gender clinic, housed in the Department of Pediatrics at UCSF Benioff Children's Hospital. where I am the chief psychologist. Our clinical practice has been instrumental in informing us of the needs and the risks and benefits of our practices to support the mental and physical health of our patients, but what we are lacking is substantive research evidence that will both evaluate the effectiveness of our interventions and inform us of the outcomes of this growing population of children. From my graduate school studies to the present, my specific interest has been the pre-pubertal set of children. In my theoretical writing in psychoanalytic journals, my clinical practice, both at UCSF and in my private practice, my books for a more general audience (*Gender Born, Gender Made; The Gender Creative Child),* and my forthcoming co-edited academic book (with Dr. Colt Keo-Meier) , The Gender Affirmative Mode: A Clinical Approach for Working with Transgender and Gender Expansive Children, to be released by American Psychological Association Publications in April 2018, I of clinical practices with children, I find myself positioned as thought leader in the field of treatment of gender-nonconforming children. I am particularly compelled to study more scientifically the pathways for young

children who are under the age of puberty, eligible for no medical interventions, but yet demand our attention as they articulate a gender other than the one matching the sex on their birth certificate. With that said, I consider myself particularly well suited to assume the role of Principal Investigator for the UCSF site in this four-site proposed grant studying the developmental pathways and mental health outcomes for pre-pubertal gender-nonconforming children.

B. Positions and Honors

Positions and Employment

2011 to present: Clinical Faculty, Pediatrics, Psychologist, University of California, San Francisco (UCSF) Gender Clinic
2009 to present: Director of Mental Health, Child and Adolescent Gender Center
1981 to present: Clinical Psychologist, Private Practice, Oakland, California
1999 to present: Faculty, Psychoanalytic Institute of Northern California
1992 to present: Senior Clinician, A Home Within (non-profit organization addressing emotional needs of children/youth in foster care
1995-1999: Clinical faculty, Mt. Zion Psychiatric Department, University of California, San Francisco
1992-1998: Clinical faculty, Ann Martin Children's Center, Piedmont, California
1986-1992: Clinical faculty, Department of Psychiatry, Children's Hospital San Francisco
1986-1990: Clinical consultant, Children's Hospital Medical Center of Northern California, Oakland
1985-1986: Consulting Psychologist Health America Rockridge, Oakland, California
1982-1988: Independent contractor to Child Development Center, Children's Hospital Medical Center of Northern California
1981-2004: Professor, The Wright Institute, Berkeley
1980-1983: Mental Health Consultant, Alameda Headstart, Alameda, CA
1979-1981: Faculty, University of San Francisco
1977-1979: Faculty, Field Studies Program, University of California, Berkeley
1974-1978: Faculty, Interdisciplinary Program on Day Care and Child Development, University of California, Berkeley
1974-1978: Faculty, School of Social Welfare, University of California, Berkeley
1972-1973: Faculty, Sociology Department, Sir George Williams University, Montreal, Quebec

Other Experience and Professional Memberships

1982: Licensure as a psychologist, in the state of California
1983 to present: Member of Division of Psychoanalysis (Div. 39) of the American Psychological Association
1990 to present: Member of the American Society of Reproductive Medicine
1992 to present: Member of the Mental Health Professionals group of the American Society of Reproductive Medicine
1993 to present: Founding member and Board of Directors, A Home Within, national organization serving the needs of children in foster care
2000 to present: Board of Directors, Gender Spectrum
2008: Guest Editor. Special Issue on Foster Care. *Journal of Infant, Child, and Adolescent Psychotherapy*, 7:2, July 2008.
2014 to present: Faculty advisor for Dr. Sabra Katx-Wise's NIH grant, "The family environment, social support, and health in transgender youth. Boston Children's Hospital, Harvard University.
2015: Co-chair of annual scientific meeting of Division of Psychoanalysis, American Psychological Association
2016: Invited member of Task force for preparation of Standards of Care, Version 8, World Professional Association for Transgender Health
2016: Planning and review committee for 1st USPATH Professional Meetings (February 2017)

Honors

2012: Annual Scholarship Award: Advancement of Gender Issues in Psychoanalysis. Section on

Women, Gender, & Psychoanalysis, Division of Psychoanalysis, American Psychological Association

2013: Recognition Award for Outstanding Service. Section on Childhood and Adolescence, Division of Psychoanalysis, American Psychological Association

2014: Community Service Award in recognition of commitment to the Child and Adolescent Gender Center, Northern California Society for Psychoanalytic Psychology

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C. Contribution to Science

1. GRANTS 2015 National Institute of Health (NIH) R01HD082554: The Impact of Early Treatment of Transgender Youth
08/01/2015-06/30/2020
Role: Co-Investigator.
This is an ongoing 4-site research project, studying the medical and mental health outcomes over a five-year period of transgender youth receiving puberty blockers and/or cross-sex hormones. This is the first such study ever to be done in the U.S., with a national sample collected from the gender clinics at Boston Children's Hospital, UCSF Benioff Children's Hospital, Anne &. Robert H. Lurie Children's Hospital in Chicago, and L.A. Children's Hospital. As co-investigator, I have played an active role in designing the mental health measures, conceptualizing the research questions regarding psychological outcomes for youth receiving one or both of the medical interventions in their treatment for gender dysphoria, and as subject data are collected, interpreting and analyzing findings, as well as contributing to scientific papers, presentations, and publications as we disseminate information on the research findings over the five year period. We consider this to be an historical piece of research in that clinical providers have moved forward to provide these interventions for transgender youth, but we are lacking the scientific evidence to demonstrate both the risks and the benefits of these measures. Not only will this be a significant contribution to the science of transgender care; it will also provide critical information to families involved in the decision-making process of consenting to these medical interventions for their children of minor age. Although no articles have yet been published on our research process, related publications include: Vance S, Ehrensaft D, Rosenthal S. M , Psychological and medical care of gender nonconforming youth. *Pediatrics*. 2014; Sherer I., Baum J., Ehrensaft D., Rosenthal S.M., Gender Nonconforming/Gender Expansive and Transgender Children and Teens., *Contemp Pediatrics*, 2014; . Hidalgo, M.A., Ehrensaft, D. Tishelman, A.C., Clark, L.F., Garofalo, R., Rosenthal, S.M., Spack, N.P., & Olson, J., The Gender affirmative model: what we know and what we aim to learn. *Human Development*, 56: 285-290, 2013; Sherer I., Rosenthal SM, Ehrensaft D., Baum J Child and Adolescent Gender Center: A multidisciplinary collaboration to improve the lives of gender nonconforming children and teens.., *Pediatric Review* 33:273-275, 2012.

2. Gender development/psychological experience of gender-nonconforming children.
This has been an ongoing project since 2000 in which I have documented my clinical work with gender-nonconforming children and their families and consolidated the data into theoretical and clinical publications and presentations. I feature it as one of my significant scientific endeavors for two reasons: 1) its relevance to the proposed project of developmental pathways and mental health outcomes for prepubertal gender-nonconforming children; 2) my position as an international thought leader in this area. As a psychoanalytic developmental and clinical psychologist, I have investigated the emotional underpinnings and psychosocial experiences of children in interaction with their parents, looking at both intra-and interpersonal factors. In a period where more and more families are seeking support for the healthy rearing of their gender-nonconforming children, this work has proven to be instrumental in offering theoretical explanations and clinical guidelines for the work involved. In addition to two trade books that I have published on this topic, *Gender Born, Gender Made* (2011) and *The Gender Creative Child* (2016), both published by The Experiment Publications, I am co-editor of a forthcoming volume to be released in 2017 by The American Psychological Association on the gender affirmative model as a guide to clinicians. I also have articles placed in several academic and professional journals, as well as chapters in professional books on the topic of gender-nonconforming children and their clinical needs. A sampling includes: Found in Transition: Our Littlest Transgender People. *Contemporary Psychoanalysis*, 50:4: 571-592, 2014; Listening and Learning from gender-nonconforming children. *The Psychoanalytic Study of the Child*, Vol. 68, 28-56, 2014; From gender

Identity disorder to gender identity creativity: True gender self child therapy. *Journal of Homosexuality*, 59:3, 337-356, 2012.

3. Developmental and psychological outcomes for children conceived with the aid of assisted reproductive Technology

In the past half century, the study of the family has taken a radical turn as increasing number of prospective parents began to build their families with the aid of science, rather than sex. Interfile couples, single parent families, gay and lesbian families have turned to various forms of ART, including gamete and embryo donation and gestational surrogacy. Parallel to the investigation measures highlighted above in #2, I began to document the experiences of children and their parents in ART families. These investigations culminated in the publication of *Mommies, Daddies, Donors, Surrogates* (Ehrensaft, 2007, Guilford Publications) and a series of published articles and professional/academic presentations of the clinical findings, specifically that children in such families have a set of unique developmental tasks and the the traditional family triangle of father, mother, child has now been expanded to a family circle including all the individuals who intended to have the child and all the individuals whose gametes or bodies helped to create that child, along with the child. Coming full circle, the work has now expanded to include family building among transgender parenting couples. Other than Dr. Susan Golombok's studies in Great Britain, there are very few other studies investigating the psychological experience and developmental outcomes for the children in these families. Sampling of published work from my own studies include: Baby Making: It Takes an Egg and Sperm and a Rainbow of Genders, in Katie Gentile (ed.), *The Business of Being Made: Producing Liminal Temporalities through ARTS*, New York: Routledge, 2015; Family complexes and Oedipal circles: mothers, fathers, babies, donors, and surrogates, in M. Mann (ed.) *Psychoanalytic Aspects of Assisted Reproductive Technology*, London: Karnac, 2014; The 'Birth Other' in Assisted Reproductive Technology, in M. O'Reilly-Landry (ed.), *A Psychodynamic Understanding of Modern Medicine*, London: Radcliffe, 2012; When Baby Makes Three or Four or More, *Psychoanalytic Study of The Child*, Vol. 63, 3-23, 2008.

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4. Qualitative study of gender and parenting

This study involved a qualitative study of mothers and fathers in intact families who were sharing the primary care of their children, with myself as principal investigator. The historical context in which this study was framed was the changing nature of American families in the 1980s in which more women were entering the workforce and gender norms were rapidly changing, with social movement toward more men taking on primary household tasks and childrearing responsibilities. The empirical question investigated was: Could men mother?, and relatedly, How successful were men and women in actually sharing the tasks of childrearing? Major findings were that men and women fairly evenly shared the day-to-day tasks of childrearing, with women doing slightly, but not significantly more of the daily tasks, but that the psychological experience of those shared roles was significantly different for fathers compared to mothers. Specifically, men saw these as discrete tasks that they performed, while mothers saw these tasks as emblematic of their central identity. IN conclusion: Men did "mothering," while women were mothers. The work was published in the book, Parenting Together: Men and Women Sharing the Care of their Children (Ehrensaft, The Free Press, 1987) and in articles and book chapters: Dual Parenting and the Duel of Intimacy, in G. Handel (ed.), *The Psychosocial Interior of the Family*, New York: Aldine Press, 1985; *Man, Woman, and Child: the New Shared Parenting Family*, ERIC Publications, Ann Arbor, Michigan, 1985; When Women and Men Mother," in Karen Hansen and Ilene Philipson (eds.), Women, Class, and the Feminist Imagination, Philadelphia: Temple University Press, 1990, 399-430. The work was presented at professional conferences (e.g.,The American Psychological Association, The American Sociology Association) and informed subsequent psychological and anthropological work on gender and family in the late 20th century, including the studies of Norma Radin on father participation; the research of Arlie Hochschild on the balance of work and family in American households, and the work of Beverly Fagot on gender and egalitarian vs. traditional families. An unexpected contritubtion of these investigations to public health and family life has been the effects of the finding on shared parenting in intact families on changes in policy for the then increasing numbers of divorcing families, providing evidence to support the ability of men to care for their children as effectively as women do as post-divorce family arrangements were being mapped out, in clinical offices, in courts of law, and in public policy.

5. Sex role socialization in preschool age children
I would like to come full circle with my first scientific investigation, my doctoral dissertation at The University of Michigan. This project included a year-long observational study, quantitative and qualitative, of teachers and children in a preschool setting, testing the following hypotheses: 1) Adults will demonstrate differential treatment of young boys and girls on a series of dimensions; 2) Adults will not be aware of their differential treatment of children based on their gender. Both hypotheses were confirmed, at robust significant levels. This study was conducted in the context of an historical shift of gender roles and a burgeoning of scientific inquiry regarding gender development in children, gender differences, and disparity in treatment of girls and boys—within families, within schools, and within public policy. The study resulted in my first publication, We Followed Them to School One Day: Sex Role Socialization in the Preschool, in Jerome and Evelyn Oremland (eds.). *The Sexual and Gender Development of Young Children,* New York: Ballinger Press, 1977, and resulted in professional trainings and academic presentations on the topic. This study was directly related to other research programs during that era, including Sandra Bem's work on sex-typing (e.g., Bem SL. Gender schema theory: A cognitive account of sex typing. *Psychological Review.* 1981;88:354–364. doi: 10.1037/0033-295X.88.4.354) and Eleanor Maccoby's work at Stanford University (e.g., Maccoby E.E. *The two sexes: Growing up apart, coming together.* Cambridge: Belknap Press/Harvard University Press; 1998).Although the doctoral dissertation on sex role socialization in preschool children predates the present proposed investigation of pre-pubertal gender-nonconforming children by several decades in an era when transgender children were on no one's radar screen except as rare anomalies, this investigation in the early 1970s put down my roots in the study of gender for the next 40+ years and contributed to the understanding of gender as neither nature nor nurture, but a transactional relationship between the two, a necessary concept when approaching scientific investigation of gender-nonconforming children.

D. Additional Information: Research Support

Ongoing research project, 2015 to 2020: National Institute of Health (NIH) R01HD082554:
The Impact of Early Treatment of Transgender Youth
My Role: Co-Investigator.

The nature of the project and description of my responsibilities as co-Investigator are described in C.1 above in the biosketch.
The goals of the project are to provide scientific evidence for the medical and mental health outcomes over a five year period in gender-nonconforming and transgender youth who have been administered puberty blockers and/or cross-sex hormones in a hospital-based clinic as part their gender care.

Ongoing research project, 2019 to 2024: National Institute of Health (NIH) R01HD097122
Gender Nonconformity in Prepubescent Children: A Longitudinal Study
My Role: Principal Investigator

This project is a prospective longitudinal observational study of pre-pubertal children who are gender-nonconforming and their care. It is a four-site study involving U.S.-based university affiliated pediatric gender clinics. With a targeted N of 320 subjects, the objective of the proposed research is to provide evidence-based data to inform clinical care for prepubescent transgender and gender-nonconforming children (TGNC).

BIOGRAPHICAL SKETCH

NAME: (b)(6)

eRA COMMONS USER NAME (credential, e.g., agency login): (b)(6)

POSITION TITLE: (b)(6)

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
(b)(6)	(b)(6)	(b)(6)	(b)(6)

A. Personal Statement

(b)(6)

(b)(6)

B. Positions and Honors (selected)

(b)(6)

Selected other experience

(b)(6)

(b)(6)

C. Contributions to Science

(b)(6)

(b)(6)

Complete List of Published Work:

(b)(6)

D. Additional Information: Research Support and/or Scholastic Performance

(b)(6)

(b)(6)

OMB No. 0925-0001 and 0925-0002 (Rev. 09/17 Approved Through 03/31/2020)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Diane Chen, PhD

eRA COMMONS USER NAME (credential, e.g., agency login): (b)(6)

POSITION TITLE: Pediatric Psychologist & Behavioral Health Director, *Potocsnak Family Division of Adolescent & Young Adult Medicine, Ann & Robert H. Lurie Children's Hospital of Chicago*; Assistant Professor of Psychiatry and Behavioral Sciences, and Pediatrics, *Northwestern University Feinberg School of Medicine*

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Michigan, Ann Arbor, MI	B.A. with Honors	05/2004	Psychology
Temple University, Philadelphia, PA	M.A.	08/2008	Clinical Psychology
Temple University, Philadelphia, PA	Ph.D.	08/2012	Clinical Psychology
Ann & Robert H. Lurie Children's Hospital of Chicago	Post-Doctoral Fellowship	07/2012 – 06/2013	Clinical Child & Pediatric Psychology

A. Personal Statement

The proposed renewal for the study, *"The Impact of Early Medical Treatment in Transgender Youth,"* will extend the initial 2-year follow-up period to evaluate longer-term physiological and psychological outcomes of pubertal suppression and gender-affirming hormone treatment in the only federally-funded cohort of transgender and non-binary (TNB) adolescents in the United States. My training, motivation, and expertise positions me well to carry out my responsibilities as Co-Investigator on this project, a role I have had throughout the initial grant funding period. I am a founding psychologist of Lurie Children's Gender & Sex Development Program (GSDP) and direct its behavioral health services. The program cares for over 1250 TNB youth. Since 2013, I have worked exclusively with TNB youth, providing direct clinical care within our multidisciplinary, subspecialty service. Thus, I recognize the need for research on long-term outcomes of early medical treatment in TNB youth.

In addition to my clinical expertise with TNB youth, I have a strong record of NIH-funded research related to the health of TNB populations. I am PI or MPI on two current and one recently-completed studies: (1) R21HD087839, which developed and evaluated a structured clinical tool to assess readiness for pubertal suppression treatment among TNB youth; (2) R21HD097459, which aims to develop and test a fertility-related decision-aid for transgender youth; and (3) R01HD097122, which aims to establish a national cohort of prepubertal TNB children and their parents to longitudinally assess gender development and cognition, mental health symptomology and functioning over time. In addition, I am Co-Investigator on R01HD082554, an observational study of psychosocial and anthropometric outcomes in TNB adolescents receiving gender-affirming medical care, and the study this competitive renewal proposes to extend.

I am eager to build on my history of collaboration with MPIs, Drs. Olson-Kennedy, Garofalo, Rosenthal, and Chan and Co-Investigators, Drs. Hidalgo, (b)(6), and Ehrensaft. As Co-Investigator for the proposed study, I will supervise the Lurie Children's study coordinator in their management of day-to-day research responsibilities, including IRB submission, recruitment and retention activities, and confidential data collection/management strategies. I will also contribute to the dissemination of our findings in collaboration with the investigative team.

1. Olson-Kennedy, J., Chan, Y.M., Garofalo, R., Spack, N., **Chen, D.**, Clark, L., Ehrensaft, D., Hidalgo, M.A., Tishelman, A.T., & Rosenthal, S. (2019). The Impact of Early Medical Treatment in Transgender

Youth: The Trans Youth Care Study. *Journal of Medical Internet Research—Research Protocols, 8*(7):e14434. DOI: 10.2196/14434. PubMed PMID: 31290407; PMCID: 6647755.

2. Olson-Kennedy, J. Chan, Y.M., Rosenthal, S. Hidalgo, M.A., **Chen, D.**, Clark, L., Ehrensaft, D., Tishelman, A.T., & Garofalo, R. (2019). Creating the Trans Youth Research Network: A collaborative research endeavor. T*ransgender Health, 4:1*, 304-312. DOI:10.1089/trgh.2019.0024. PubMed PMID: 31701011; PMCID: 6830532.
3. Olson-Kennedy, J., Hidalgo, M.A., Clark, L., Garofalo, R., **Chen, D.**, Rosenthal, S., Lee, J., Ehrensaft, D., Chan, Y.M., & Tishelman, A.T. (2019, September). *Baseline findings of a multisite study on physiologic and psychosocial impact of early medical treatment among US transgender youth: The Trans Youth Care study*. Symposium presentation at the biennial meeting of the United States Professional Association of Transgender Health, Washington, DC.
4. Hidalgo, M.A., **Chen, D.**, Clark, L., Ehrensaft, D., & Tishelman, A.T. (2019, August). *Psychosocial health of youth seeking gender-affirming multidisciplinary care: Baseline TYC findings*. Symposium presentation at the American Psychological Association Convention, Chicago, IL.

B. Positions and Honors

Positions and Employment

2013-2016	Instructor of Psychiatry and Behavioral Sciences, Northwestern University Feinberg School of Medicine, Chicago, IL
2013-present	Licensed Clinical Psychologist (Illinois License #: 071.008667)
2013-present	Pediatric Psychologist, Gender & Sex Development Program, Potocsnak Family Division of Adolescent and Young Adult Medicine, Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, IL
2015-present	Co-chair, American Psychological Association, Division 53 (Society of Child and Adolescent Psychology), Gender Variance Special Interest Group
2016-present	Assistant Professor of Psychiatry and Behavioral Sciences, Northwestern University Feinberg School of Medicine, Chicago, IL
2016-present	Assistant Professor of Pediatrics, Northwestern University Feinberg School of Medicine, Chicago, IL
2018-present	Founding Member and Case Conference Committee Member, Differences of Sex Development (DSD) Special Interest Group, American Psychological Association, Division 54 (Society of Pediatric Psychology)
2018- present	Behavioral Health Director, Potocsnak Family Division of Adolescent and Young Adult Medicine, Ann & Robert H. Lurie Children's Hospital of Chicago

Honors/Awards

2002-2004	University Honors, University of Michigan
2003	Psi Chi, National Psychologist Honors Society, University of Michigan
2003	Order of Omega, National Greek Honors Society, University of Michigan
2003	Summer Biomedical Research Fellowship, University of Michigan
2004	James B. Angell Scholar Award, University of Michigan
2004	College of Literature, Science, and Arts Travel Award, University of Michigan
2004	High Honors in Psychology, University of Michigan
2007-2010	Faculty Commendation for Excellence, Department of Psychology, Temple University
2008, 2009	Early Career Preventionist Network Travel Award, Society for Prevention Research (SPR)
2009, 2010	Department of Psychology Graduate Student Travel Award, Temple University
2009, 2011	"Graduate Fund for Excellence" Travel Award, College of Liberal Arts, Temple University
2009, 2011	Student Travel Award, Society for Research in Child Development (SRCD)
2009	Student Poster Award, Society for Prevention Research (SPR)
2011, 2012	Minority Travel Award, Society for Prevention Research (SPR)
2016-2018	NIH Loan Repayment Program Award (NIH LRP), Extramural Clinical Research focused on Evidence-based Clinical Care for Gender Diverse Youth.
2018-2020	NIH Loan Repayment Program Renewal Award (NIH LRP), Extramural Clinical Research focused on Evidence-based Clinical Care for Gender Diverse Youth

C. Contributions to Science

1. As Behavioral Health Director for Lurie Children's Gender & Sex Development Program (GSDP), I have been instrumental in implementing a psychosocial screening protocol into standard-of-care clinical practice. The following publications are based on data drawn from TGNC children and adolescents engaged in care within GSDP and their families.
   a. Kolbuck, V.D., Muldoon, A.L., Rychlik, K., Hidalgo, M.A., & **Chen, D.** (2019). Psychological and family functioning among clinic-referred prepubertal gender expansive children. *Clinical Practice in Pediatric Psychology, 7,* 254-266. DOI: 10.1037/cpp0000293.
   b. Hidalgo, M.A., Petras, H., **Chen, D**., & Chodzen, G. (2019). The Gender Minority Stress and Resilience Measure: Psychometric validity of an adolescent extension. *Clinical Practice in Pediatric Psychology, 7,* 278-290. DOI: 10.1037/cpp0000297.
   c. Chodzen, G., Hidalgo, M.A., **Chen, D.,** & Garofalo, R. (2019). Factors associated with depression and anxiety among transgender and gender-nonconforming youth. *Journal of Adolescent Health, 64,* 467-471. DOI: 10.1080/15532739.2018.1505575. PubMed PMID: 30241721; PMCID: 6528476.
   d. **Chen, D.,** Hidalgo, M.A., & Garofalo, R. (2017). Parental perceptions of emotional and behavioral difficulties among prepubertal gender-nonconforming children. *Clinical Practice in Pediatric Psychology, 5,* 342-352. DOI:10.1037/cpp0000217. PubMed PMID: 30416908; PMCID: 6223326.

2. I also actively engage in patient-centered research with youth with differences of sex development (DSD)/intersex traits to improve quality of care and psychosocial outcomes in this population.
   a. (b)(4)
   b. Ernst, M., **Chen, D.,** Kennedy, K., Jewell, T., Sajwani, A., Foley, C., Sandberg, D.E., in collaboration with the DSD-TRN Psychosocial Workgroup and Accord Alliance (2019). DSD web-based information: Quality survey of DSD team websites. *International Journal of Pediatric Endocrinology.* DOI: 10.1186/s13633-019-0065-x. PubMed PMID: 31149017. PMCID: 6537388.
   c. Miller, L., Leeth, E.A., Johnson, E.K., Rosoklija, I., **Chen, D**., Aufox, S.A., & Finlayson, C. (2018). Attitudes toward "Disorders of sex development" nomenclature among physicians, genetic counselors, and mental health clinicians. *Journal of Pediatric Urology, 14*, 418.e1-418.e7. DOI:10.1016/j.jpurol.2018.08/009. PubMed PMID: 30224300.
   d. Johnson, E. K., Rosoklija, I., Finlayson, C., **Chen, D**., Yerkes, E. B., Madonna, B. M., Holl, J. L., Baratz, A. B., Davis, G., & Cheng, E. Y. (2017). Attitudes toward "Disorders of sex development" nomenclature among affected individuals. *Journal of Pediatric Urology,* 2017 May 8.pii: S1477-5131(17)30183-3. DOI:10.1016/j.jpurol.2017.03.035. PubMed PMID: 28713007.

3. More recently, my research efforts have focused on expanding the field of Oncofertility to TGNC youth for whom gender affirming medical and surgical interventions (e.g., testosterone/estrogen therapy; hysterectomy/oophorectomy; vaginoplasty) have the potential to negatively affect fertility.
   a. **Chen, D.**, Kyweluk, M.A., Sajwani, A., Gordon, E.J., Johnson, E.K., Finlayson, C., & Woodruff, T. (2019). Factors affecting fertility decision-making among transgender adolescents and young adults. *LGBT Health, 6,* 107-115. DOI: 10.1089/lgbt.2018.0250. PubMed PMID: 30985275.
   b. **Chen, D.,** Kolbuck, V.D., Sutter, M.E, Tishelman, A.C., Quinn, G.P., & Nahata, L. (2019). Knowledge, practice behaviors, and perceived barriers to fertility care among providers of transgender care. *Journal of Adolescent Health, 64,* 226-234. DOI: 10.1016/j.jadohealth.2018.08.025. PubMed PMID: 30661518.
   c. **Chen, D.,** Matson, M., Macapagal, K., Johnson, E.K., Rosoklija, I., Finlayson, C., Fisher, C.B., & Mustanski, B. (2018). Attitudes towards fertility and reproductive health among transgender and gender-nonconforming adolescents. *Journal of Adolescent Health,* 63: 62-68. DOI:10.1016/j.jadohelth.2017.11.306. PubMed PMID: 29503031; PMCID: 6067953.
   d. **Chen, D.**, Simons, L, Johnson, E.K., Lockart, B.A. & Finlayson, C. (2017). Fertility preservation for transgender adolescents. *Journal of Adolescent Health,* 61(1): 120-123. DOI:10.1016/j.jadohealth.2017.01.022. PubMed PMID: 28363716; PMCID: 5604229.

4. The relative lack of empirical evidence informing best practices for gender and sexual minority populations has prompted my recent focus on bioethics. These publications highlight ethical issues in pediatric transgender healthcare and fertility preservation with gender and sex diverse populations.
   a. Nahata, L., **Chen, D.,** Moravek, M.B., Quinn, G.P., Sutter, M.E., Taylor, J., Tishelman, A.G., & Gomez-Lobo, V. (2019). Understudied and underreported: Fertility issues in transgender youth—a narrative review. *Journal of Pediatrics, 205*, 265-271. DOI: 10.1016/j.peds.2018.09.009. PubMed PMID: 30293639.
   b. Campo-Engelstein, L., **Chen, D.,** Baratz, A.B., Johnson, E.K., & Finlayson, C. (2019). Fertility preservation for a teenager with differences (disorders) of sex development: An ethics case study. *The Journal of Clinical Ethics, 30*, 143-153. PubMed PMID: 31188791.
   c. **Chen, D.**, & Simons, L. (2018). Ethical considerations in fertility preservation for transgender youth: A case illustration. *Clinical Practice in Pediatric Psychology, 6*, 93-100. PubMed PMID: 29963344; PMCID: 0623412.
   d. Campo-Engelstein, L., **Chen, D.,** Baratz, A.B., Johnson, E.K., & Finlayson, C. (2017). The ethics of fertility preservation for youth with differences (disorders) of sex development (DSD). *Journal of the Endocrine Society, 1*, 638-645. DOI: https://doi.org/10.1210/js.2017-00110. PubMed PMID: 28944319; PMCID: 5607629.

5. My early publications utilized a developmental psychopathology framework to better understand risk factors for externalizing behavior problems among at-risk, ethnic-minority children and adolescents.
   a. **Chen, D.,** Drabick, D. A. G., & Burgers, D. E. (2015). A developmental perspective on peer rejection, deviant peer affiliation, and conduct problems among youth. *Child Psychiatry and Human Development, 46*, 823-838. DOI: 10.1007/s10578-014-0522-y; PubMed PMID: 25410430; PMCID: 4440840.
   b. Keenan, K., Boeldt, D., **Chen, D.,** Coyne, C., Donald, R., Duax, J., Hart, K., Perrott, J., Strickland, J., Danis, B., Hill, C, Davis, S., Kampani, S., & Humphries, M., (2011). Predictive validity of DSM-IV oppositional defiant and conduct disorders in a clinically referred sample of preschoolers. *Journal of Child Psychology and Psychiatry, 52*, 47-55. DOI: 10.1111/j.1469-7610.2010.02290.x; PubMed PMID: 20738448; PMCID: 3005994.
   c. Drabick, D. A. G., Bubier, J., **Chen, D.**, Lanza, H. I., & Price, J. (2011). Source-specific oppositional defiant disorder among inner-city children: Prospective prediction and moderation. *Journal of Clinical Child and Adolescent Psychology, 40*, 23-35. DOI:10.1080/15374416.2011.533401; PubMed PMID: 21229441; PMCID: 3076609.
   d. Xie, H., Drabick, D. A. G., & **Chen, D.** (2011). Developmental trajectories of aggression from late childhood through adolescence: Similarities and differences across gender. *Aggressive Behavior, 37*, 387-404. DOI: 10.1002/ab.20404; PubMed PMID: 21748751; PMCID: 4332584.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/diane.chen.1/bibliography/47478501/public/?sort=date&direction=ascending

D. Additional Information: Research Support

Ongoing Research Support

LGBTQIA Adolescent and Young Adult Health Research Award J. Poquiz 04/01/20 – 03/31/21
(b)(4)
Non-binary Youth: A Mixed Methods Study to Examine Identity and Clinical Needs
This study will examine identity development and identify clinical care needs in non-binary adolescents.
Role: Mentor

Combined Pilot Research Grant S. Jordan 07/01/19 – 06/30/20
(b)(4)
Chest Dysphoria in Transmasculine Adolescents
This study will prospectively examine the impact of gender affirming top surgery on chest dysphoria, body image, gender congruence, and mental health outcomes in transmasculine youth.
Role: Co-Investigator

R01 HD097122 **D. Chen**/D. Ehrensaft/M. Hidalgo/A. Tishelman 03/21/19 – 02/29/24
NICHD
A Longitudinal Study of Gender Nonconformity in Prepubescent Children
This study will establish a national cohort of prepubertal TNB and their parents to longitudinally assess gender development and cognition, mental health symptomology and functioning over time.

R21 HD097459 **D. Chen (PI)** 09/21/18 – 8/31/20
NICHD
Fertility Decision-Making in Youth and Young Adults
This study will develop and test the feasibility and efficacy of a patient-centered Aid For Fertility-Related Medical Decisions (AFFRMED) targeted for transgender youth facing decisions about fertility preservation.

R01 NR017098 M. Mimiaga/R. Garofalo (MPI) 10/01/16 – 09/30/21
NINR
Adaptive Intervention Strategies for Strengthening Adherence to Antiretroviral Treatment among Youth
This multisite RCT tests the efficacy of a stepped-care (adaptive) intervention in comparison to standard care on HIV viral load and ART adherence among 16-24 year-old HIV infected adolescents.
Role: Co-Investigator

R01 HD082554 J. Olson, S. Rosenthal, R. Garofalo, & Y. Chan (MPI) 08/01/15 – 06/30/20
NICHD
The Impact of Early Medical Treatment in Transgender Youth
This project forms a 4-city network to evaluate long-term outcomes of early medical interventions for transgender youth.
Role: Co-Investigator

Completed Research Support

R21 HD087839 **D. Chen (PI)** 01/23/17 – 12/31/19
NICHD
Structured Pubertal Suppression Readiness Assessment for Gender Dysphoric Youth
This study will develop an assessment tool that can aid mental health clinicians in systematically assessing readiness for pubertal suppression treatment from a medical decisional capacity framework.

Foundation Research Grant **D. Chen (PI)** 06/01/18 – 05/31/19
(b)(4)
Neurocognitive Correlates of Pubertal Suppression Treatment among Transgender Youth.
This study used survey and Delphi methodology to identify key neurocognitive domains and associated assessment approaches to effectively measure the real-world neurocognitive impact of puberty suppression.

Targeted Research Grant **D. Chen (PI)** 01/01/17 – 12/31/17
(b)(4)
Development of a Fertility-Related Decision Aid for Transgender Youth and Their Parents
This study comprised a decisional needs assessment of peri-pubertal transgender youth and their parents to inform the development of a patient-centered decision aid about fertility.

Research Excellence Award from the Chairman **D. Chen (PI)** 09/01/16 – 08/31/17
Department of Psychiatry and Behavioral Sciences, Northwestern University Feinberg School of Medicine
Development of a Fertility-Related Decision Aid for Transgender Youth and Their Parents
This study comprised a decisional needs assessment of pubertal transgender youth and their parents in an effort to develop a patient-centered decision aid about fertility.

OMB No. 0925-0001 and 0925-0002 (Rev. 09/17 Approved Through 03/31/2020)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: (b)(6)

eRA COMMONS USER NAME (credential, e.g., agency login): (b)(6)

POSITION TITLE: (b)(6)

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
(b)(6)	(b)(6)	(b)(6)	(b)(6)

A. Personal Statement

(b)(6)

(b)(6)

B. Positions and Honors

(b)(6)

C. Contributions to Science

(b)(6)

(b)(6)

(b)(6)

D. Additional Information: Research Support and/or Scholastic Performance

(b)(6)

OMB No. 0925-0001 and 0925-0002 (Rev. 09/17 Approved Through 03/31/2020)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Wong, Carolyn F.

eRA COMMONS USER NAME (credential, e.g., agency login): (b)(6)

POSITION TITLE: Assistant Professor, University of Southern California, Keck School of Medicine; Children's Hospital Los Angeles

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of California, Berkeley	B.A.	05/1997	Psychology
University of California, Irvine	Ph.D.	05/2005	Psychology and Social Behavior (Health Psychology)

A. Personal Statement

I have a long history of engaging in research with vulnerable and socially disenfranchised young adult populations, including sexual minority youth such as young men who have sex with men (YMSM) and have recently begun to expand my research to also include transgender youth. My training as a Social Health Psychologist is rooted in the Social Ecological framework and I am particularly interested in understanding how stress interacts with individual-level and social-level risk and protective factors to lead to different health outcomes. I have participated in studies that examined psychosocial risk and resilient factors of adolescent and young adult populations from diverse social, socio-economic, and ethnic backgrounds, and different developmental experiences, including homeless youth, young adults with complex medical conditions, young men who have sex with men (YMSM), and specifically, YMSM of color, prescription-drug misusing young adults, and marijuana-using young adults. My goal is to utilize my knowledge to develop meaningful, effective, practical, and cost-effective tools, programs, and interventions for at-risk adolescents and young adults.

I have over ten years of experience working on NIDA-funded studies by contributing my theoretical knowledge and my extensive expertise and experience in quantitative research methods and statistical analysis, particularly in using advanced statistical methods as described in the proposal. I have served as a Co-Investigator for two NIDA-funded R01 focused on HIV-risk among YMSM, most recently a NIDA-funded U01 that examined barriers to engage in the HIV continuum of care among African American and Latino young men who have sex with men. This study received a research supplement to also better understand how transgender young adults engage in the HIV continuum of care. I have also served as a Co-I in three NIDA-funded studies related to substance misuse among high-risk populations and as a Site-PI for one of those studies focused on cannabis use among young adults in Los Angeles (the study spans from 2013-2023). Between 2016-2018, I also served as the Interim Director of the Biostatistics Core at CHLA, a wonderful opportunity to further hone my skill as a Research Scientist, Methodologist, and Statistician through my work with my colleagues at CHLA/USC.

My interest, experience, and training makes me uniquely qualify to contribute to the proposed continuation of the Transgender Youth Care (TYC) study, which is focused on understanding the short-term and long-term physiological and psychological effects of early medical intervention for adolescents with gender dysphoria. This innovative and highly significant study has the potential to critically inform the practice of clinical care, the design of programs and interventions, and to enrich/challenge our understanding of this population. I look forward to advising Dr. Olson, other PIs, Co-Is, and the rest of the research team on any research and data-related issues and participate in the interpretation and publication of these findings.

The following articles highlight my key scientific contributions, including the ways developmental risk factors and stressors impact the health and health behaviors of highly vulnerable young adult populations. These papers also demonstrate my ability to conceptualize and apply advanced statistical techniques to effectively investigate complex research questions.

1. **Wong CF**, Schrager SM, Holloway I, Meyer I, & Kipke MD. (2014). Minority stress experiences and psychological well-being: the impact of support from and connection to social networks within the Los Angeles House and Ball communities, *Prevention Science*, 15, 44-55. PMCID: PMC3796016
2. **Wong CF**, Silva K, Kecojevic A, Schrager S, Jackson Bloom J, Iverson E, & Lankenau S. (2013). Coping and emotional regulation profiles as predictors of nonmedical prescription drug and illicit drug use among high-risk young adults. *Drug and Alcohol Dependence*, 132: 165-71. PMCID: PMC4180492
3. **Wong CF**, Schrager SM, Chou CP, Weiss G, & Kipke MD. (2013). Changes in developmental contexts as predictors of transitions in HIV-risk behaviors among young men who have sex with men (YMSM), *American Journal of Community Psychology*, 51, 439-450. PMID: 23254866

B. Positions and Honors

Positions and Employment

2002–2005	Research Project Coordinator, *Women's Bio-behavioral Processes and Health Study*, UCI/UCI Medical Center (UCIMC) (funded by Department of Defense)
2002–2003	Member/consultant, Psycho-Oncology Task Force, UCIMC, Chao Family Comprehensive Cancer Center
2004	Consultant, Carney Education Services, Los Angeles
2006–2007	Co-instructor of Research Methods Course for Pediatric Subspecialty Fellows, Children's Hospital Los Angeles, CA
2006–2008	Biostatistician, *Healthy Young Men Study*, Children's Hospital Los Angeles (CHLA), Los Angeles, CA (NIDA, R01)
2008–present	Assistant Professor of Research, USC/CHLA, Los Angeles, CA (appointment on April 2008)
2010–2011	*Leave-of-absence from February 2010 to June 2011*
Spring 2012	Instructor for course on *Maternal and Child Health*, Health Promotion and Disease Prevention Program, Keck School of Medicine, USC, Los Angeles, CA
2016-2018	Director, Biostatistics Core, The Saban Research Institute, Children's Hospital Los Angeles, Los Angeles, CA

Other Experience and Professional Membership

1999–present	Member, American Psychological Association
2002–2003	Member/consultant, Psycho-Oncology Task Force, University of California, Irvine, Medical Center (UCIMC)
2003–2006	Member, Society of Behavioral Medicine
2006	Summer Institute on Longitudinal Research, University of California, Los Angeles
2007 & 2008	Summer Research Institute on Mental Health Research, Longitudinal analyses with latent variables, Johns Hopkins Bloomberg School of Public Health
2007–present	Member, American Public Health Association
2007–present	Reviewer, Journal of Adolescence
2008–present	Member, Society for Prevention Research
2009	Member, National Runaway Switchboard – Program, Education, and Research Taskforce
2009–present	Reviewer, American Journal of Public Health
2011–2012	Reviewer, Journal of Youth and Adolescence
2012–present	Reviewer, Addictive Behaviors
2013–present	Editorial Board Member, Journal of Youth and Adolescence
2016–present	Healthcare Leadership Academy Member, Keck School of Medicine at USC and Children's Hospital Los Angeles

Honors and Awards

1. 1998–2002	Cota Robles Graduate Research Fellowship, University of California, Irvine, CA
2. 2000–2001	Faculty Mentor Program Fellowship, University of California, Irvine, CA
3. 2014–2016	Research Supplement to Promote Diversity in Health-Related Research Award (NIDA)

C. Contribution to Science

1. **Stress and Minority Stress Experiences of Young Men who have Sex with Men (YMSM).** YMSM are among the most vulnerable to HIV-infection and substance misuse. I have applied my background and training to investigate the role of psychosocial risk and protective factors that impact the mental health, drug use, and HIV risk-taking of this high-risk emerging young adult population. YMSM face a constellation of psychosocial health problems (i.e., drug use, depression, violence) and especially so for African American YMSM (AAYMSM), who are members of multiple stigmatized minority groups (e.g., sexual and racial/ethnic minority). In one of the first studies to examine minority stress experiences of an understudied population of AAYMSM from the "House and Ball Community" in Los Angeles published in *Prevention Science*, we found that despite the pervasive experience of minority stress in this group, the support and cohesion within "fictive-kinship" networks in this community significantly buffered their negative experiences and improved the mental health of AAYMSM. Findings with another group of AAYMSM indicated that while they exhibited lower likelihood of drug use as a group compared to their Caucasian counterparts, they were more likely to engage in illicit drug use when they reported high experiences of institutional racism and being subjected to sexual objectification. This and other related-research have contributed to the knowledge base of this understudied population and led to the development of a new intervention targeting African American YMSM. This body of work also contributed to the development of new NIDA-funded studies, for which I serve as Co-Investigator.

    a. Kipke, MD, Kubicek K, **Wong CF,** Robinson YA, Akinyemi I, Beyer WJ, Hawkins W, Rice CE, Layland E, Bray B, Belzer M. (2018). The Healthy Young Men's Cohort Study: Study design and methodology. *JMIR Research Protocol, in press.*
    b. **Wong CF**, Schrager SM, Holloway I, Meyer I, & Kipke MD. (2014). Minority stress experiences and psychological well-being: the impact of support from and connection to social networks within the Los Angeles House and Ball communities, *Prevention Science*, 15, 44-55. PMCID: PMC3796016
    c. **Wong CF**, Weiss G, Ayala G, & Kipke MD. (2010) Harassment, discrimination, violence, and illicit drug use among Young Men who have Sex with Men, *AIDS Education and Prevention*, 22, 4, 286-298. PMCID: PMC2962624
    d. **Wong CF**, Kipke MD, Weiss G, & McDavitt B. (2010). The impact of recent stressful experiences on HIV-risk related behaviors among YMSM. *Journal of Adolescence*, 33, 3, 467-475. PMCID: PMC2862810

2. **Profiles of Substance Use and HIV-Risk among High-Risk Emerging Adults.** In order to design targeted prevention and intervention programs, we need to understand commonalities and differences in terms of the strengths and vulnerabilities of different groups of high-risk young adults. My colleagues and I have used Latent Profile Analysis to identify substantive profiles of risk among misusers of prescription drugs in a paper, published in *Drug and Alcohol Dependence,* which identified coping and emotion regulation profiles among prescription drug misusing young adults. Studies of risk profiles enable us to meaningfully organize individuals from diverse backgrounds and life experiences, and design interventions that specifically address their vulnerabilities while building on their strengths. I also contributed to recent work focused on understanding factors associated with emerging trends in marijuana use.

    a. Lankenau SE, Tabb LP, Kioumarsi A, Ataiants J., Iverson E, **Wong CF**. (2019). Density of medical marijuana dispensaries and current marijuana use among young adults in Los Angeles. *Substance Use & Misuse, in press.*
    b. Lankenau, S., Ataiants, J., Mohanty, S., Schrager, S., Iverson, E. & **Wong, CF.** (2017). Health conditions and motivations for marijuana use among young adult medical marijuana patients and non-patient marijuana users. *Drug and Alcohol Review.*
    c. Lankenau, S., Fedorova, E., Reed, M., Schrager, S., Iverson, E. & **Wong, CF.** (2017). Marijuana practices and patterns of use among young adult medical marijuana patients and non-patient marijuana users. *Drug and Alcohol Dependence, 70, 181-188.*
    d. **Wong CF**, Silva K, Kecojevic A, Schrager S, Jackson Bloom J, Iverson E, & Lankenau S. (2013). Coping and emotional regulation profiles as predictors of nonmedical prescription drug and illicit drug use among high-risk young adults. *Drug and Alcohol Dependence*, 132: 165-71. PMCID: PMC4180492

3. **Impact of Early Life Stress/Trauma among Vulnerable Young Adult Populations.** While it is well-established that childhood abuse and early traumatic experiences can have significant long-term impact on the health, development, and well-being of children and adolescents, the complex ways these early childhood experiences interact and impact later experiences of trauma and stress are less understood. Similarly, how these processes impact later mental health and substance use among different high-risk young adult populations is not known. Findings from the studies cited below contributed to current knowledge about trauma – including a novel conceptualization and operationalization of "complex trauma" and how this impact mental health and substance use from the paper published in the *Journal of Interpersonal Violence*. These studies have greatly influenced my thinking about the lingering impact of developmental contextual influences on current life experiences and mental health in my work.

    a. Kecojevic A, **Wong CF**, Corliss, HL, & Lankenau S. (2015). Risk factors for high levels of prescription drug misuse and illicit drug use among substance-using young men who have sex with men (YMSM). *Drug and Alcohol Dependence*, 150:156-63. PMID: 5772436
    b. **Wong CF**, Clark LF, & Marlotte L. (2014). The impact of specific and complex trauma on the mental health of homeless youth. *Journal of Interpersonal Violence*, available online. DOI:10.1177/0886260514556770, PMID:25392379
    c. Friedman MS, Marshal MP, Guadamuz TE, Wei C, **Wong CF**, Saewyc E, Stall R. (2011). A meta-analysis of disparities in childhood sexual abuse, parental physical abuse, and peer victimization among sexual minority and sexual nonminority individuals, *American Journal of Public Health*, Aug;101(8):1481-94. PMCID: PMC3134495

4. **Social Network Influence on Substance Use and Related Behaviors.** Social network analyses enable researchers to understand the nature of a given person's social relationships and the way individuals within the network impact a person's thoughts, beliefs, and behaviors. There is a huge body of theoretical and empirical literature that discusses the ways these influences take place. This area of research is particularly relevant to the study of substance use and HIV risk, as the initiation and maintenance of these behaviors are strongly influenced and shaped by social norms and social control processes. Social networks have also been found to be promising for disseminating interventions. Social network measures have been used in all the studies in which I participated for the last nine year. I was able to learn from expert collaborators and colleagues in the field that allowed me to make substantive contribution to the design of social network questions in new studies, and development of manuscripts that have examined the influence of social network characteristics on health and risk behaviors as listed below.

    a. Holloway IW, Schrager SM, **Wong CF**, Dunlap S, Kipke MD. (2014). Network correlates of sexual health advice seeking and substance use among members of the Los Angeles House and Ball communities, *Health Education Research*, 29.2, 306-318 (April). PMCID: PMC3959205
    b. Wagner K, Iverson E, **Wong CF**, Jackson-Bloom J, McNeeley M., Davidson PJ, McCarthy C, Lankenau S. (2013). Personal social network factors associated with overdose prevention training participation: Herd immunity or social influence? *Substance Use and Misuse*, 48, 1-2, 21-30. PMCID: PMC3698974

5. **Epidemiology of Prescription Drug Misuse.** The misuse of prescription drug has received national attention given the escalating rates of abuse. I had the opportunity to explore why young adults, particularly high-risk ones (e.g., homeless youth, poly-drug users) initiate non-medical use of prescription drugs, and to investigate the association between prescription drug misuse to other drug use. My participation to this project challenged me to think about risk factors that lead not only to substance use, but also to the progression toward problematic use, dependence, and addiction.

    a. Kecojevic A, **Wong CF**, Schrager SM, Silva, K, Jackson-Bloom J, Iverson E, & Lankenau S. (2012). Initiation into prescription drug misuse: differences between lesbian, gay, bisexual, transgender (LGBT) and heterosexual high-risk young adults in Los Angeles and New York. *Addictive Behaviors*, 37, 11, 1289-1293. PMCID: PMC3409829
    b. Lankenau S, Schrager SM, Silver K, Kecojevic A, Jackson-Bloom J, **Wong CF**, Iverson E. (2012). Misuse of prescription and illicit drugs among high-risk young adults in Los Angeles and New York. *Journal of Public Health Research*, Feb 4; 1(1), 22-30. PMCID: PMC3396434

Complete list of published work can be found in PubMed:
https://www.ncbi.nlm.nih.gov/sites/myncbi/1feyusbRv-6s99/bibliography/56710652/public/?sort=date&direction=ascending

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

2R01DA034067-06A1 Lankenau (PI) 10/01/18 - 6/30/23
NIH/NIDA – Drexel University
Medical Marijuana, Emerging Adults & Community: Connecting Health and Policy
This project is a continuation of a NIDA study that began in 2014 to research the impact of medical cannabis laws on health, drug use, and cannabis use among 300 young adult medical cannabis patient and non-patient users in Los Angeles. This new study is the first project funded by NIDA to specifically examine cannabis use among young adults in California following the legalization of cannabis for non-medical use in 2016.
Role: Co-I (site Co-PI)

UK1HP32721 Wong (subcontract PI) 7/1/2018-6/30/2022
US Department of Health and Health Services, Health Resources and Services Administration (HRSA)
Awarded to Altamed, (subcontract to CHLA)
Nursing Education, Practice, Quality, and Retention (NEPQR) Training Program
This program will support the "people" strategic focus area by creating an infrastructure for training registered nurses to serve as a key member of the care team. This will serve as an early part of the nursing workforce development pipeline and support existing plans at AltaMed to expand the scope of practice for clinical RNs.

Completed Research Support

UD7HP28523 Wong (subcontract PI) 9/1/2016-6/30/2018
US Department of Health and Health Services, Health Resources and Services Administration (HRSA)
Awarded to Altamed, (subcontract to CHLA)
Patient-Centered Medical Home Interprofessional Collaborative Nursing Project
The Interprofessional Collaborative Nursing Project is designed to help strengthen nursing's capacity to achieve better health outcomes for patients through a Patient Centered Medical Home Practice Model. Through this project, AltaMed will enhance and advance the team-based concepts of the Interprofessional Collaborative Practice. The model will be expanded within the AltaMed network of primary care community clinics, targeting low-income, predominantly Latino safety-net populations.

1U01DA036926-01A1 Kipke (PI) 12/01/14 – 06/30/18
NIH/NIDA
Young Men of Color Who Have Sex with Men Cohort Study
There is an urgent need to address increasing rates of HIV/AIDS among high-risk Black, Latino and multiracial young men who have sex with men in Los Angeles. The overarching goal of the proposed research is to develop new interventions designed to reduce HIV/STI risk and transmission, reduce HIV/AIDS disease progression, and improve the health and quality of life of HIV+ young men. This research will also inform the development of new HIV service delivery models given that the U.S. is now reevaluating all models of care.
Role: Co-I

R01DA034067-03 Lankenau (PI) 4/01/16 - 3/31/18
NIH/NIDA – Drexel University
Medical Marijuana, Emerging Adults & Community: Connecting Health and Policy
A critical knowledge gap exists in the understanding of how medical marijuana (MM) policies have impacted emerging adults since MM became legal in California in 1996. Many questions remain to be addressed. The current study focuses on understanding the natural history of marijuana use among emerging young adult marijuana users and factors that contribute to their mental and physical health.
Role: Co-I

OMB No. 0925-0001 and 0925-0002 (Rev. 09/17 Approved Through 03/31/2020)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: Radix, Asa E

eRA COMMONS USER NAME (credential, e.g., agency login): (b)(6)

POSITION TITLE: Director of Research and Education

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
St. George's University, Grenada, WI	MD	12/1988	Medicine
London School of Hygiene and Tropical Medicine, UK	DTMH	4/1994	Tropical Medicine
University of Connecticut Health Center, CT	Residency	6/1992	Internal Medicine
University of Connecticut Health Center, CT	Fellowship	6/1994	Infectious Diseases
University of Cambridge, UK	MPhil	4/1995	Epidemiology
University of Connecticut, CT	MPH	5/1997	Public Health
Columbia University, NY	PhD	2/2020	Epidemiology

A. Personal Statement

I am well suited to this project due having over two decades of experience in the clinical care of transgender people. My background is in internal medicine and infectious diseases, with specific training in epidemiology and public health. I am very familiar with the medical and bio-psychosocial issues affecting transgender communities. Previously I worked as a public health clinician and HIV specialist in the Caribbean implementing HIV/STI treatment and prevention programs. It was through these experiences that I decided to change my direction and focus more on clinical research. I have undertaken training in epidemiology at the doctoral level (Columbia University, Mailman School of Public Health) which has enhanced my ability to engage productively in all aspects of study design and implementation. In my role as a co-investigator on several research projects, I have demonstrated excellent communication with team members and the ability to adhere to strict timelines. I have a record of strong collaboration with researchers from external agencies on NIH grants. I have assisted with recruitment, enrollment and tracking of participants, especially those from hard to reach communities. I serve in advisory roles as co-chair of the PAHO HIV/STI technical advisory committee, several committees for the NYS AIDS Institute, co-chair of the World Professional Association of Transgender Health Stands of Care Revision Committee and a member of the HHS Panel on Antiretroviral Guidelines for Adults and Adolescents. I have collaborated with several of the investigators on other projects (Garofalo, Olson, Hidalgo, Rosenthal, Ehrensaft and Tishelman). In summary, I have a demonstrated a record of success in prior clinical and administrative areas, have substantial knowledge of the populations and extensive experience to serve as an investigator on this project. I look forward to embarking on this important work.

1. Poteat, T., Reisner, S.L., **Radix, A**. HIV epidemics among transgender women. *Current Opinion in HIV and AIDS*, 2014 March 1: 9(2):168-173. PMID: 24322537
2. Reisner SL, Deutsch MB, Bhasin S, Bockting W, Brown GR, Feldman J, Garofalo R, Kreukels B, **Radix A,** Safer JD, Tangpricha V. Advancing methods for US transgender health research. *Current Opinion in Endocrinology, Diabetes and Obesity*. 2016 Apr 1;23(2):198-207. PMCID: 4916925

3. Reisner SL, **Radix A**, Deutsch MB. Integrated and gender-affirming transgender clinical care and research. *Journal of acquired immune deficiency syndromes* (1999). 2016 Aug 15;72(Suppl 3):S235. PMC4969060

B. Positions and Honors

I am a member of the HHS Panel on Antiretroviral Guidelines for Adults and Adolescents, the New York State AIDS Institute's Medical Care Criteria Committee and HIV Quality of Care Advisory Committee, co-chair of the World Professional Association of Transgender Health Revision Committee and co-chair of PAHO's Technical Advisory Committee (TAC) on HIV/STI and Regional PrEP Task Force and vice-chair of the American Sexual Health Association. I gave the first plenary related to transgender people at the 10th IAS Conference on HIV Science (IAS2019) in Mexico City.

Positions and Employment

1991-1992:	Emergency Room Physician (per Diem): Hartford Hospital, Hartford, CT
1992-1994:	Attending Physician (per Diem) VA Medical Center, Newington, CT
1993-1996:	Ambulatory Care Physician, (part-time) Immediate Medical Care Center, Wethersfield, CT
1995-1999:	Physician; Collin's Medical Associates, Hartford, CT, USA
1997-1999:	Medical Director, University of Hartford Health Services, Bloomfield Ave, Hartford, CT, USA
1999- 2006:	Medical Director, A.M. Edwards Medical Centre, Island Territory of Saba
1999- 2006:	Head of Public Health, Island Territory of Saba, Netherlands Antilles
03/06-03/10	Associate Medical Director, Callen Lorde Community Health Center, NY
03/10-	Director of Research and Education, Callen Lorde Community Health Center, NY

Other Experience and Professional Memberships

2015	Associate editor, Transgender Health
2015	Guest editor, Women's Health Issues (special supplement)
2015	IDSA membership
2014	International Journal of Transgenderism (editorial board)
2010	Physicians Research Network (editorial board)
2013	International Journal of transgenderism (ad hoc reviewer)
2013	Plos One (ad hoc reviewer)
2005	American College of Physicians (Fellow)

Honors

2009	Allan Rosenfield Scholar, Columbia University
1994	Cambridge Commonwealth Trust Award
1994	The Tate and Lyle Award (Cambridge University)
1992	University of Connecticut Ambulatory Care Award (Internal medicine)
1988	The International Student Award (St. George's University)

C. Contribution to Science

1. My main focus of the last years has been on LGBT health and barriers to care. I have written on clinical issues affecting transgender women, predominantly around HIV risk, treatment and care. These publications found that transgender women have low perception of HIV risk, and will prioritize gender affirming treatments over HIV prevention and antiretroviral therapy. The key finding has been that providing gender affirming treatments is key to engaging and retaining transgender women in care.

    a. Safer, J. D., Coleman, E., Feldman, J., Garofalo, R., Hembree, W., **Radix, A.**, & Sevelius, J. (2016). Barriers to healthcare for transgender individuals. *Current Opinion in Endocrinology, Diabetes and Obesity, 23*(2), 168-171. PMCID: 4802845
    b. **Radix A**, Sevelius J, Deutsch MB. Transgender women, hormonal therapy and HIV treatment: a comprehensive review of the literature and recommendations for best practices. *J Int AIDS Soc.* 2016 Jul 17;19(3 Suppl 2):20810. doi:10.7448/IAS.19.3.20810. Review. PMID: 27431475

c. **Radix A. E.**, Lelutiu-Weinberger Corina, and Gamarel Kristi E. Satisfaction and Health Care Utilization of Transgender and Gender Non-Conforming Individuals in NYC: A Community-Based Participatory Study. *LGBT Health*, December 2014, 1(4): 302-308. PMID: 26789858
d. Deutsch MB, **Radix A**, Reisner S. What's in a Guideline? Developing Collaborative and Sound Research Designs that Substantiate Best Practice Recommendations for Transgender Health Care. *AMA J Ethics*. 2016 Nov 1;18(11):1098-1106. doi: 10.1001/journalofethics.2016.18.11.stas1-1611. PMID: 27883301

2. I was a co-investigator for the CDC STOP study that investigated acute HIV infection among high risk MSM. This permitted evaluations of a new HIV diagnostic testing algorithm that will enhance detection of early HIV, an essential part of the HIV care continuum and necessary to ending the HIV epidemic.

   a. Westheimer E, Fu J, **Radix A**, Giancotti FR, Hall L, Daskalakis D, Tsoi B, Peters P. An HIV-1 RNA Test Following a Reactive Fourth-Generation Antigen/Antibody Combination Assay Confirms a High Proportion of HIV Infections. Journal of Clinical Virology. 2014 Dec;61(4):623-4. PMID: 25453336
   b. Peters PJ, Westheimer E, Cohen S, Hightow-Weidman LB, Moss N, Tsoi B, Hall L, Fann C, Daskalakis DC, Beagle S, Patel P, **Radix A**, Foust E, Kohn RP, Marmorino J, Pandori M, Fu J, Samandari T, Gay CL. Screening Yield of HIV Antigen/Antibody Combination and Pooled HIV RNA Testing for Acute HIV Infection in a High-Prevalence Population. JAMA. 2016 Feb 16;315(7):682-90. doi: 10.1001/jama.2016.0286. PMID: 26881371.

Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/sites/myncbi/asa.radix.1/bibliography/49737375/public/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support

1R01MD013554-01 Duncan (PI) 09/11/18-4/30/23
Impact of Social Cohesion and Social Capital in PrEP Uptake and Adherence among Transwomen of Color
This project will use real-time geospatial methods to investigate relationships between social cohesion and social capital within Global Positioning System defined activity space neighborhoods and social networks in relation to HIV pre-exposure prophylaxis (PrEP) uptake and adherence among transgender women (TW) of color (TWOC) in New York City.
Role: Consultant

PCORI/ AD-2017C1-6569 Reisner (PI) 11/17-05/22
Transgender Cohort Study of Gender Affirmation and HIV-related Health
To evaluate the effects of medical gender affirmation delivered in primary care as an intervention to improve HIV-related outcomes for TG adult patients
Role: Co-investigator

U01MD011279 Schnall (PI) 09/01/16-04/30/21
A Pragmatic Clinical Trial of MyPEEPS Mobile to Improve HIV prevention Behaviors in Diverse Adolescent MSM
Testing the efficacy of the MyPEEPS Mobile intervention to deliver HIV prevention information specifically developed for diverse young men who have sex with men (YMSM).
Role: Co-investigator

1UG3AI133669-01 Wirtz & Reisner (MPIs) 08/01/17-06/30/20
LITE Cohort
This study will assess HIV incidence, estimate the HIV Prevention/Care Continuum and evaluate health risks among transgender women.
Role: Co-investigator

Completed Research Support

R01MH106380 Golub (PI) 01/01/15-11/30/19
Preparing for implementation of sustained release antiretrovirals for HIV prevention
This project takes a multi-modal approach to understanding the social, behavioral, and health care system factors that may impact uptake, persistence, and real world feasibility and effectiveness of sustained release antiretrovirals (ARVs) for HIV prevention.
Role: Co-investigator

1R21MH116757-01 Golub (PI) 04/01/18-01/31/20
Biomedical Prevention Adherence Dynamics in a High Priority Population
This study will identify factors associated with PrEP initiation and persistence among a sample of TW with access to health care; (2) Identify correlates, motivators, and predictors associated with objective and self-report measures of PrEP adherence among a cohort of TW and (3) Examine the association between self-reported adherence, TFV-DP concentrations, and estradiol levels among TW on PrEP.
Role: Co-investigator

R01 AA022067 Golub (PI) 09/01/12-07/31/18
Intervention to Enhance PrEP Uptake and Adherence
This is a demonstration project to evaluate social and behavioral factors likely to influence PrEP acceptability and adherence among MSM within implementation of PrEP program at a community health center.
Role: Co-investigator

R01 MH097651 Wilson & Hansen (PI) 04/01/12-03/31/18
Efficacy trial of a brief health enhancement intervention for newly diagnosed men
The goal of this study is to compare the effects of behavioral interventions on health outcomes in newly diagnosed HIV+ MSM.
Role: Co-investigator

NCT02140775 Rabkin (PI) 04/01/14-02/28/18
Return to work randomized controlled trial: counseling after fatigue treatment in HIV/AIDS. A study to is a randomized clinical trial comparing Behavioral Activation counseling with Supportive counseling for HIV+ participants presenting with clinically significant fatigue whose energy has improved with armodafinil, who have the goal of returning to work or vocational training but have not done so on their own.
Role: Co-investigator

R01 DA034661 Parsons (PI) 08/01/12-07/31/17
Multicomponent intervention to reduce sexual risk and substance use
The goal of this study is compare the effects of behavioral interventions on health outcomes in high risk transgender women.
Role: Co-Investigator

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 1

ORGANIZATIONAL DUNS*: 0522779360000

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: CHILDREN'S HOSPITAL LOS ANGELES

Start Date*: 09-01-2020 **End Date*:** 08-31-2021 **Budget Period:** 1

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Johanna	L	Olson-Kennedy	M.D.	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Marco		Hidalgo	Ph.D	Co-Investigator							
3 .				(b)(6)									
4 .	Dr.	Carolyn		Wong	Ph.D	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Licensed Psychologist	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Study Coordinator						
1	Data Analyst						
1	Research Manager						
1	Clinical Research Manager						
1	Database Manager						
6	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT13040415

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 1

ORGANIZATIONAL DUNS*: 0522779360000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: CHILDREN'S HOSPITAL LOS ANGELES

Start Date*: 09-01-2020 **End Date*:** 08-31-2021 **Budget Period:** 1

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 1

ORGANIZATIONAL DUNS*: 0522779360000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: CHILDREN'S HOSPITAL LOS ANGELES

Start Date*: 09-01-2020 **End Date*:** 08-31-2021 **Budget Period:** 1

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	(b)(4)
7. Alterations and Renovations	
8 . Outpatient Care Costs - Laboratory Expenses	
9 . Participant Compensation	
10 . Participant Transportation Assistance	
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . MTDC	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): Department of Health & Human Services: Robert Lee, 415#437#7820

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification* File Name: CHLA_Budget_Justification.pdf
(Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

Tracking Number: GRANT13040415
Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 2

ORGANIZATIONAL DUNS*: 0522779360000

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: CHILDREN'S HOSPITAL LOS ANGELES

Start Date*: 09-01-2021 **End Date*:** 08-31-2022 **Budget Period:** 2

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Dr.	Johanna	L	Olson-Kennedy	M.D.	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2.	Dr.	Marco		Hidalgo	Ph.D	Co-Investigator							
3.				(b)(6)									
4.	Dr.	Carolyn		Wong	Ph.D	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Licensed Psychologist	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Study Coordinator						
1	Data Analyst						
1	Research Manager						
1	Clinical Research Manager						
1	Database Manager						
6	**Total Number Other Personnel**						

Total Other Personnel (b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 2

ORGANIZATIONAL DUNS*: 0522779360000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: CHILDREN'S HOSPITAL LOS ANGELES

Start Date*: 09-01-2021 **End Date*:** 08-31-2022 **Budget Period:** 2

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 2

ORGANIZATIONAL DUNS*: 0522779360000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: CHILDREN'S HOSPITAL LOS ANGELES

Start Date*: 09-01-2021 **End Date*:** 08-31-2022 **Budget Period:** 2

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	(b)(4)
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Outpatient Care Costs - Laboratory Expenses	
9 . Participant Compensation	
10 . Participant Transportation Assistance	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . MTDC	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): Department of Health & Human Services: Robert Lee, 415#437# 7820

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification* File Name: CHLA_Budget_Justification.pdf
(Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 3

ORGANIZATIONAL DUNS*: 0522779360000

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: CHILDREN'S HOSPITAL LOS ANGELES

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period:** 3

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Johanna	L	Olson-Kennedy	M.D.	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Marco		Hidalgo	Ph.D	Co-Investigator							
3 .	Dr.	Carolyn		Wong	Ph.D	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Licensed Psychologist	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Study Coordinator						
1	Data Analyst						
1	Research Manager						
1	Clinical Research Manager						
1	Database Manager						
6	**Total Number Other Personnel**						

Total Other Personnel (b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT13040415

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 3

ORGANIZATIONAL DUNS*: 0522779360000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: CHILDREN'S HOSPITAL LOS ANGELES

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period:** 3

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 3

ORGANIZATIONAL DUNS*: 0522779360000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: CHILDREN'S HOSPITAL LOS ANGELES

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period:** 3

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	(b)(4)
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Outpatient Care Costs - Laboratory Expenses	
9 . Participant Compensation	
10 . Participant Transportation Assistance	
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . MTDC	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): Department of Health & Human Services: Robert Lee, 415#437# 7820

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification* File Name: CHLA_Budget_Justification.pdf
(Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 4

ORGANIZATIONAL DUNS*: 0522779360000

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: CHILDREN'S HOSPITAL LOS ANGELES

Start Date*: 09-01-2023 **End Date*:** 08-31-2024 **Budget Period:** 4

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Johanna	L	Olson-Kennedy	M.D.	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Marco		Hidalgo	Ph.D	Co-Investigator							
3 .	Dr.	Carolyn		Wong	Ph.D	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Licensed Psychologist	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Study Coordinator						
1	Data Analyst						
1	Research Manager						
1	Clinical Research Manager						
1	Database Manager						
6	**Total Number Other Personnel**						

Total Other Personnel (b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT13040415

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 4

ORGANIZATIONAL DUNS*: 0522779360000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: CHILDREN'S HOSPITAL LOS ANGELES

Start Date*: 09-01-2023 **End Date*:** 08-31-2024 **Budget Period:** 4

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 4

ORGANIZATIONAL DUNS*: 0522779360000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: CHILDREN'S HOSPITAL LOS ANGELES

Start Date*: 09-01-2023 **End Date*:** 08-31-2024 **Budget Period:** 4

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	(b)(4)
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Outpatient Care Costs - Laboratory Expenses	
9 . Participant Compensation	
10 . Participant Transportation Assistance	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . MTDC	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): Department of Health & Human Services: Robert Lee, 415#437#7820

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification* File Name: CHLA_Budget_Justification.pdf
(Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 5

ORGANIZATIONAL DUNS*: 0522779360000

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: CHILDREN'S HOSPITAL LOS ANGELES

Start Date*: 09-01-2024 **End Date*:** 08-31-2025 **Budget Period:** 5

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Johanna	L	Olson-Kennedy	M.D.	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Marco		Hidalgo	Ph.D	Co-Investigator							
3 .	Dr.	Carolyn		Wong	Ph.D	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Licensed Psychologist	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Study Coordinator						
1	Data Analyst						
1	Research Manager						
1	Clinical Research Manager						
1	Database Manager						
6	**Total Number Other Personnel**						

Total Other Personnel (b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT13040415

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 5

ORGANIZATIONAL DUNS*: 0522779360000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: CHILDREN'S HOSPITAL LOS ANGELES

Start Date*: 09-01-2024 **End Date*:** 08-31-2025 **Budget Period:** 5

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 5

ORGANIZATIONAL DUNS*: 0522779360000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: CHILDREN'S HOSPITAL LOS ANGELES

Start Date*: 09-01-2024 **End Date*:** 08-31-2025 **Budget Period:** 5

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	(b)(4)
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Outpatient Care Costs - Laboratory Expenses	
9 . Participant Compensation	
10 . Participant Transportation Assistance	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . MTDC	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): Department of Health & Human Services: Robert Lee, 415#437# 7820

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification* File Name: CHLA_Budget_Justification.pdf
(Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

BUDGET JUSTIFICATION: CHILDREN'S HOSPITAL LOS ANGELES

PERSONNEL

Senior/Key Personnel

(b)(4)

Johanna L. Olson-Kennedy, MD, Contact Principal Investigator (calendar months years 1-5). Dr. Olson-Kennedy is an Associate Professor of Clinical Pediatrics at the Keck School of Medicine at the University of Southern California. She is also the Medical Director for the Center for Transyouth Health and Development at Children's Hospital Los Angeles, which is the largest care provider in the United States for children, youth, and young adults who identify as transgender or gender diverse. She is the Contact Principal Investigator of the current R01 and will continue to be so in the renewal. As the Contact Principal Investigator, Dr. Olson-Kennedy will be responsible for directing the coordinating center at Children's Hospital Los Angeles, communicating and coordinating with the multiple principal investigators and co-investigators, and overseeing study implementation at the Children's Hospital Los Angeles site.

(b)(4)

Marco A. Hidalgo, PhD, Co-Investigator (calendar months years 1-5). Dr. Hidalgo is an Assistant Professor of Clinical Pediatrics at the Keck School of Medicine at the University of Southern California. He is also a licensed clinical psychologist in the Center for Transyouth Health and Development where he conducts psychotherapy and research. Immediately prior to his relocation to CHLA/USC in January 2018, Dr. Hidalgo was faculty at Lurie Children's/Northwestern University Feinberg School of Medicine (2012-2017) where he, alongside Drs. Chen and Garofalo, co-established Lurie Children's Gender and Sex Development Program. Along with Drs. Chen, Ehrensaft, and Tishelman, he was recently awarded a multi-PI R01 in which he is the Contact Principal Investigator. The study aims to expand the body of empirical knowledge pertaining to gender development and cognition in transgender/gender nonconforming (TGNC) children and their mental health symptomology and functioning over time and understand how family-initiated social gender transition may predict or alleviate mental health symptoms and/or diagnoses. He has provided clinical care to TGNC youth since 2006, and he has a growing record of clinical and research collaboration and national professional leadership in the field of TGNC mental health. As co-investigator at the coordinating center, Dr. Hidalgo will collaborate with the other co-investigators to obtain meaningful mental health information from the youth, young adults, and parent/caregiver participants; conduct data analysis and interpretation; and disseminate the findings to community and professionals.

(b)(4)

(b)(6) **Co-Investigator (calendar months years 1-2).** (b)(6) is an Associate Professor of Research Pediatrics at the Keck School of Medicine at the University of Southern California. (b)(6) is a social health psychologist with training in public health and the Director of Research for the Division of Adolescent and Young Adult Medicine at Children's Hospital Los Angeles. (b)(6) has worked on issues of gay and transgender youth for more than two decades. Her CDC- and NIH-funded work include development, implementation, and evaluation of behavioral interventions for minority adolescents, young gay men, transgender youth, homeless youth, and youth living with HIV. (b)(6) was a founding member of the Behavioral Leadership Group of the NIH-funded Adolescent Trials Network and has extensive research experience with standardized measures, instrument development, implementation fidelity, and analysis of longitudinal data sets. (b)(6) will provide mentorship and expertise in the methodological decision-making, collaborate in data analysis, and assist in manuscript preparation and dissemination of results. (b)(6) will retire at the end of Year 2 of the project, and her role will be assumed by Dr. Wong.

(b)(4) (b)(4)

Carolyn F. Wong, PhD, Co-Investigator (calendar months years 1-2 and calendar months years 3-5). Dr. Wong is an Assistant Professor of Research in the Department of Pediatrics at the Keck School of Medicine of the University of Southern California. She has also recently served as the Director of the Biostatistics Core at The Saban Research Institute, CHLA. As a Health Psychologist, Dr. Wong has contributed her scientific expertise on studies that examined the psychosocial risk and resilient factors that impact the health and well-being of vulnerable adolescent and young adult populations from diverse backgrounds, including young men who have sex with men and substance-using young adults. Dr. Wong has over ten years of experience working on NIDA-funded studies by contributing her scientific background and extensive expertise and knowledge in quantitative research methods, statistical analysis, and particularly advanced statistical methods as described in the proposal. As a Co-I on the project, Dr. Wong will oversee and direct quantitative data management and analysis and provide advanced statistical consultation to the project, including developing and executing

analytical plans and advising the data team on appropriate longitudinal data analysis methods and procedures. She will work closely with the MPIs and Co-Is in determining the most rigorous approach to conceptualize constructs from survey measures to address key research questions from the study. Dr. Wong and the quantitative Data Analyst at CHLA will work closely with the three site biostatisticians to ensure clear communication and coordination between sites on analytical and data-related issues. Dr. Wong will also actively participate in preparation of publications for peer reviewed journals and presentations at professional meetings to disseminate study findings. In the start of Year 3, she will assume some of (b)(6) responsibilities upon (b)(6) retirement at the close of Year 2.

Fringe Benefits are calculated as (b)(4)% for faculty.

Other Personnel

(b)(6) **Study Coordinator ((b)(4) calendar months years 1-5).** (b)(6) is an experienced study coordinator who has been conducting study coordination activities since the first year of the grant. As a study coordinator of (b)(6) working at the coordinating site, (b)(6) has provided informative feedback to the protocol team about how best to conduct the study in a supportive manner while obtaining valuable data from participants. (b)(6) input has been instrumental in shaping the protocol, and he has championed activities to increase community engagement in the research. (b)(6) will continue to conduct study activities with participants including recruitment activities to increase targeted enrollment and retention activities to preserve the ongoing cohort.

(b)(6) **Data Analyst ((b)(4) calendar months years 1-5).** (b)(6) has expertise in data management (e.g., data cleaning, dataset curation, variable manipulations) and analysis. (b)(6) is intimately involved with the study data submitted to the coordinating center throughout the study and conducts activities such as data cleaning, ensuring that data are complete, querying the study coordinators about problematic data, running analyses, providing data to the protocol team, and assisting with interpretation of analysis results. Under the guidance of (b)(6) and Dr. Wong, (b)(6) will continue to be the primary data analyst at the coordinating center and will respond to requests for data analysis and data sets from the sites' biostaticians. The percent time of this role is increasing due to the large amount of data that has already been collected and will continue to be collected over the next grant period. (b)(6) primary responsibility is to ensure incoming data are consistent and of high quality by running ongoing analyses as the cohorts move through the data points. (b)(6) also focuses on responding, in a timely manner, to the many requests for data for site analysis, interpretation, and publication as the investigative team have ramped up their dissemination efforts.

(b)(6) **Research Manager ((b)(4) calendar months year 1; (b)(4) calendar months years 2-5).** (b)(6) (b)(6) has extensive experience in quantitative and qualitative research, including the development of data collection protocols, the design of data collection instruments, quality control, and the management of large, complex data sets. (b)(6) will continue to be responsible for overseeing the data management systems, data cleaning and merging, and data analysis activities throughout the study. (b)(6) also coordinates the Data Coordination Committee per the Multiple PI Leadership and the Data Sharing Plans to ensure that significant and valuable study results are disseminated.

(b)(6) (b)(6) **Clinical Research Manager ((b)(4) calendar months year 1; (b)(4) calendar months years 2-5).** (b)(6) has a strong background in managing clinical research studies and trials. (b)(6) has been managing the operations related to study activities since the study was first funded, including guiding and acting as a resource for the study coordinators, being point with the CHLA institutional review board, communicating with the sites regarding protocol or study activity amendments, and ensuring that human subject research protection guidelines are followed.

(b)(6) **Database Manager ((b)(4) calendar months years 1-5).** (b)(6) has extensive experience in the development of databases for cross-sectional and longitudinal data collection. (b)(6) developed and maintains the database that collects the participant clinical data, edits the database as needed, and creates reports to support study implementation and data analysis. (b)(6) works closely with the Data Analyst under the guidance of (b)(6).

(b)(6), **Licensed Psychologist (** (b)(4) **calendar months years 1-5).** (b)(6) provides clinical supervision and research bias management support for the (b)(4) (b)(6) has many years of direct service and research experience serving the transgender population. (b)(4) (b)(4) on the protocol team who is interacting with study participants has provided valuable feedback that has been incorporated into the research study. However, the daily interactions with transgender youth and their parents/caregivers can be challenging and triggering, and clinical supervision can provide vital support to the study coordinator. In addition, support with bias management ensures that bias does not enter the interaction between the participant and the study coordinator, which supports data integrity.

Fringe benefits are calculated as (b)(4)% for staff and (b)(4)% for faculty (b)(6).

TRAVEL

Domestic Travel of $(b)(4) is requested per year for all 5 years to send the principal investigator and/or co-investigators to domestic conferences to present the findings from this research project. Domestic travel for each conference is budgeted for 2 trips as follows: $369 per night for accommodation for 4 nights; $267 per diem for 3 full days and 2 travel days; $800 airfare; $200 airport parking; $200 ground transportation such as between airport and conference location; and $500 for conference registration. Total is $(b)(4) per person per conference. $(b)(4) is requested for domestic travel per year.

OTHER DIRECT COSTS

Materials and Supplies include the purchase of 2 project-specific laptops in year 1 for documentation, collection of data from participants via computerized surveys, and communication of study activities. Each laptop costs $(b)(4), which includes business licenses, software, and warranties for a total of $(b)(4) for two laptops. All years include an annual ASEBA software license for the CBCL and YSR instruments at $600 per year. $(b)(4) per year is requested for project-specific supplies, study retention materials since the frequency of study visits after month 24 is reduced from every 6 months to annually, and light snacks for participants during study visits to support data integrity. We have found that snacks are helpful during the study visits as participants are often at the study site for an extended period of time due to first having a care visit followed by a study visit. $(b)(4) per year is requested for annual protocol team meeting expenses. Totals are: Year 1, $(b)(4) and Years 2-5, $(b)(4) per year.

Publication Costs include funds to pay for publications in professional journal publications to disseminate study results. All publications and journal articles will bear an acknowledgement of this federal award. We are requesting $(b)(4) per year that will be held centrally at CHLA and will be used by all sites as needed. Total for Years 1-5 is $(b)(4).

Subawards/Consortium/Contractual Costs include direct and F&A costs for the three consortium institutions (Ann & Robert H. Lurie Children's Hospital, Boston Children's Hospital, and the University of California San Francisco) and the subaward institution (Callen-Lorde Community Health Center). All institutions are domestic.

The Direct Cost for the 5 years is $(b)(4) (Year 1 $(b)(4); Years 2-5 $(b)(4)).
The F&A Cost for the 5 years is $(b)(4) (Year 1 $(b)(4); Years 2-5 $(b)(4)).
The Total Direct & F&A Cost is $(b)(4) (Year 1 $(b)(4); Years 2-5 $(b)(4)).

Ann & Robert H. Lurie Children's Hospital of Chicago
A consortium will be established with Dr. Robert Garofalo. Total costs are Year 1 $(b)(4) and Years 2-5 $(b)(4). Ann & Robert H. Lurie Children's Hospital of Chicago F&A has been calculated based on the DHHS approved rate of (b)(4)% MTDC. Fringe benefits have been calculated based on the following DHHS approved rate of (b)(4)%.

Boston Children's Hospital (The Children's Hospital Corporation)
A consortium will be established with Dr. Yee-Ming Chan. Total costs are Year 1 $(b)(4) and Years 2-5 $(b)(4). Boston Children's Hospital F&A has been calculated based on the DHHS approved rate of (b)(4)% MTDC. Fringe benefits have been calculated based on the following DHHS approved rate of (b)(4)%.

University of California, San Francisco
A consortium will be established with Dr. Stephen Rosenthal. Total costs are Year 1 $ (b)(4) and Years 2-5 $ (b)(4) . University of California, San Francisco's F&A has been calculated based on the DHHS approved rate of (b)(4)% MTDC. Fringe benefits have been calculated based on the following DHHS approved rates: Faculty (b)(4)% and staff (b)(4)%.

Callen-Lorde Community Health Center
A subaward will be established with Dr. Asa Radix. Total costs are Years 1-5 $ (b)(4) . Callen-Lorde Community Health Center F&A has been calculated based on the DHHS approved rate of % MTDC. Fringe benefits have been calculated based on the DHHS approved rate of (b)(4)%. (b)(4)

OUTPATIENT CARE COSTS

Laboratory Expenses: While it is our expectation that for the most part insurance will cover the clinical visits and labs for patients, we acknowledge that there may be instances where obstacles are encountered due to patients being uninsured or underinsured. We are requesting $ (b)(4) per year to assist in obtaining important clinical measures for participants who are uninsured or underinsured. Children's Hospital Los Angeles has a HHS-negotiated research patient care rate agreement for in-house clinical research labs at % of cost; however, many of these labs are sent to off-site laboratories such as Quest, and those charges are at cost. F&A is not applied to these costs per NIH policy. Examples of expected labs and their associated costs are: (b)(4)
-CBC $ (b)(4)
-Comprehensive Metabolic Panel $ (b)(4)
-Lipid Panel $ (b)(4)
-Free Testosterone Assay $ (b)(4)
-Total Testosterone Assay $ (b)(4)
-Estradiol Ultra Sensitive Assay $ (b)(4)

OTHER EXPENSES

Participant Compensation: Participants are compensated $50 to $150 per study visit dependent on study visit activities (e.g., longer baseline vs. shorter 6-month visit) and how long they have been participating in the study (e.g., month 6 vs. year 7 visit) to support study retention. At CHLA, we currently have 142 participants enrolled in the study, and we plan to enroll an additional 71 participants for a total of 213 participants. Participant compensation is requested at $ (b)(4) per year for years 1-5.

Participant Transportation Assistance: Funds are requested to support participants who need assistance with transportation to the study site. Assistance may be through mileage reimbursement, provision of transportation, or parking validation. Based on the current study, this averages to $10 per study visit. Funds are requested at $ (b)(4) per year for years 1-5.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		
Section B, Other Personnel		
Total Number Other Personnel		
Total Salary, Wages and Fringe Benefits (A+B)		
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		
1. Materials and Supplies	(b)(4)	(b)(4)
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1		
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		
Section H, Indirect Costs		
Section I, Total Direct and Indirect Costs (G + H)		
Section J, Fee		
Section K, Total Costs and Fee (I + J)		

Tracking Number: GRANT13040415

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 1

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Ann & Robert H. Lurie Children's Hospital of Chicago

Start Date*: 09-01-2020 **End Date*:** 08-31-2021 **Budget Period:** 1

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Robert		Garofalo	M.D.	MPI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Diane		Chen	Ph.D	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates	(b)(4)					
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Biostatistician				(b)(4)	(b)(4)	(b)(4)
1	Study Coordinator						
2	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT13040415

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 1

ORGANIZATIONAL DUNS*: 0744387550000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Ann & Robert H. Lurie Children's Hospital of Chicago

Start Date*: 09-01-2020 **End Date*:** 08-31-2021 **Budget Period:** 1

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 1

ORGANIZATIONAL DUNS*: 0744387550000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Ann & Robert H. Lurie Children's Hospital of Chicago

Start Date*: 09-01-2020 **End Date*:** 08-31-2021 **Budget Period:** 1

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	(b)(4)
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Participant Compensation	
9 . Participant Transportation Assistance	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . MTDC	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification*	File Name: Lurie_Consortium_Budget_Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 2

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Ann & Robert H. Lurie Children's Hospital of Chicago

Start Date*: 09-01-2021 **End Date*:** 08-31-2022 **Budget Period:** 2

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Robert		Garofalo	M.D.	MPI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Diane		Chen	Ph.D	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Biostatistician	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Study Coordinator						
2	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT13040415

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 2

ORGANIZATIONAL DUNS*: 0744387550000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Ann & Robert H. Lurie Children's Hospital of Chicago

Start Date*: 09-01-2021 **End Date*:** 08-31-2022 **Budget Period:** 2

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 2

ORGANIZATIONAL DUNS*: 0744387550000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Ann & Robert H. Lurie Children's Hospital of Chicago

Start Date*: 09-01-2021 **End Date*:** 08-31-2022 **Budget Period:** 2

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	(b)(4)
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Participant Compensation	
9 . Participant Transportation Assistance	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . MTDC	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification*	File Name: Lurie_Consortium_Budget_Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 3

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Ann & Robert H. Lurie Children's Hospital of Chicago

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period:** 3

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Robert		Garofalo	M.D.	MPI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Diane		Chen	Ph.D	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Biostatistician	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Study Coordinator						
2	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT13040415

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 3

ORGANIZATIONAL DUNS*: 0744387550000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Ann & Robert H. Lurie Children's Hospital of Chicago

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period:** 3

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	0.00

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	0.00

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 3

ORGANIZATIONAL DUNS*: 0744387550000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Ann & Robert H. Lurie Children's Hospital of Chicago

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period:** 3

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	(b)(4)
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Participant Compensation	
9 . Participant Transportation Assistance	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . MTDC	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification*	File Name: Lurie_Consortium_Budget_Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 4

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Ann & Robert H. Lurie Children's Hospital of Chicago

Start Date*: 09-01-2023 **End Date*:** 08-31-2024 **Budget Period:** 4

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Robert		Garofalo	M.D.	MPI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Diane		Chen	Ph.D	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Biostatistician	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Study Coordinator						
2	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT13040415

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 4

ORGANIZATIONAL DUNS*: 0744387550000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Ann & Robert H. Lurie Children's Hospital of Chicago

Start Date*: 09-01-2023 **End Date*:** 08-31-2024 **Budget Period:** 4

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 4

ORGANIZATIONAL DUNS*: 0744387550000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Ann & Robert H. Lurie Children's Hospital of Chicago

Start Date*: 09-01-2023 **End Date*:** 08-31-2024 **Budget Period:** 4

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	(b)(4)
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Participant Compensation	
9 . Participant Transportation Assistance	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . MTDC	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification*	File Name: Lurie_Consortium_Budget_Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

Tracking Number: GRANT13040415
Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 5

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Ann & Robert H. Lurie Children's Hospital of Chicago

Start Date*: 09-01-2024 **End Date*:** 08-31-2025 **Budget Period:** 5

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Robert		Garofalo	M.D.	MPI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Diane		Chen	Ph.D	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Biostatistician	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Study Coordinator						
2	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT13040415

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 5

ORGANIZATIONAL DUNS*: 0744387550000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Ann & Robert H. Lurie Children's Hospital of Chicago

Start Date*: 09-01-2024 **End Date*:** 08-31-2025 **Budget Period:** 5

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 5

ORGANIZATIONAL DUNS*: 0744387550000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Ann & Robert H. Lurie Children's Hospital of Chicago

Start Date*: 09-01-2024 **End Date*:** 08-31-2025 **Budget Period:** 5

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	(b)(4)
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Participant Compensation	
9 . Participant Transportation Assistance	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . MTDC	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification*	File Name: Lurie_Consortium_Budget_Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

Budget Justification: Ann and Robert H. Lurie Children's Hospital of Chicago

Personnel Justification

Rob Garofalo, M.D., MPH, Principal Investigator ((b)(4) Calendar Months (CM), Y1-Y5), is Co-Director of the Gender & Sex Development Program, Director of Adolescent HIV Services and Director of the Center for Gender, Sexuality and HIV Prevention at Lurie Children's. He is also Professor in the Departments of Pediatrics and Preventive Medicine, Northwest University's Feinberg School of Medicine. Dr. Garofalo has extensive experience in the clinical care of gender non-conforming children and young adults. His research career has focused on the collection of data, both behavioral and clinical biomarkers, in marginalized populations and the translation of this data into intervention development. As a PI on numerous federally funded studies, he has developed the skills to collaborate with and/or lead interdisciplinary and multi-site research teams. He will take primary responsibility for the implementation of the scientific aims of this project at Lurie Children's as well as collaborate to disseminate findings.

Diane Chen, Ph.D., Co-Investigator ((b)(4) CM, Y1-Y5), is a founding psychologist of the Gender & Sex Development Program and Behavioral Health Director for the Potocsnak Family Division of Adolescent and Young Adult Medicine at Lurie Children's. She is also Assistant Professor in the Departments of Psychiatry and Behavioral Sciences and Pediatrics at Northwestern University's Feinberg School of Medicine. As Co-Investigator, Dr. Chen will assist the Principal Investigators in directly supervising and managing frontline research activities involving project direction and data management at Lurie Children's. Specifically, Dr. Chen will supervise the Lurie Children's Research Coordinator in their management of day-to-day tasks by coordinating IRB submissions, developing and overseeing effective recruitment strategies and providing ongoing supervision regarding confidential data collection/ management procedures. Dr. Chen will attend all study-related meetings and contribute to the dissemination of study findings in collaboration with the larger investigative team.

(b)(6) **((b)(4) CM Y1-5)** is a biostatistician with the Biostatistics Research Core (BRC) within the Stanley Manne Children's Research Institute at Lurie Children's. (b)(6) will participate in all dissemination-related study meeting calls and work with Lurie Children's investigators on designing analysis plans to reflect their research questions, conduct analyses, and write-up relevant methods and results sections for manuscript submissions. (b)(6) will also collaborate on analyses for presentation of study findings at national conferences.

TBH – Project Coordinator ((b)(4) CM Y1-Y5) will be an individual with a clinical master's degree and substantial research experience with LGBT populations. They will meet regularly with project investigators and will coordinate project development, participant recruitment, and overall project implementation. They will work with the Co-I to coordinate all IRB-related communication, coordinate recruitment and retention, manage day-to-day operations of the project, including overseeing confidential data collection procedures. They will also assist in refining assessment instruments, preparation of procedural manuals and assist in maintaining IRB approval. They will coordinate and attend staff meetings and other study related collaborations as needed.

Fringe Calculations are based on the Anne and Robert H. Lurie Children's Hospital of Chicago rate of (b)(4)%.

Consultant costs are for the purchase of clinical supervision for the (b)(6). Having a (b)(6) on the protocol team who is interacting with the study participants has provided valuable feedback that has been incorporated into the research study. However, the daily interactions with transgender youth and their parents/caregivers can be challenging and triggering, and clinical supervision can provide vital support to the study coordinator. Costs are budgeted at $50 per session for 26 sessions per year for a total of $(b)(4) per year.

Travel [Total=$(b)(4); YR1-5=$(b)(4)]
$(b)(4) is requested per year for all 5 years to send the principal investigator and/or co-investigators to domestic conferences to present the findings from this research project. Domestic travel for each conference is budgeted for 2 trips as follows: $369 per night for accommodation for 4 nights; $267 per diem for 3 full days and 2 travel days; $800 airfare; $200 airport parking; $200 ground transportation such as between airport and

conference location; and $500 for conference registration. Total is $(b)(4) per person per conference x 2 = $(b)(4). In addition, $(b)(4) is requested per year for 3 team members to attend the annual protocol team meeting in Los Angeles. Travel is budgeted as follows: $222 per night for accommodation for 4 nights; $232 per diem for 2 full days and 2 travel days; $500 airfare; $200 airport parking; $200 ground transportation such as between airport and the hotel or meeting site. Total is $(b)(4) per person per meeting x 3 team members = $(b)(4). Total domestic travel requested per year, $(b)(4).

SUPPLIES

Materials and supplies [Total=$(b)(4); YR1=$(b)(4), YR2=$(b)(4), YR3=$(b)(4), YR4=$(b)(4), YR5=$(b)(4)].

Data Collection Devices (YR1, $(b)(4)) A total of $(b)(4) is requested in Year 1 to purchase 2 tablets and necessary accessories and software for mobile data collection and intervention deployment to be distributed across sites (i.e., 2 at each site). The tablets will be programmed to function solely for this study and will follow all institutional protocols regarding security, protection of HIPAA protected PHI and data sharing and storage. Tablets will be secured in double locked storage when not in use and will be checked out by project staff when recruitment or visit activities occur.

Project specific supplies: Total requested for these supplies is $(b)(4) ($(b)(4) per years 1-5). Funds are requested for supplies specific to this project to include (but limited to) color coded binders, fastener folders, copy paper.

Data Quality Supplies- Included is $(b)(4) total for data quality supplies ($(b)(4) year, YRs 1-5). Costs are budgeted per participant and number of visits to be able to provide for light snacks (for data quality), materials and props.

Retention supplies: Total requested for these supplies is $(b)(4). Funds are requested ($(b)(4)/year, YRs1-5) for supplies to build a sense of identification with the project and encourage retention. These supplies include birthday cards, thank you cards, and study-related goods (e.g., t-shirts, key chains, magnets).

OTHER COSTS

Other costs [Total=$(b)(4); YR1=$(b)(4), YR2=$(b)(4), YR3=$(b)(4), YR4=$(b)(4), YR5=$(b)(4)]

Participant Incentives ($(b)(4); YR1-5=$(b)(4))
Participants will receive compensation for completing assessments in the amount of $50 to $150 per study visit dependent on study visit activities (e.g., longer baseline vs. shorter 6-month visit) and how long they have been participating (e.g., month 6 vs. year 7 visit) in the study to support study retention.

Participant Transportation or Parking ($(b)(4); YR1-5=$(b)(4)/year)
Funds are requested to assist participants and their families with transportation needs to fund either parking or other transportation costs associated with study visits.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		
Section B, Other Personnel		
Total Number Other Personnel		
Total Salary, Wages and Fringe Benefits (A+B)		
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		
1. Materials and Supplies	(b)(4)	(b)(4)
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1		
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		
Section H, Indirect Costs		
Section I, Total Direct and Indirect Costs (G + H)		
Section J, Fee		
Section K, Total Costs and Fee (I + J)		

Tracking Number: GRANT13040415

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 1

ORGANIZATIONAL DUNS*: 0765937220000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Boston Children's Hospital

Start Date*: 09-01-2020 **End Date*:** 08-31-2021 **Budget Period:** 1

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Dr.	Yee-Ming		Chan	M.D.	Multiple PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2.				(b)(6)									

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Biostatistician	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Study Coordinator						
2	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)
						Total Salary, Wages and Fringe Benefits (A+B)	(b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 1

ORGANIZATIONAL DUNS*: 0765937220000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Boston Children's Hospital

Start Date*: 09-01-2020 **End Date*:** 08-31-2021 **Budget Period:** 1

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	0.00

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	0.00

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 1

ORGANIZATIONAL DUNS*: 0765937220000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Boston Children's Hospital

Start Date*: 09-01-2020 **End Date*:** 08-31-2021 **Budget Period:** 1

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	(b)(4)
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Participant Compensation	
9 . Participant Transportation Assistance	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . MTDC	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): Department of Health and Human Services, Darryl Mayes, 212-264-2069

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification* File Name: BCH_Budget_Justification.pdf
(Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 2

ORGANIZATIONAL DUNS*: 0765937220000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Boston Children's Hospital

Start Date*: 09-01-2021 **End Date*:** 08-31-2022 **Budget Period:** 2

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Dr.	Yee-Ming		Chan	M.D.	Multiple PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2.				(b)(6)									

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Biostatistician	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Study Coordinator						
2	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT13040415

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 2

ORGANIZATIONAL DUNS*: 0765937220000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Boston Children's Hospital

Start Date*: 09-01-2021 **End Date*:** 08-31-2022 **Budget Period:** 2

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 2

ORGANIZATIONAL DUNS*: 0765937220000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Boston Children's Hospital

Start Date*: 09-01-2021 **End Date*:** 08-31-2022 **Budget Period:** 2

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	(b)(4)
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Participant Compensation	
9 . Participant Transportation Assistance	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . MTDC	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): Department of Health and Human Services, Darryl Mayes, 212-264-2069

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification* File Name: BCH_Budget_Justification.pdf
(Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 3

ORGANIZATIONAL DUNS*: 0765937220000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Boston Children's Hospital

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period:** 3

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Dr.	Yee-Ming		Chan	M.D.	Multiple PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2.				(b)(6)									

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Biostatistician	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Study Coordinator						
2	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT13040415

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 3

ORGANIZATIONAL DUNS*: 0765937220000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Boston Children's Hospital

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period:** 3

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 3

ORGANIZATIONAL DUNS*: 0765937220000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Boston Children's Hospital

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period:** 3

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	(b)(4)
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Participant Compensation	
9 . Participant Transportation Assistance	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . MTDC	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): Department of Health and Human Services, Darryl Mayes, 212-264-2069

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification* File Name: BCH_Budget_Justification.pdf
(Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 4

ORGANIZATIONAL DUNS*: 0765937220000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Boston Children's Hospital

Start Date*: 09-01-2023 **End Date*:** 08-31-2024 **Budget Period:** 4

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Dr.	Yee-Ming		Chan	M.D.	Multiple PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2.				(b)(6)									

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Biostatistician	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Study Coordinator						
2	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT13040415

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 4

ORGANIZATIONAL DUNS*: 0765937220000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Boston Children's Hospital

Start Date*: 09-01-2023 **End Date*:** 08-31-2024 **Budget Period:** 4

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 4

ORGANIZATIONAL DUNS*: 0765937220000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Boston Children's Hospital

Start Date*: 09-01-2023 **End Date*:** 08-31-2024 **Budget Period:** 4

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	(b)(4)
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Participant Compensation	
9 . Participant Transportation Assistance	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . MTDC	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): Department of Health and Human Services, Darryl Mayes, 212-264-2069

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification* File Name: BCH_Budget_Justification.pdf
(Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 5

ORGANIZATIONAL DUNS*: 0765937220000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Boston Children's Hospital

Start Date*: 09-01-2024 **End Date*:** 08-31-2025 **Budget Period:** 5

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Dr.	Yee-Ming		Chan	M.D.	Multiple PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2.				(b)(6)									

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Biostatistician	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Study Coordinator						
2	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT13040415

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 5

ORGANIZATIONAL DUNS*: 0765937220000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Boston Children's Hospital

Start Date*: 09-01-2024 **End Date*:** 08-31-2025 **Budget Period:** 5

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 5

ORGANIZATIONAL DUNS*: 0765937220000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Boston Children's Hospital

Start Date*: 09-01-2024 **End Date*:** 08-31-2025 **Budget Period:** 5

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	(b)(4)
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Participant Compensation	
9 . Participant Transportation Assistance	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . MTDC	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): Department of Health and Human Services, Darryl Mayes, 212-264-2069

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification* File Name: BCH_Budget_Justification.pdf
(Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

Budget Justification: Boston Children's Hospital

Personnel

The Boston Children's Hospital (BCH) institutional fringe benefit rate of (b)(4)% is applied to all requested salary support.

Principal Investigator: Yee-Ming Chan, M.D., Ph.D. (b)(4) **months (Years 1-5)**

Dr. Chan is an Assistant Professor of Pediatrics at Harvard Medical School and an Associate Physician in Medicine at BCH, where he serves as Director of the Pediatric Reproductive Hormone Program. He is a practicing pediatric endocrinologist with an interest in precocious and delayed puberty, disorders/differences of sex development, and transgender health and is board certified in Pediatric Endocrinology. He will be responsible for study activities at the BCH site. He will coordinate with the psychologist and biostatistician, oversee the clinical research coordinator, analyze data, draft and revise manuscripts, help disseminate results at conferences, and supervise trainees working on this project. He will communicate with the other sites through annual meetings, monthly PI phone calls, and ad hoc phone calls and EMails as needed.

(b)(6) (b)(4) **months (Years 1-5)**

(b)(6) is an Assistant Professor at Harvard Medical School, a (b)(6) at BCH, and (b)(6) for the BCH Gender Management Service (GeMS)/Behavioral Health, (b)(6) Endocrinology, and Urology (BE-U) Programs. As a (b)(6) has expertise in pediatric and adolescent transgender health, disorders/differences of sex development, and child abuse and trauma. (b)(6) will assist with selection of psychosocial measures for the TYC study, analyze data, (b)(6) draft and revise manuscripts, help disseminate results at conferences, and supervise trainees working on this project. (b)(6) will participate in monthly co-I phone calls and attend the annual TYC meeting.

Biostatistician: (b)(6) (b)(4) **months (Years 1-5)**

The Biostatistics Core of the BCH Institutional Centers for Clinical and Translational Research supports biostatistical needs for researchers across the Hospital. The biostatistician will assist and advise the study team on data analysis.

Clinical Research Coordinator: TBD (b)(4) **months (Years 1-5)**

Under supervision of the Co-PI, the research coordinator will recruit participants, obtain informed consent, administer surveys and interviews, extract data from the medical record, coordinate follow-up visits, and maintain and update the IRB protocol. The coordinator will participate in regular coordinator phone calls and may attend the annual TYC meeting.

Consultants

We have learned through our experience with the TYC study that it can be taxing for the clinical research coordinators to learn of the challenges faced by transgender and gender non-conforming youth. To address this emotional toll we have budgeted $(b)(4) for clinical supervision for the clinical research coordinator.

Travel

Funds are budgeted annually for Co-PI Chan and Co-I Tishelman to attend the annual TYC meeting. Funds are also budgeted for travel to attend and present at national conferences. Funds may also be used for the Clinical Research Coordinator to attend the annual TYC meeting.

Other Direct Costs

Materials and Supplies (study-wide)

Year 1 budgets $(b)(4) for two computers to administer surveys. In addition, $(b)(4) is budgeted annually for study-related supplies.

Study Participant Costs (for BCH)

Each year budgets $(b)(4) for each of the 68 participants to receive $50 to $150 per study visit dependent on study visit activities (e.g., longer baseline vs. shorter 6-month visit) and how long they have been participating (e.g., month 6 vs. year 7 visit) in the study to support study retention.

Participant Transportation Assistance (for BCH)
Funds are requested to support participants who need assistance with transportation to the study site. Assistance may be through mileage reimbursement, provision of transportation, or parking validation. Based on the current study, this averages to $40 per study visit. Funds are requested at $(b)(4) per year for years 1-5.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		
Section B, Other Personnel		
Total Number Other Personnel		
Total Salary, Wages and Fringe Benefits (A+B)		
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		
1. Materials and Supplies	(b)(4)	(b)(4)
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1		
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		
Section H, Indirect Costs		
Section I, Total Direct and Indirect Costs (G + H)		
Section J, Fee		
Section K, Total Costs and Fee (I + J)		

Tracking Number: GRANT13040415

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 1

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: The Regents of the University of California, San Francisco

Start Date*: 09-01-2020 **End Date*:** 08-31-2021 **Budget Period:** 1

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Stephen		Rosenthal		PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2.		Diane		Ehrensaft		Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Study Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Biostatistician						
2	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT13040415

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 1

ORGANIZATIONAL DUNS*: 0948783370000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: The Regents of the University of California, San Francisco

Start Date*: 09-01-2020 **End Date*:** 08-31-2021 **Budget Period:** 1

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	**0.00**

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	**0.00**

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 1

ORGANIZATIONAL DUNS*: 0948783370000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: The Regents of the University of California, San Francisco

Start Date*: 09-01-2020 **End Date*:** 08-31-2021 **Budget Period:** 1

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	(b)(4)
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . participant compensation, participant transportation/parking	
9 . CCDSS	
10 . Data Network	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Cost (MTDC)	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Jeanette Lu, 415-437-7820
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification*	File Name: UCSF_Budget_Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 2

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: The Regents of the University of California, San Francisco

Start Date*: 09-01-2021 **End Date*:** 08-31-2022 **Budget Period:** 2

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Stephen		Rosenthal		PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2.		Diane		Ehrensaft		Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Study Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Biostatistician						
2	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT13040415

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 2

ORGANIZATIONAL DUNS*: 0948783370000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: The Regents of the University of California, San Francisco

Start Date*: 09-01-2021 **End Date*:** 08-31-2022 **Budget Period:** 2

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 2

ORGANIZATIONAL DUNS*: 0948783370000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: The Regents of the University of California, San Francisco

Start Date*: 09-01-2021 **End Date*:** 08-31-2022 **Budget Period:** 2

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	(b)(4)
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . participant compensation, participant transportation/parking	
9 . CCDSS	
10 . Data Network	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Cost (MTDC)	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Jeanette Lu, 415-437-7820
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification*	File Name: UCSF_Budget_Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 3

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: The Regents of the University of California, San Francisco

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period:** 3

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Stephen		Rosenthal		PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2.		Diane		Ehrensaft		Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Study Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Biostatistician						
2	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT13040415

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 3

ORGANIZATIONAL DUNS*: 0948783370000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: The Regents of the University of California, San Francisco

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period:** 3

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 3

ORGANIZATIONAL DUNS*: 0948783370000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: The Regents of the University of California, San Francisco

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period:** 3

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	(b)(4)
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . participant compensation, participant transportation/parking	
9 . CCDSS	
10 . Data Network	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Cost (MTDC)	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Jeanette Lu, 415-437-7820
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification*	File Name: UCSF_Budget_Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 4

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: The Regents of the University of California, San Francisco

Start Date*: 09-01-2023 **End Date*:** 08-31-2024 **Budget Period:** 4

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Stephen		Rosenthal		PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2.		Diane		Ehrensaft		Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Study Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Biostatistician						
2	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT13040415

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 4

ORGANIZATIONAL DUNS*: 0948783370000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: The Regents of the University of California, San Francisco

Start Date*: 09-01-2023 **End Date*:** 08-31-2024 **Budget Period:** 4

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 4

ORGANIZATIONAL DUNS*: 0948783370000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: The Regents of the University of California, San Francisco

Start Date*: 09-01-2023 **End Date*:** 08-31-2024 **Budget Period:** 4

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	(b)(4)
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . participant compensation, participant transportation/parking	
9 . CCDSS	
10 . Data Network	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Cost (MTDC)	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Jeanette Lu, 415-437-7820
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification* File Name: UCSF_Budget_Justification.pdf
(Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

Tracking Number: GRANT13040415
Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 5

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: The Regents of the University of California, San Francisco

Start Date*: 09-01-2024 **End Date*:** 08-31-2025 **Budget Period:** 5

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.		Stephen		Rosenthal		PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2.		Diane		Ehrensaft		Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Study Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Biostatistician						
2	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 5

ORGANIZATIONAL DUNS*: 0948783370000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: The Regents of the University of California, San Francisco

Start Date*: 09-01-2024 **End Date*:** 08-31-2025 **Budget Period:** 5

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 5

ORGANIZATIONAL DUNS*: 0948783370000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: The Regents of the University of California, San Francisco

Start Date*: 09-01-2024 **End Date*:** 08-31-2025 **Budget Period:** 5

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	(b)(4)
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . participant compensation, participant transportation/parking	
9 . CCDSS	
10 . Data Network	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Cost (MTDC)	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Jeanette Lu, 415-437-7820
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification* File Name: UCSF_Budget_Justification.pdf
(Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

Budget Justification

PERSONNEL

Pursuant to University of California (UC) policy, salaries in the initial budget period are based on current published UC salary scales and include University mandated range adjustments and merit increases scheduled to occur before the proposed project start date.

The NIH cap rate of $ (b)(4) was applied to all applicable salaries.

(b)(4) (b)(4)

Stephen Rosenthal, MD, Principal Investigator, salary and fringe benefits requested at calendar months, % effort, over 5 years

Qualifications: Dr. Rosenthal is Professor of Pediatrics at UCSF and co-founder and Medical Director of the UCSF Child and Adolescent Gender Center (CAGC). The UCSF CAGC serves as the Pediatric/Adolescent clinical arm of the widely recognized UCSF Center of Excellence for Transgender Health. The CAGC provides multidisciplinary care to gender non-conforming/transgender youth and adolescents and is the only such multidisciplinary gender program in Northern California, attracting patients not only from California, but from as far away as Alaska, Florida, and Egypt. Dr. Rosenthal is a nationally and internationally recognized expert in the care of gender nonconforming and transgender youth. He was recently appointed to the World Professional Association for Transgender Health (WPATH) Task Force for revision of the WPATH Standards of Care, and previously served on the WPATH Consensus Committee for revisions of the International Classification of Disease (ICD)-11 pertaining to transgender youth and adults. Dr. Rosenthal is also Past President of the Pediatric Endocrine Society (PES), has served as Vice President of the Endocrine Society (ES), Clinical Scientist Position, and is currently a member of the Endocrine Society Board of Directors. He has authored multiple manuscripts on transgender youth, including a "State-of-the-art" invited review in *Pediatrics,* an invited review in the "Approach to the Patient" series for the *Journal of Clinical Endocrinology and Metabolism (JCEM)*, and is co-author on the revised Endocrine Society Clinical Practice Guideline for Gender-Dysphoric/Gender-Incongruent Persons, published in *JCEM* in 2017. Dr. Rosenthal has also served as Associate Editor for *Transgender Health.* He has been an invited speaker on transgender youth at annual meetings of PES and ES as well as at international meetings of WPATH, and has lectured on this subject at academic centers throughout the U.S. and in several countries in Europe, Asia, and South America. Dr. Rosenthal is also the recipient of the UCSF Chancellor Award for LGBT leadership in recognition of his work with transgender youth, and was recently (2018) awarded the WPATH Harry Benjamin Lectureship "for significant contributions to the field of transgender health through research, healthcare provision, and medical education". Dr. Rosenthal has also had significant experience conducting multi-center trials. He has served as site PI for NIH/NICHD "Disorders of Sex Development: Platform for Basic and Translational Research" (1R01HD068138-01A1), and is currently PI (multiple PI format) for NIH/NICHD "The Impact of Early Medical Treatment in Transgender Youth" (1R01HD082554) and co-Investigator for "Sex Hormone effect on Neurodevelopment: Controlled puberty in transgender adolescents" (1R01MH115349), and "Gender Nonconformity in Prepubescent Children: A Longitudinal Study" (1R01HD097122).

Role on Project: Dr. Rosenthal will have primary responsibility for the implementation of the scientific aims of this project at UCSF. He will collaborate in continued protocol development (in particular, the endocrine/metabolic parameters), data analysis, and dissemination of findings.

(b)(4) (b)(4)

Diane Ehrensaft, PhD, Co-Investigator, salary and fringe benefits requested at calendar months, % effort, over 5 years

Qualifications: Dr. Ehrensaft is Associate Professor of Pediatrics at UCSF and Mental Health Director and co-founder of the UCSF Child and Adolescent Gender Center. As a developmental and clinical psychologist, Dr. Ehrensaft is a nationally and internationally recognized expert in the care of gender nonconforming and transgender youth. She was recently appointed to the World Professional Association for Transgender Health (WPATH) Task Force for revision of the WPATH Standards of Care, and previously served on the WPATH Consensus Committee for revisions of the International Classification of Disease (ICD)-11 pertaining to transgender youth and adults. Dr. Ehrensaft has authored two books and over twenty journal articles or book chapters on the clinical needs and developmental trajectories of gender-nonconforming and transgender youth, and has lectured nationally and internationally (Europe, South America, and Australia) on this topic, as well as having been featured in several documentaries (e.g. National Public Radio, BBC, CNN). Dr. Ehrensaft is currently serving as co-Investigator for NIH/NICHD "The Impact of Early Medical Treatment in Transgender

Youth" (1R01HD082554) and as Principal Investigator (multiple PI format) for "Gender Nonconformity in Prepubescent Children: A Longitudinal Study" (1R01HD097122).
Role on Project: Dr. Ehrensaft will have a primary role in continued protocol development and implementation of mental health measures, and will collaborate in data analysis and dissemination of findings.

(b)(4) (b)(6) **, Study Coordinator, salary and fringe benefits requested at** (b)(4) **calendar months,** (b)(4) **% effort, over 5 years**
(b)(6) will meet regularly with project investigators and will coordinate project development, participant recruitment, follow-up study visits, and overall project implementation. They will also work with the site PI to coordinate all Institutional Review Board (IRB)-related communications and will manage day-to-day operations of the project.

TBN Biostatistician, salary and fringe benefits requested at (b)(4) **calendar months,** (b)(4) **% effort, over 5 years**
The biostatistician will provide advice and support on analytic approaches. This individual will focus the bulk of their activities on the analysis of the physiologic/metabolic data. This individual will be responsible for the design, analysis plan development, and execution of these analyses.

Effective October 15, 2019 in preparation for the introduction of UCPath (a new University-wide payroll system) the Composite Benefit Rates (CBR) are being applied to proposal budgets. Benefits supported include retirement, payroll taxes and assessments, and health & welfare. CBRs are an average of all eligible benefits applicable to a benefits group. Employees are assigned to a benefits group based on job code and benefits eligibility. The composite benefit rate equals the total cost of benefits for the group divided by the total salaries for the group. The CBRs escalate July 1, 2020 and are prorated to conform to the grant year of this project. Note: This campus implements a Faculty Family-Friendly policy to provide faculty a childbearing and childrearing leave benefit, which are assessed separately. The assessment rate is (b)(4)% of requested salary for faculty in addition to the CBR.

Employee Benefit Group	FY 2020-2021
Faculty Tenured Ladder Rank, In Residence and Clinical	(b)(4)%
Faculty Non-Tenured Ladder Rank and Adjunct	(b)(4)%
Management and Professional	(b)(4)%
Academic and Staff General	(b)(4)%
Postdoctoral Fellows	(b)(4)%
Partial Benefit and Students	(b)(4)%

TRAVEL

Domestic Travel ($ (b)(4) per year)
$(b)(4) is requested per year for all 5 years to send the principal investigator and/or co-investigators to domestic conferences to present the findings from this research project. Domestic travel for each conference is budgeted for 2 trips as follows: $369 per night for accommodation for 4 nights; $266 per diem for 3 full days and 2 travel days; $800 airfare; $200 airport parking; $200 ground transportation such as between airport and conference location; and $500 for conference registration. Total is $(b)(4) per person per conference x 2 = $(b)(4). In addition, $(b)(4) is requested per year for 3 team members to attend the annual protocol team meeting in Los Angeles. Travel is budgeted as follows: $222 per night for accommodation for 4 nights; $231 per diem for 2 full days and 2 travel days; $275 airfare; $200 airport parking; $200 ground transportation such as between airport and the hotel or meeting site. Total is $(b)(4) per person per meeting x 3 team members = $(b)(4). Total domestic travel requested per year, $ (b)(4)

SUPPLIES

Laptop ($(b)(4), year 1)
Funds are requested for the purchase of two laptops and associated software for writing papers, preparing presentations, assembling figures, and keeping track of academic literature.

Project specific supplies ($(b)(4) per year, all years)
Project specific supplies are requested at $(b)(4) per year for study retention materials since the frequency of study visits after month 24 is reduced from every 6 months to annually and for light snacks for participants during study visits to support data integrity. We have found that snacks are helpful during the study visits as participants are often at the study site for an extended period of time due to first having a care visit followed by a study visit.

CONSULTANT COSTS

Clinical supervision ($(b)(4) per year, all years)
Consultant costs are for the purchase of clinical supervision for the (b)(6). Having a (b)(6) on the protocol team who is interacting with the study participants has provided valuable feedback that has been incorporated into the research study. However, the daily interactions with transgender and gender diverse youth and their parents/caregivers can be challenging and triggering, and clinical supervision can provide vital support to the study coordinator. Costs are budgeted at $50 per session for 26 sessions per year for a total of $(b)(4) per year.

OTHER EXPENSES

Participant compensation ($(b)(4) per year, all years)
Participants are compensated $50 to $150 per study visit dependent on study visit activities (e.g., longer baseline vs. shorter 6-month visit) and how long they have been participating in the study (e.g., month 6 vs. year 7 visit) to support study retention. At UCSF, we currently have 109 participants enrolled in the study, and we plan to enroll an additional 55 participants for a total of 164 participants. Participant compensation is requested at $(b)(4) per year for years 1-5.

Participant transportation/parking ($(b)(4) per year, all years)
The transportation/parking budget of $30/study visit allots for parking at UCSF as well as toll costs. Transportation reimbursements will be offered on an as-needed basis, and this amount will allow for travel costs to be covered for some participants coming from out-of-state who would not otherwise be able to continue study participation. Participant transportation and travel costs are requested at $30/visit x 164 participants for a total of $(b)(4) per year for years 1-5.

Computing and Communication Device Support Services (CCDSS) ($(b)(4) per year, all years)
On July 1, 2013 the University initiated direct charging for CCDSS has an integral component of its Enterprise Network Services (ENS) to provide support to campus voice and data technology functions. CCDSS includes software installation/updates, internet security, hardware setup/configuration, and centrally managed patching, storage and backup. Direct charging of these support services in conjunction with the Data Network Recharge are covered under Part 3.2.0 – Service Centers, Communication Services, of the University's Cost Accounting Standards Board Disclosure Statement (CASB Form DS-2) ensuring that there is no duplicate reimbursement from Federal and non-Federal sponsors. The CCDSS charge is based on the current rate per FTE, consistent with the current billing rates for CCDSS. Recharge rates are computed in accordance with the requirements of 2 CFR Part 200 and will be reviewed and adjusted annually. Calculations are based on the percent effort to be charged to the project for each person named in the grant.

(b)(4)

UCSF Data Network Recharge ($ per year, all years)
The data network services recharge or data network recharge is a vital component of the University's Enterprise Network Services (ENS), which provides funding for critical equipment in support of UCSF's electronic information flow. Per agreement signed January 24, 2008 with The Department of Health & Human Services (DHHS), Division of Cost Allocation, (cognizant agency to the University), the University does not disclose ENS costs as F&A pool costs and can charge for ENS costs as direct costs. This cost must adhere to the UCSF Costing Guidelines for the Allowability of Computing Device Support Recharges on Sponsored Project Awards and are permissible under our approved Cost Accounting Standards Board Disclosure

Statement (CASB Form DS-2) ensuring that there is no duplicate reimbursement from Federal and non-Federal sponsors. The data network recharge is based on the current rate per FTE, consistent with the current billing rates for the data network recharge. Recharge rates are computed in accordance with the requirements of 2 CFR Part 200 and will be reviewed and adjusted annually. Calculations are based on the percent effort to be charged to the project for each person named in the grant.

FACILITIES AND ADMINISTRATIVE EXPENSES

UCSF's indirect costs are calculated based on Modified Total Direct Costs (MTDC) as defined in 2 CFR Part 200.68 using facilities and administration (F&A) rates approved by the U.S. Department of Health and Human Services (DHHS). MTDC is comprised of total direct costs less capital equipment, alterations and renovations, patient care costs, off-campus rent, tuition and fee remission, scholarships and fellowships, participant support costs, and that portion of subcontract costs in excess of $ (b)(4). Additionally, the total amount of subawards to other UC campuses are excluded. Proration is based on the number of days at the applicable rate.

This project will be located On-Campus. UCSF's F&A rate agreement dated November 27, 2017, provides for an escalating rate for on-campus research: July 1, 2020, until amended: % (b)(4)

Contact at DHHS Office of Inspector General: Janette Lu, 415-437-7820, with questions about UCSF's F&A rate.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		
Section B, Other Personnel		
Total Number Other Personnel		
Total Salary, Wages and Fringe Benefits (A+B)		
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		
1. Materials and Supplies	(b)(4)	(b)(4)
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1		
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		
Section H, Indirect Costs		
Section I, Total Direct and Indirect Costs (G + H)		
Section J, Fee		
Section K, Total Costs and Fee (I + J)		

Tracking Number: GRANT13040415

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 1

ORGANIZATIONAL DUNS*: 6082374830000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Callen-Lorde Community Health Center

Start Date*: 09-01-2020 **End Date*:** 08-31-2021 **Budget Period:** 1

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Asa		Radix		Co-Investigator	(b)(4)				(b)(4)		

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*

Total Number Other Personnel

Total Other Personnel

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 1

ORGANIZATIONAL DUNS*: 6082374830000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Callen-Lorde Community Health Center

Start Date*: 09-01-2020 **End Date*:** 08-31-2021 **Budget Period:** 1

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 1

ORGANIZATIONAL DUNS*: 6082374830000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Callen-Lorde Community Health Center

Start Date*: 09-01-2020 **End Date*:** 08-31-2021 **Budget Period:** 1

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	(b)(4)
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Fixed	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Darryl W. Mayes, 212-264-2069
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification*	File Name: Callen-Lorde_Budget_Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 2

ORGANIZATIONAL DUNS*: 6082374830000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Callen-Lorde Community Health Center

Start Date*: 09-01-2021 **End Date*:** 08-31-2022 **Budget Period: 2**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Asa		Radix		Co-Investigator	(b)(4)				(b)(4)		

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*

Total Number Other Personnel

Total Other Personnel

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 2

ORGANIZATIONAL DUNS*: 6082374830000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Callen-Lorde Community Health Center

Start Date*: 09-01-2021 **End Date*:** 08-31-2022 **Budget Period:** 2

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 2

ORGANIZATIONAL DUNS*: 6082374830000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Callen-Lorde Community Health Center

Start Date*: 09-01-2021 **End Date*:** 08-31-2022 **Budget Period:** 2

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	(b)(4)
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Fixed	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Darryl W. Mayes, 212-264-2069
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification*	File Name: Callen-Lorde_Budget_Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 3

ORGANIZATIONAL DUNS*: 6082374830000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Callen-Lorde Community Health Center

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period:** 3

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Asa		Radix		Co-Investigator	(b)(4)				(b)(4)		

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*

Total Number Other Personnel

Total Other Personnel

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 3

ORGANIZATIONAL DUNS*: 6082374830000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Callen-Lorde Community Health Center

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period:** 3

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 3

ORGANIZATIONAL DUNS*: 6082374830000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Callen-Lorde Community Health Center

Start Date*: 09-01-2022 **End Date*:** 08-31-2023 **Budget Period:** 3

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	(b)(4)
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Fixed	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Darryl W. Mayes, 212-264-2069

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification*	File Name: Callen-Lorde_Budget_Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 4

ORGANIZATIONAL DUNS*: 6082374830000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Callen-Lorde Community Health Center

Start Date*: 09-01-2023 **End Date*:** 08-31-2024 **Budget Period:** 4

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Asa		Radix		Co-Investigator	(b)(4)				(b)(4)		

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*

Total Number Other Personnel

Total Other Personnel

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 4

ORGANIZATIONAL DUNS*: 6082374830000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Callen-Lorde Community Health Center

Start Date*: 09-01-2023 **End Date*:** 08-31-2024 **Budget Period:** 4

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 4

ORGANIZATIONAL DUNS*: 6082374830000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Callen-Lorde Community Health Center

Start Date*: 09-01-2023 **End Date*:** 08-31-2024 **Budget Period:** 4

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	(b)(4)
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Fixed	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Darryl W. Mayes, 212-264-2069
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification*	File Name: Callen-Lorde_Budget_Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0010
Expiration Date: 12/31/2022

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 5

ORGANIZATIONAL DUNS*: 6082374830000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Callen-Lorde Community Health Center

Start Date*: 09-01-2024 **End Date*:** 08-31-2025 **Budget Period:** 5

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Asa		Radix		Co-Investigator	197,300.00	1.2			19,730.00	6,840.00	26,570.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **26,570.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Total Number Other Personnel					**Total Other Personnel**	

(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) **26,570.00**

RESEARCH & RELATED Budget (A-B) (Funds Requested)

(b)(4)

Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 5

ORGANIZATIONAL DUNS*: 6082374830000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Callen-Lorde Community Health Center

Start Date*: 09-01-2024 **End Date*:** 08-31-2025 **Budget Period:** 5

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 5

ORGANIZATIONAL DUNS*: 6082374830000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Callen-Lorde Community Health Center

Start Date*: 09-01-2024 **End Date*:** 08-31-2025 **Budget Period:** 5

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	(b)(4)
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Fixed	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Darryl W. Mayes, 212-264-2069
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	(b)(4)

L. Budget Justification*	File Name: Callen-Lorde_Budget_Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

Budget Justification: Callen-Lorde Community Health Center

Personnel

(b)(4)

Asa Radix, MD (Yrs 1-5, [redacted] calendar months), Co-Investigator, will assist the MPIs and other Co-Investigators with all aspects of the project; participate in planning, implementation, and data meetings; and ensure compliance with federal, state, and local regulations. Dr. Radix has extensive professional experience in transgender medicine and will provide additional expertise to the team. Dr. Radix will assist the investigators to develop plans to facilitate enrollment of participants who are racially and ethnically diverse. Dr Radix will participate in additional planning, analysis and manuscript writing.

Fringe Calculations are based on Callen-Lorde Community Health Center rate of (b)(4)%.

Travel [Total = $(b)(4)]

Domestic Travel: $(b)(4) is requested per year for all 5 years for Dr. Radix to attend domestic conferences to present the findings from this research project. Domestic travel for each conference is budgeted for 1 trip as follows: $369 per night for accommodation for 4 nights; $267 per diem for 3 full days and 2 travel days; $800 airfare; $200 airport parking; $200 ground transportation such as between airport and conference location; and $500 for conference registration. In addition, $2,020 is requested per year for Dr. Radix to attend the annual protocol team meeting in Los Angeles. Travel is budgeted as follows: $222 per night for accommodation for 4 nights; $232 per diem for 2 full days and 2 travel days; $500 airfare; $200 airport parking; $200 ground transportation such as between airport and the hotel or meeting site. Total domestic travel requested per year, $(b)(4)

Other Direct Costs [Total = $500]

Materials and Supplies: Project specific supplies such as paper, printer ink, and office supplies are requested at $100 per year for Years 1-5.

Indirect Costs

The indirect cost rate is 18.2%.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		
Section B, Other Personnel		
Total Number Other Personnel		
Total Salary, Wages and Fringe Benefits (A+B)		
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs	(b)(4)	(b)(4)
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1		
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		
Section H, Indirect Costs		
Section I, Total Direct and Indirect Costs (G + H)		
Section J, Fee		
Section K, Total Costs and Fee (I + J)		

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Funding Opportunity Number: PA-18-729 . Received Date: 2020-03-05T18:03:06.000-05:00

Total Direct Costs less Consortium F&A

NIH policy (NOT-OD-05-004) allows applicants to exclude consortium/contractual F&A costs when determining if an application falls at or beneath any applicable direct cost limit. When a direct cost limit is specified in an FOA, the following table can be used to determine if your application falls within that limit.

Categories	Budget Period 1	Budget Period 2	Budget Period 3	Budget Period 4	Budget Period 5	TOTALS
Total Direct Costs less Consortium F&A	(b)(4)					

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 03/31/2020

1. Vertebrate Animals Section

Are vertebrate animals euthanized? ○ Yes ● No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

○ Yes ○ No

If "No" to AVMA guidelines, describe method and provide scientific justification

2. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

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3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

❑ Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

4. Inventions and Patents Section (Renewal applications)

*Inventions and Patents: ○ Yes ● No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

5. Change of Investigator/Change of Institution Section

❑ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 02/28/2023

Introduction	
1. Introduction to Application (for Resubmission and Revision applications)	Introduction_to_Application.pdf
Research Plan Section	
2. Specific Aims	Specific_Aims.pdf
3. Research Strategy*	Research_Strategy.pdf
4. Progress Report Publication List	Progress_Report_Publication_List.pdf
Other Research Plan Section	
5. Vertebrate Animals	
6. Select Agent Research	
7. Multiple PD/PI Leadership Plan	Multiple_PI_Leadership_Plan.pdf
8. Consortium/Contractual Arrangements	Consortium-Contractual_Arrangements.pdf
9. Letters of Support	Letters_of_Support.pdf
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11. Authentication of Key Biological and/or Chemical Resources	
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Tracking Number: GRANT13040415
Funding Opportunity Number: PA-18-729. Received Date: 2020-03-05T18:03:06.000-05:00

INTRODUCTION TO APPLICATION

(b)(4)

In 2015, in response to an Institute of Medicine report calling for research to understand and improve the lives of gender minority populations, four academic sites historically committed to providing care for transgender and gender-diverse (TGD) youth were awarded NIH grant R01HD082554 to develop and implement a multidisciplinary, prospective, observational study – the **Trans Youth Care Study (TYC)**. These four sites are Children's Hospital Los Angeles/University of Southern California, Boston Children's Hospital/Harvard Medical School, Benioff Children's Hospital/University of California San Francisco, and Lurie Children's Hospital of Chicago/Northwestern University. While observational cohort studies are being carried out abroad, this study is **the first US study to evaluate the impact of current clinical practice guidelines for transgender youth and represents a substantial investment by NIH**. TYC initially aimed to understand short-term physiological and psychological effects of early medical intervention for adolescents with gender dysphoria, observed for 24 months following their initiation of treatment. Data collected from the initial cohort included demographic, physiological, mental health, psychosocial, and behavioral information (see Appendix A). To date, TYC has successfully recruited *beyond* its proposed baseline sample in two distinct cohorts: 1) 95 youth initiating puberty suppression with gonadotropin releasing hormone analogs **(GnRHa)** along with a parent/caretaker (n=95), and 2) 316 youth initiating gender-affirming hormones **(GAH),** either testosterone or estrogen. Now in its final year of funding, TYC data collection is ongoing and has collected critically important health outcomes at baseline and at 6, 12, 18 and 24 months after initiation of medical intervention. TYC results from the 24-month follow-up period (complete in September 2020) will provide sorely needed outcome data on the short-term side effects and safety of these treatments. However, **longer-term follow-up across the span of pubertal development and into early adulthood is essential to meaningfully assess the impact of early medical intervention on both physiological and psychosocial well-being of TGD youth**. Preliminary findings indicate a trend of improvement across psychological domains, but longer-term data collection is imperative to observe meaningful changes in functioning and psychosocial outcomes (e.g., gender minority stress and resilience, quality of life, family support, anxiety, gender dysphoria) that we anticipate changing over a longer timeframe. Finally, further follow-up will yield critical information on physiological health effects including cardiovascular, metabolic, and bone health for which currently no prospective data exist. Therefore, in the second 5-year funding period, we propose to:

Aim 1: Evaluate the longer-term physiological and psychosocial impact of GnRHa initiated in early puberty on youth with gender dysphoria by extending follow-up for an additional 4 years (3, 4, 5 and 6 years after initiation of puberty blockers). Aim 1a: Examine the trajectories of height, weight, and bone mineralization as youth continue treatment with pubertal suppression and initiate treatment with gender-affirming hormones. **Aim 1b:** Continue assessment of mental health and psychosocial well-being with the existing measures and with the addition of new measures as these children progress from preteen to adolescent development. **Aim 1c:** Selectively enroll more non-Hispanic ethnic/racial minority youth (n=43) to better reflect the increasingly diverse clinical population.

Aim 2: Evaluate the longer-term physiological and psychosocial impact of GAH (estrogen or testosterone) in later puberty in youth with gender dysphoria by extending follow-up for an additional 4 years (3, 4, 5 and 6 years after initiation of gender-affirming hormones). Aim 2a: Evaluate longer-term effects of sex steroids on cardiovascular risk factors such as obesity, blood pressure, and lipids. **Aim 2b**: Employ a developmental framework to assess mental health and psychosocial well-being with the existing measures and with the addition of new measures as youth move into later adolescence and early adulthood. **Aim 2c:** Selectively enroll more transfeminine (assigned male at birth) and/or ethnic/racial minority youth into the GAH cohort (n=156) to better reflect the increasingly diverse clinical population.

Aim 3: Compare effects of gender-affirming hormones within and outside the context of prior pubertal suppression. Many within GnRHa cohort will begin GAH for induction of masculinization or feminization over time. In addition, a subset of GAH cohort was receiving GnRHa at enrollment. These two sets together can be considered a GnRHa + GAH group. We propose to longitudinally examine across 2-3 year follow-up this GnRHa + GAH group with age- and sex assigned at birth- matched GAH only group to compare psychosocial well-being between GAH youth with and without a history of GnRHa use.

Exploratory Aim 4: Characterize emerging sub-cohorts. Examination of emerging sub-groups from the first five years will inform optimal care models for the increasing diversity of youth with gender dysphoria. We propose to explore the demographics, challenges, and medical needs of non-binary youth (i.e., youth who identify outside of a male/female binary) as well as those youth who discontinue GnRHa or GAH. In sum, TYC is the first (and only) U.S. study examining the impact of early medical interventions on transgender young people. Continuing to follow these cohorts over the next 5 years will **provide critically needed longer-term outcome data** to inform and guide the clinical management of transgender youth.

A. SIGNIFICANCE

A1. The Trans Youth Care Study is the first longitudinal study in the United States (U.S.) to examine the impact of medical interventions currently recommended for transgender and gender diverse (TGD) youth. First published in 2009[1] and updated in 2017,[2] the Endocrine Society clinical practice guidelines for treatment of transgender youth recommend pubertal suppression with gonadotropin releasing hormone analogs (**GnRHa's)** for youth with gender dysphoria at the beginning stages of puberty (Tanner stage 2 or 3) regardless of age, followed by appropriate gender affirming hormone **(GAH)** therapy as youth get older, typically around the age of 16 years. These guidelines largely inform care of TGD youth in the U.S., with many specialized clinics initiating GAH in youth with gender dysphoria under the age of 16 years.[3] As described in detail below, there are limited published data on outcomes of this approach to gender-affirming care. Following a 2011 report by the Institute of Medicine calling for research to understand and improve the health of gender minority populations across the lifespan,[4] the NIH issued several calls for TGD-focused health research, with special emphasis on youth. In 2015, Children's Hospital Los Angeles (CHLA)/University of Southern California (USC), Boston Children's Hospital/Harvard University, Benioff Children's Hospital/University of California San Francisco (UCSF), and Lurie Children's Hospital of Chicago/Northwestern University, four academic sites committed to providing care for TGD youth, were awarded NIH grant R01HD082554 to develop and implement a multidisciplinary, prospective, observational study – the **Trans Youth Care Study (TYC)**. TYC aimed to examine physiological and psychosocial effects of medical intervention for adolescents with gender dysphoria observed for 24 months following initiation of treatment. To date, TYC has successfully recruited *beyond* its targeted baseline sample in two distinct cohorts: (i) 95 youth initiating pubertal suppression with GnRHa along with one parent/guardian (n=95), and (ii) 316 youth initiating GAH therapy (testosterone or estrogen).

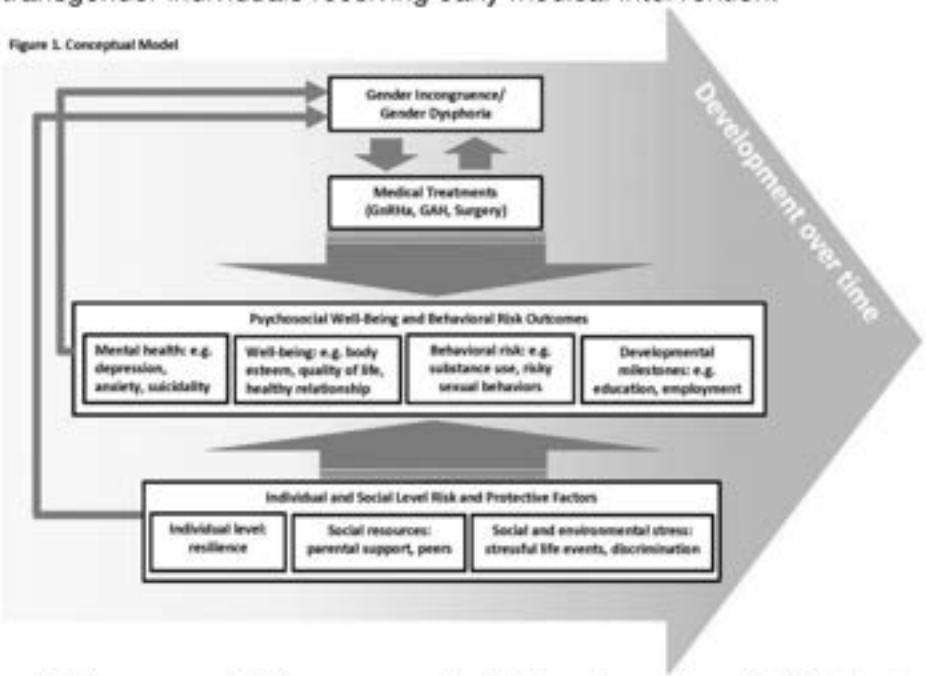
A2. No U.S. data have been collected on the longer-term physiological impact on TGD youth initiating GnRHa in early puberty. In youth with gender dysphoria who are just entering puberty, the Endocrine Society and the World Professional Association for Transgender Health (WPATH) recommend pubertal suppression be initiated in early puberty (Tanner stage 2 or 3), which most often occurs between ages 8 to 13 years. Most published data describing GnRHa have originated from a Dutch protocol in which pubertal suppression is not initiated until age 12 years,[5] an age at which most U.S. children have already undergone significant pubertal progression beyond Tanner stages 2-3.[6] GnRHa administration at earlier pubertal stages is expected to pose distinct benefits, chiefly, avoidance of unwanted endogenous secondary sex characteristics that might only be addressed surgically in the future. Little is known about the impact of GnRHa's on the **bone health** of youth with gender dysphoria, especially in those initiating GnRHa's younger than age 12. Studies reporting the impact of GnRHa in youth ages 12 years and older have demonstrated lower bone mineral density (BMD) prior to treatment and subsequently exacerbated by GnRHa use, but have lacked critical information regarding three elements important for BMD acquisition: dietary calcium intake, vitamin D levels, and weight-bearing exercise.[7,8] TYC's GnRHa cohort (N=95) provides a unique opportunity to evaluate longer-term bone health and other physiological outcomes across the span of pubertal development. Youth initiating pubertal suppression in later puberty may not experience the full benefits of puberty suppression and may encounter side effects such as hot flashes, abnormal uterine bleeding, and fatigue compared to those who initiate suppression in the earliest stages of puberty. The ages of our GnRHa cohort span from 8 to 16 years, with 85% in early puberty (Tanner stages 2 or 3) and 15% in later puberty (Tanner stages 4 or 5), providing a rare opportunity to examine participant growth and bone-mineral acquisition.

A3. Similarly, no data (extending beyond 24 months) have been published in the U.S. on longer-term *physiological effects* on TGD adolescents initiating GAH therapy, particularly under age 16 years. Per a recent literature review, no data have been reported on the long-term safety or the medical health outcomes of GAH initiation in youth with gender dysphoria under age 16 years.[9] Previous studies have outlined the long-term physiological impact of GAH initiated *in adulthood*, suggesting higher incidence of cardiovascular events in both transgender men and women).[10] Similar data of youth are sparse (particularly early in adolescence), and none extend beyond 2 year follow-up. While the updated Endocrine Society Guidelines explicitly recognize compelling reasons clinicians may initiate GAH under age 16 years, the guideline made evident these recommendations derived from expert consensus, and scientific evidence is critically needed to inform current treatment recommendations with respect to safety, tolerability, and health outcomes over time.[2] The current evidence gap contributes to significant barriers to care that result in health disparities particularly impacting TGD youth.[11]

A4. Very limited data also exist on the longer-term *psychosocial outcomes* of TGD youth initiating any gender-affirming medical care. TGD youth who undergo an undesired endogenous puberty often experience distress, with gender dysphoria significantly eroding their emotional, academic, and family functioning.[5,12] Only a few studies have examined the impact of medical interventions on mental health in TGD youth. A Dutch study

examining the effect of GnRHa treatment in youth with gender dysphoria demonstrated a decrease in behavioral and emotional problems, a decrease in depressive symptoms, and improved general functioning.[13] Within this same Dutch cohort, psychological functioning and gender dysphoria improved in youth following treatment with GnRHa, GAH, and surgery.[14] The researchers did not assess psychological outcomes of youth who missed the opportunity for GnRHa treatment to suppress endogenous pubertal changes and were treated solely with GAH. In another study, researchers found a positive impact of GAH on disordered eating and body satisfaction, but the study scope was limited to these two outcomes.[14,15] Because the prevalence of depression, self-harm and suicidality is so disproportionately high among TGD youth, it is essential to inform treatment guidelines and recommendations with an understanding of how psychopathology interacts with, and/or responds to recommended interventions. Understanding the role of gender-related social stigma (i.e., minority stress) on these psychological symptoms may further optimize treatment plans and environments. Profound psychological differences may be present between youth who received GnRHa treatment in puberty versus those who did not. Additionally, there are likely psychological differences between those initiating GnRHa treatment at later-stage puberty versus those whose endogenous pubertal changes were prevented from progressing beyond the earliest stages (e.g., puberty suppression may prevent gender dysphoria typically associated with puberty onset). Finally, consideration of additional well-being indicators as adolescents move into adulthood (e.g., school completion, employment, healthy relationships), can expand current literature through a broad characterization of transgender individuals receiving early medical intervention.

Figure 1. Conceptual Model



■ **The Conceptual Model: (Figure 1)** illustrates the relationships amongst gender dysphoria, medical treatment, well-being, and behavioral outcomes. Individual, social and environmental influences across developmental age have never been comprehensively modeled for the health and wellbeing of TGD youth receiving care. Our model is situated against a backdrop of a yellow/gold hue that grows more intense (left to right) to represent two cohorts moving from late childhood into adolescence and finally into early adulthood. Our life-course conceptual approach recognizes the importance of both developmental and treatment factors on youths' specific transitions and turning points affecting their overall trajectories. The utilization of multiple waves of follow-up, coupled with advanced analytical structural equation modeling framework (e.g., latent growth curve modeling (LGCM) and its variants, multiple group GCM, and piece-wise GCM)[16] enables us to address our aims more comprehensively to capture within and between stage variability, as well as cumulative effects attributable to chronologic age and Tanner stage at treatment initiation.

A5. Although White/European youth predominate clinic-referred samples, an increasingly racially diverse clinical population may provide opportunities to examine early medical intervention for gender dysphoria among youth of color (YOC). Transgender people of color are at a disproportionate risk for a wide range of psychosocial sequelae, including homelessness, discrimination, unemployment, HIV acquisition, emotional and physical violence, and homicide due to the intersectionality of race and transgender identity.[17] Studies have indicated that being physically identifiable as transgender increases one's risk for these and other sequelae.[18] The gender of individuals who maintain the physical features that resulted from undergoing an endogenous puberty are more frequently misperceived, subjecting them to discrimination and lethal violence. Puberty suppression and subsequent early access to GAH provides an opportunity to avoid these physical changes and thus could be lifesaving for many. The TYC cohort of youth is racially diverse (40% non-white), and we aim for further racial/ethnic diversification with new enrollment emphasizing YOC.

A6. A key feature of the renewal period is that many individuals in the original GnRHa group will be starting GAH treatment. By examining outcomes of TGD youth who initiated GAH treatment with and without prior puberty suppression with GnRHa, TYC will be able to answer vital questions about how puberty suppression

modulates the effect of GAH treatment on health outcomes, including: (1) Does prior treatment with a GnRHa attenuate the impact of GAH treatment on cardiovascular risk factors such as obesity, high blood pressure, and dyslipidemia? (2) In youth previously treated with GnRHa, does GAH treatment result in bone mineralization rates comparable to those seen in adolescents undergoing endogenous puberty? and (3) Does the combined sequence of GnRHa followed by GAH therapy produce improved psychosocial and mental health outcomes over GAH treatment alone? Results from these analyses will also deepen empirical understanding of how sex steroids (and changes in the sex-steroid milieu) affect risk for cardiovascular disease and other health outcomes.

A7. TYC is the first U.S. study to evaluate the impact of current clinical practice guidelines for TGD youth over the life course. Our conceptual model (Figure 1) drives our aim to comprehensively understand mental health and psychosocial outcomes impacting TGD youth. To date, TYC has exceeded recruitment targets by recruiting: (i) 95 youth initiating **GnRHa** along with their parent/guardian (95) and (ii) 316 youth initiating **GAH** therapy. Baseline and short-term follow-up data are currently being analyzed. Results from ongoing 24-month follow-up data will provide sorely needed evidence of the short-term safety of these treatments. However, longer-term follow-up, as proposed in this competitive continuation application, provides a unique opportunity to examine trajectories of physiological and psychosocial outcomes across the span of pubertal development and into early adulthood. Preliminary findings suggest improvement across psychological domains, but longer-term data collection is imperative to observe functioning and psychosocial outcomes that we anticipate changing over a longer time frame (e.g. quality of life, family support, education completion, employment acquisition and retention, romantic relationships). Finally, only ongoing follow-up will yield critical information on treatment's longer-term health effects on physiological health including cardiovascular, metabolic and bone health, as well as growth. Table 1 illustrates movement of the original cohorts during the proposed continued observation period.

Table 1. Age progression of existing cohorts	Initial TYC Observational Period			Proposed Continued Observation Period			
	2016-18	12m F/U	24m F/U	3 y F/U	4 y F/U	5 y F/U	6 y F/U
GnRHa Enrollment and F/U (Initial Grant)	8-16 y	9-17 y	10 -18 y				
GnRHa (extended) (ages)				11- 19 y	12 - 21 y	13 - 22 y	14 - 23 y
GAH (ages)	11-21 y	12 - 22 y	13 - 23 y				
GAH (extended) (ages)				14 - 24 y	15 - 25 y	16 - 26 y	17 - 27 y

A8. Contribution of the Proposed Work. The lack of data on medical interventions for TGD youth combined with a shortage of providers knowledgeable in the complex psychosocial risk factors facing TGD youth contributes to a health disparity and public health crisis of substantial magnitude. In its final year of initial funding, TYC data consist of critically important physiological and psychosocial health outcomes collected at baseline and at 6, 12, 18, and 24 months after initiation of medical intervention. **To meaningfully assess the physiologic and psychosocial impact of current clinical practice guidelines, study of longer-term outcomes beyond 24 months is essential.** Results from TYC have the potential to significantly impact the medical and mental health services provided to U.S. TGD youth by yielding rigorous scientific evidence outlining the longer-term impact and safety of early medical intervention.

B. INNOVATION This proposal demonstrates innovation in the following ways: **(1) This will be the first U.S. study to collect long-term physiologic and psychosocial data in TGD youth accessing gender-affirming medical intervention in early puberty or later (those in early puberty, specifically)**. This geographically diverse, four-site network has enrolled and has ongoing access to hundreds of TGD youth, paving the way for longitudinal investigation of this unique population as they grow into adulthood. This is the largest research cohort of U.S. TGD. **(2) This proposal employs a developmental, life-course framework to understand how youth navigate gender development as they age from late childhood through adolescence and into young adulthood.** Given that participants initiate GnRHa and GAH across a range of chronologic ages and developmental stages, the use of growth curve analyses enables examination of effects of earlier versus later initiation of treatments in ways that other studies with smaller sample sizes and shorter follow-up cannot. For example, we can examine ways that timing of treatment initiation affects youth's optimal health trajectories (e.g., mental health, quality of life, behavioral risk) while accounting for influences of risk and protective factors which may be changing across time (see Figure 1: Conceptual Model). This continuation proposal has a unique opportunity to examine the interacting complexities of both phenotypic gender transition and adolescent development to further elucidate the psychosocial and behavioral health of TGD youth accessing medical treatment. **(3) Capturing a unique transition in gender affirming care.** Our previously funded research enrolled two cohorts; a) those initiating GnRHa and b) those initiating GAH (40 of whom had previous GnRHa experience), to observe the effects of these medical treatments over 24-months. Many participants in the GnRHa cohort have, over time, begun gender affirming hormones (GAH) for induction of masculinization or feminization.

Combined with GAH participants who were on GnRHa at study baseline these participants across the two cohorts represent a GnRHa (experience) + GAH subset. We propose to compare this new GnRHa + GAH group with an age and assigned sex at birth-matched subset of the original GAH cohort who have had no experience of GnRHa (GAH only) to identify differences among GAH youth with a history of GnRHa use versus those without. With our existing cohorts and estimated retention, we calculate this sub-study to include 158 participants (79 per group). With additional new enrollees in the continuation period we anticipate having an overall sample size of 210. These analyses will provide unique insight into how the cumulative effects of GnRHa + GAH treatment as well as how prior GnRHa use affects both the physiological and psychosocial effects of GAH. The two groups, (GnRHa + GAH and GAH only) represent two trajectories of medical care being prescribed across the U.S., both of which will continue to grow as more providers begin to offer medical intervention. **(4) Increased presence of community voice in design, implementation, and translation.** This renewal includes among the scientific team an NIH-funded co-investigator, **Asa Radix**, who is both a physician-researcher and (b)(6) (b)(6). (b)(6) will contribute by offering practice knowledge, research expertise and community wisdom. An active community advisory board including TGD youth and parents/caregivers will contribute community-member expertise. These additions will enhance this work's conceptualization, implementation and dissemination of meaningful and practical scientific evidence. **Summary of Innovation.** The proposed research is uniquely positioned and has the capacity to substantially inform and optimize national clinical practice guidelines by providing data demonstrating the impact of early medical treatment and ultimately decrease the health disparity currently existing for TGD youth.

C. APPROACH

C1. Study Team. The 4 PI's on this renewal are recognized as national experts and leaders in the field of TGD youth care and represent the sub-specialties predominantly involved in this care. ■ **Dr. Johanna Olson-Kennedy** (Pediatrics and Adolescent Medicine) is the Medical Director for the Center for Transyouth Health and Development and PI at CHLA/USC and has successfully spearheaded the implementation of TYC. Her 14 years of work and dissemination has advanced TGD youth care around the US. The Center has provided TGD youth care services since the mid-1990s, and under Dr. Olson-Kennedy's leadership currently has 1,700 TGD youth in active care, with 20-25 new patients each month. ■ **Dr. Robert Garofalo** (Pediatrics and Adolescent Medicine) is Co-Director of the Gender and Sex Development Program and PI for Lurie Children's Hospital of Chicago/Northwestern University. He has extensive experience engaging transgender women and MSM age 16-24 in longitudinal prevention research and has been the PI on 13 NIH grants, 2 CDC research grants, and Co-Investigator on 16 NIH grants. He is the Editor-in-Chief of the journal *Transgender Health*. Dr. Garofalo has been providing clinical services for TGD youth for 15 years. His program currently has over 1,200 TGD youth in care and on average enrolls 10-12 new patients each month. ■ **Dr. Yee Ming-Chan** (Pediatric Endocrinology) is the Medical Director of the Pediatric Reproductive Hormone Program, which includes the Gender Multispecialty Service (GeMS) and is PI at Boston Children's Hospital. Under Dr. Ming-Chan's direction, the program provides care for patients with pubertal disorders, patients with differences/disorders of sex development (DSD), and 780 TGD youth, enrolling 10-15 new patients into care each month. ■ **Dr. Stephen M. Rosenthal** (Pediatric Endocrinology) is the co-founder and Medical Director of the Child and Adolescent Gender Center (CAGC) and PI at Benioff Children's Hospital/UCSF. He is a co-author of the updated version of the Endocrine Society Clinical Practice Guidelines related to the care of TGD persons across the lifespan. He has significant experience conducting multi-center trials and was site PI for NIH/NICHD Disorders of Sex Development: Platform for Basic and Translational Research. The UCSF CAGC team has been providing multi-disciplinary care for TGD youth for years. Currently, the program has 900 youth in clinical services and enrolls 15-20 new patients into care each month. Additionally, this PI team is strengthened significantly by the Co-Investigators at each site, who are renowned experts in clinical, health and/or developmental psychology (see biosketches).

C2. TYC Progress Report. ■ **Enrollment.** Since initiation of funding in 2015, a total of 506 participants have been enrolled in TYC across the four sites; GnRHa cohort youth (n=95), GnRHa cohort parents (n=95), and GAH cohort youth (n=316). The data presented here represent an enrollment period of approximately 3 years. Baseline visits were completed in September 2018, and 24-month data collection will conclude in September 2020. *Retention rates:* Retention rates for the GnRHa cohort are as follows: 6m: 83% (100% visits complete); 12m: 78% (96% visits complete); 18m: 73% (86% visits complete); 24m: 89% (55% visits complete), and for the GAH cohort: 6m: 92% (100% visits complete); 12m: 83% (97% visits complete); 18m: 73% (93% visits complete); 24 m: 80% (79% visits complete). *Sample Characteristics:* The median age range of the GnRHa cohort was 11 years with the (b)(4); (b)(6) (b)(4); (b)(6). Within the GnRHa cohort, 48% were AFAB (assigned female at birth), and 52% AMAB (assigned male at birth). The median age of youth starting GAH was 16 years, with the

(b)(4); (b)(6)

(b)(4); (b)(6) . Within the GAH cohort, 65% were AFAB, 35% AMAB.

C2a. Results Relating to Specific Aims. Aim 1 of the initial grant was to evaluate the impact of GnRHa administered for puberty suppression on psychological and physiological parameters, including bone health, as well as document their safety profile in an early-pubertal cohort during a treatment interval of 2 years. While 24-month data are not yet available, preliminary results from 77 cases with 6-month and 69 with 12-month follow-up data available have been positive and inform new questions and hypotheses worthy of further exploration in the proposed study, which are highlighted at the end of each section. ■ **Psychological Well-being and Mental Health (GnRHa cohort)** *Quality of Life*: We examined baseline to 12-month Quality of Life for participants in the GnRHa cohort (n=69). Total quality of life and the domain of psychosocial functioning showed significant improvement at 12 months after initiation of GnRHa ($p < .05$), while social functioning and school domains showed marginally significant trends indicating improvement. *We hypothesize quality of life will further improve as youth on GnRHa add GAH to their intervention profile.* *Suicide:* Within the GnRHa cohort at baseline, five participants reported having attempted suicide within the prior 6 months. At 12-month follow-up, **none** of those participants had thought about suicide in the prior six months. *We hypothesize that suicidal ideation and attempts will continue to diminish over time for the entire cohort.* As the youth who initiated care with GnRHa age, many will be initiating GAH to develop masculinizing or feminizing characteristics. Furthermore, *we hypothesize that the mental health of youth treated with GnRHa over time will be impacted by two variables: pubertal development (Tanner Stage) at starting GnRHa and chronological age at initiation of GAH.* ■ **Physiological impact (GnRHa cohort).** *Expected Effects* All 77 cases (with 6-month data) successfully experienced puberty suppression by 6 months of treatment. Among AFAB youth, 23 of 35 (66%) experienced a decrease in glandular breast tissue, and among AMAB youth, 19 of 42 (45%) experienced a decrease in testicular size. *Side Effects* Of the 77 cases, 40% reported mood lability and 44% reported weight gain after 6 months of GnRHa treatment. While we will continue to observe these trends as TYC follow-up data are collected, examining them beyond a 24-month period is important to determine if they are permanent or temporary effects. *For example, we will test whether mood lability reported by some youth is an effect of the short-lasting surge of endogenous hormones that immediately follows GnRHa initiation, or if it is a longer effect related to puberty suppression.* Preliminary analysis of anthropometric data in the GnRHa cohort showed that BMI scores were in the overweight range for 9.5% of AMAB and 8.5% of AFAB youth at baseline. Only one participant was in the obese range at baseline (AFAB). With weight gain being a commonly reported side effect of GnRHa treatment, analysis will examine the rates of obesity over time and the impact on longer-term cardiovascular health. With the opportunity to follow these youth, we can examine under what conditions BMI is likely to change by comparing growth acceleration among youth who underwent GAH therapy following GnRHa versus youth with GnRHa monotherapy alone. *Bone Health* A cross-sectional analysis of our cohort prior to initiation of GnRHa at baseline demonstrated aBMD or vBMD Z-scores of < -2 in **30%** (10/33, 95% CI [15.6%, 48.7%]) of AMAB, and **13%** (4/30, 95% CI [3.8%, 30.7%]) of AFAB, significantly higher rates than the 2.3% expected in a normal distribution. Among our *early pubertal* participants, AMAB participants have even lower BMD Z-scores compared to AFAB participants at baseline. A similar finding has only been previously reported in *late pubertal* gender dysphoric adolescents in two small studies in the Netherlands.[7,8] **Physical Activity Questionnaire (PAQ-C) scores were also low, with lower activity in the AMAB vs. AFAB participants (mean 2.22 vs 2.64; p=.008), providing a potential explanation for the difference in baseline BMD Z-scores.** No significant differences in 25-OH vitamin D levels, dietary calcium intake, and BMI Z-scores were found between the AFAB vs. AMAB participants at baseline. Our observation that low baseline BMD Z-scores can already be observed in early pubertal TGD youth and is associated with decreased physical activity suggests that this disparity may be addressed by interventions to increase physical activity, with childhood as the key developmental window to apply this intervention. **Longitudinal follow-up of this cohort with continued skeletal imaging will be critical for understanding if bone mineralization occurs at rates comparable to those seen in adolescents undergoing endogenous puberty as these youth in our study progress to treatment with gender-affirming sex steroids.** *We hypothesize that introduction of GAH will induce both pubertal growth (height) acceleration and acceleration of bone mineralization. For those initiating estrogen, we hypothesize that peak growth velocity will occur within the first year of treatment; and for those initiating testosterone, about 1-2 years after such treatment is initiated. Finally, we hypothesize that peak bone mineralization velocity will lag about a year behind peak growth velocity.*

Aim 2 of the initial grant was to evaluate the impact of GAH administered for phenotypic gender transition on mental health and metabolic/physiologic parameters as well as to document the safety of gender affirming hormones in adolescents during a treatment interval of two years. Half of the GAH cohort initiated

gender-affirming hormones younger than age 16, allowing our team the opportunity to observe the impact of GAH within the context of the newest Endocrine Society Guidelines. ■ **Psychological Well-being and Mental Health (GAH cohort)** *Body Esteem and Quality of Life:* As can be seen in Table 2 using paired t tests, body esteem and quality of life appear to be improving at 12-month follow up. Specifically, GAH participants reported significantly greater body esteem from baseline to one year after GAH. Likewise, GAH participants reported significant increases in their life satisfaction and significant decreases in burden from baseline to 12 months. *We hypothesize continued improvement over time (see Section C8. Analytical Plan).* *Depression.* Preliminary results from 233 youth with 12-month BDI data indicated an increase in cases of "minimal depression" from 50.6% at baseline to 59.2% at 12 months. However, the prevalence of severe depression went from 13.8% at baseline to 15.5% at 12 months.

Table 2. Body esteem and quality of life at baseline (BL) and 12 months following GAH treatment.

	N	BL Mean; SD (range)	M12 Mean; SD (range)
Body Esteem* Range 17-68**	221	36.4; 9 (17-67)	41.4; 9.4 (19.13-68)
Health Related Quality of Life (QOL)**			
Life Satisfaction*	224	25.5; 5.4 (10-40)	27.7; 5.9 (11-40)
'Illness-Related' Anxiety	224	13.6; 6.6 (0-32)	13.1; 6.9 (0-32)
'Illness Burden'*	224	21.5; 8.3 (0-41)	19.8; 7.9 (2.36-41.17)

*significant at p < .0001 **higher scores indicate higher amounts of each construct

Per clinical experience, youth initiating GAH may have high expectations of the desired treatment effects of treatment and the timing of these changes, some of which take years. We theorize that depressive symptoms are closely tied to gender dysphoria, and 12 months may be an insufficient window to reflect improvement in depressive symptoms. *We hypothesize that the proportion of moderate to severely depressed youth will decrease over time, and the proportion of minimally depressed youth will increase over time.* Ongoing data collection in our GAH cohort will examine if and when youth experience a decrease in symptomatology in their process of phenotypic gender development. These findings will inform providers of the characteristics of those youth for whom psychopathology persists and what additional services they may need. *We hypothesize that most youth will continue to show improvement in mental health over time.* ■ **Physiological Impact (GAH cohort)** Of the GAH cohort, 223 (71%) had 12-month data regarding physical changes and side effects. *Expected effects* After 12 months of testosterone administration, among AFAB youth (n=153), 98% reported deepening of the voice, development of male pattern facial (92%) and body hair (97%), muscle development (73%), enlarged clitoral tissue (88%), and masculinization of the face (85%). Among AMAB youth (n=70), effects reported included breast development (89%), softening of the skin (74%), fat redistribution (71%), fewer spontaneous erections (69%), decrease in body (60%) and facial hair growth (57%), and decrease in testicular size (51%). *Side Effects* Undesirable side effects reported at one year in AFAB youth; acne (91%), irritability (57%), headaches (40%), and hair loss (12%), and among AMAB youth; breast tenderness (69%), moodiness (60%), decreased libido (41%), headaches (36%), weight gain (33%), nausea (24%), vomiting (14%), and nipple discharge (11%). *Obesity and cardiovascular health* Rates of obesity at baseline within the GAH cohort were 11% of AFAB and 7% of AMAB youth, no greater than in the general population. HDL cholesterol was lower than age- and ethnicity-matched NHANES controls (50.6 ± 12.3 mg/dL vs. 53.3 ± 13.3 mg/dL, p = 0.001). Whether and how rates change with GAH treatment remains to be determined as 24-month study visits are completed. ***In Sum**: As can be seen, continued follow-up of the cohorts we have established and retained is of paramount importance to answer research and clinical questions of consider public health significance for TGD youth.*

C3. Renewal Study Objectives. The primary objective of this observational, longitudinal, multicenter renewal study is to **extend the initial 2-year follow-up period to evaluate physiological and psychological effects of GnRHa and GAH on participants for an additional 4 years.** A second objective is to **enhance the diversity and size of existing cohorts by enrolling additional youth of color (YOC) into both cohorts and enroll additional AMAB youth into the GAH cohort.** A third objective is to **add measurements of psychosocial variables required to answer new questions posed by longer term follow-up**. The proposed project aligns with the objectives outlined by the Institute of Medicine in "The Health of Lesbian, Gay, Bisexual, and Transgender People."[19] Long-term follow-up on this ethnically diverse population is critical for generating the scientific evidence required to optimize treatment protocols and update standards of care.

C4. New Enrollment. During the original grant period, we noted a lack of diversity in the enrolled study population. Within the GnRHa cohort, there is a (b)(4); (b)(6)

(b)(4); (b)(6)

(b)(4); (b)(6) UCSF has opened a second site at Benioff Children's Hospital Oakland, a more ethnically diverse neighborhood. Recruitment here, in addition to selective recruitment of YOC

at the other sites, has provided additional diversity to the study. In order for this study to better reflect an increasingly diverse clinical population, we propose to selectively enroll additional non-Hispanic ethnic/racial minority youth in the GnRHa cohort (n=43), AMAB non-Hispanic ethnic/racial minority youth into the GAH cohort (n=110) and non-Hispanic ethnic/racial minority AFAB youth (n=46). Under the same protocol used for the existing TYC cohort[20] we will collect BL, 6, 12, 18 and 24-month data and longer-term annual follow-up data from newly enrolled youth over the proposed funding period (see Recruitment and Retention Plan). To assist with identifying additional recruitment strategies, Dr. Olson-Kennedy obtained intramural funding to conduct qualitative focus groups with TGD young adults of color to gather data about the challenges YOC face in accessing care. The first three focus groups have been conducted, and additional focus groups have been scheduled in 2020. These strategies form the backbone of recruitment efforts to diversify the study population.

C5. Study Design. The TYC study is a longitudinal, observational study of two cohorts receiving medical treatment: GnRHa initiating youth and those initiating GAH. Anthropometric and physiologic data will be abstracted from medical charts. REDCap[21] will be used to collect demographic, mental health, psychosocial, and behavioral data from youth as well as from one parent/guardian of each GnRHa participant. New measures will be added to enable new analyses. Both new enrollees and existing participants will be administered the measures utilized in the original TYC grant. As the cohorts age, appropriate versions of measures will be administered. Table 3 lists the constructs that will continue to be measured for both existing and new enrollees. Table 4 lists new constructs that will be added (see Appendix A for all measures).

C6. GnRHa Cohort. C6a. Study recruitment. The existing GnRHa cohort was recruited from youth initiating puberty suppression at one of the four study sites along with one parent/primary caregiver. Enrollment of new participants will now also include UCSF-Benioff Children's Hospital Oakland. Potential new enrollees will be screened by the primary medical provider at each site for participation in the study with the following criteria: **Inclusion criteria**: 1) gender dysphoria (as defined by treating medical provider); 2) Tanner stage 2, 3 or 4 of sexual development; 3) ages 8 – 16 years inclusive; 4) desire to undergo puberty suppression; and 5) ability to read and understand English; 6) able to provide assent. **Exclusion criteria:** 1) prior utilization of GnRHa's; 2) precocious puberty (AMAB younger than 9 years or AFAB younger than 8 years); 3) pre-existing osteoporosis; 4) Visibly distraught or; 5) presence of serious psychiatric symptoms. **Additional inclusion criteria for newly enrolled youth in renewal period:** 1) youth who identify their ethnicity as non-white, with emphasis on non-Hispanic/LatinX. Youth who meet inclusion criteria will provide assent, and their parent/caretaker will provide informed consent for participation in the study. **Parent/Caretaker inclusion criteria include**: 1) parent or caregiver of a child who meets the GnRHa cohort inclusion/exclusion criteria; 2) aged 18 or older; 3) ability to read and understand English; and 4) willing and able to provide signed informed consent. Exclusion criteria include: 1) presence of serious psychiatric symptoms that would impair the individual's ability to provide true informed consent or participate in the baseline survey; 2) visibly distraught (e.g., suicidal, homicidal, exhibiting violent behavior) at the time of consent or the baseline survey; or 3) intoxicated or under the influence of alcohol or other substances which might impair ability to give true informed consent or to understand and answer the questions is impaired. **C6b.Treatment Plan.** Medications used in this study are the standard of care at the four study sites. As the study is observational, it will not influence prescription patterns among the clinical providers. Decisions about medication doses are individually determined by the clinical care team based on adequate and appropriate response to medications, as well as tolerability of side effects. Data on specific agents of pubertal suppression and dosing will be collected to evaluate differences as part of the analysis. **C6c. Data Collection.** For newly enrolled youth, data collection, including computer assisted surveys will be collected at 6-month intervals (BL through 24-month) followed by extended annual data collection. **For extended follow-up** of both the existing cohort and new enrollees, data collection will be done annually (3, 4, 5 and 6 years). ■ **Anthropometric measures,** including height, weight, BMI, and Tanner stage as well as ■ **physiologic parameters** including blood pressure, electrolytes, glycosylated hemoglobin, ultrasensitive luteinizing hormone and estradiol or testosterone based on assigned sex at birth, will be collected via chart abstraction. **Measures related to bone health,** including bone mineral density (BMD), bone age, 25-hydroxy vitamin D, calcium, phosphate, and serum bone-specific alkaline phosphatase, will be collected at baseline and annually following initiation of GnRHa treatment. ■ **Psychosocial and M.I.N.I. Assessments.** GnRHa participant questions will include: 1) <u>transgender specific experiences</u> including gender identity, gender dysphoria, gender expression, age of realization, gender transition; 2) <u>mental health assessment</u> including depression, anxiety, quality of life, suicidality, self-harm, trauma events, autism symptoms, body esteem and self-perception; 3) <u>risk and protective factors</u> including gender minority stress and resilience, self-efficacy, perceived parental support, social relationships, psychological strengths, coping, and social connectedness. Psychiatric diagnosis questions are assessed at baseline and annually via the Mini International Neuropsychiatric Inventory for Children and

Adolescents (M.I.N.I. Kid). The M.I.N.I. is a short, structured diagnostic interview for DSM-IV and ICD-10 psychiatric disorders in children and adolescents.[22] As the cohort ages into adolescence, questions will be added to assess sexual orientation, sexual behavior, and alcohol and substance use. ■ **Parent/Caretaker questions include:** 1) Demographic information; 2) transgender-specific experiences including child gender identity, child's age of realization of transgender identity, child's age of first living in the desired gender role across domains (school, home), parental/guardian support, and disclosure of child's transgender identity to others; 3) mental health assessments include parent report of child's quality of life, autism symptoms, self-harm, and suicide (ideation and attempts). Parents complete the CBCL to identify internalizing and externalizing psychopathology.[23] 4) Risk and protective factors include self-efficacy (of child), social relationships (NIH Toolbox), religiosity, and parent stress and support (see tables 3 and 4 for a complete construct list and Appendix A for complete measures).

Table 3. Existing constructs	GAH Youth	GnRHa Youth	GnRHa Parent
Demographics	x		x
Religiosity & Spirituality	x		x
Socio-Economic Status	x		x
Gender Identity	x	x	x
Gender Dysphoria	x	x	x
Service Utilization	x		x
Depression	x	x	x
Anxiety	x	x	
Quality of Life	x	x	x
Suicidality/self-harm	x	x	x
Body Esteem	x	x	
Body Image	x		
Social Relationships	x	x	x
Negative Affect	x		x
Psychological Well-being	x		x
Gender Minority Stress/Resilience	x	x	
Self-Efficacy	x	x	x
Perceived Parent Support	x	x	x
Resiliency	x	x	
Sexual Behavior	x	x*	
STI History	x	x*	
Alcohol/Drug Use	x	x*	
Autism Symptoms	x		x
DSM Diagnosis	x	x	
Externalizing/Internalizing symptoms	x		x
Self-Perception		x	

*represents new measures to be administered to the aging GnRHa cohort

Table 4. Additional Measures for extended longer-term follow up data collection	GAH Youth	GnRHa Youth	GnRHa Parent
Trauma Symptoms	x	X	
Psychological Strengths	x	X	
Coping Attitudes/Behavior	x	X	
Childhood Social Adversity	x	X	
Social Connectedness	x	X	
Gender Expression; Identity	x	X	x

C7. GAH Cohort. C7a. Study Recruitment. Recruitment strategy will follow the existing protocol.[24] Enrollment of new participants will now include Benioff Children's Hospital Oakland to the existing four sites. New enrollees will be selectively recruited from those youth with gender dysphoria initiating GAH for the purpose of phenotypic gender transition at any of the sites. They will be **screened for study participation by the site's primary medical provider using: Inclusion criteria** 1) gender dysphoria (as defined by treating medical provider) 2) Tanner stage 3 or above of pubertal development; 3) interested in pursuing a phenotypic gender change with gender-affirming hormones; and 4) ability to read and understand English. **Additional inclusion criteria for newly enrolled youth in renewal period:** 1) youth who identify their ethnicity as non-white/non-Hispanic and/or 2) youth who identify as transfeminine (AMAB). **Exclusion criteria** 1) <8 or >21 years old or 2) prior utilization of gender-affirming hormones. Youth who are minors will provide assent for participation, and their parent/legal guardian will provide permission. Youth aged 18 or older will provide consent for participation. **C7b.Treatment Plan.** Medications used in this study (i.e., feminizing or masculinizing hormones) are the standard of care at the four study sites. As the study is observational, it will not influence prescription patterns among the clinical providers. Decisions about medication doses are individually determined by the clinical care team based on adequate and appropriate response to medications, as well as tolerability of side effects. Data on specific hormone type and dosing will be collected to evaluate differences as part of the analysis. **C7c. Data Collection.** For newly enrolled youth, data collection, including computer assisted surveys will be collected and administered at 6-month intervals (BL through 24-month) followed by extended annual data collection. **For extended follow-up** of both the existing cohort and new enrollees, data collection will be done annually (3, 4, 5 and 6 years). ■ **Anthropometric measures** include height, weight, BMI, Tanner stage, and breast hemi-circumference (AMAB). ■ **Physiologic parameters** include blood pressure; CBC, liver function tests, chemistry panel, fasting glucose, lipid profile, HgbA1c; and **hormone levels** used to assess adequate efficacy of gender-affirming hormones (estradiol or testosterone). Physical changes including expected changes, undesirable side effects, and treatment regret will be collected via computer survey instrument. ■ **Psychosocial**

and M.I.N.I. Assessments. Existing and new GAH cohort measures include: 1) demographic data (e.g. age, ethnicity, race, religion, education, employment, and birth city/country); 2) transgender experience including gender identity, gender expression, age of realization of TG identity, age of first living in authentic gender, gender dysphoria, body esteem, and body image; 3) mental health and behavioral risk assessments including gender congruence, depression, anxiety, autism symptoms, suicide, self-harm, substance use, and sexual activity; 4) risk and protective factors including resilience,[26] **gender minority stress and resilience**, quality of life,[27] peer relationships, and stressful life events. Psychiatric diagnoses are assessed at baseline and annually by the Mini International Neuropsychiatric Inventory (M.I.N.I) for Children and Adolescents.[22] (see tables 3 and 4 for a complete construct list and Appendix A for complete measures). **C8. Analytical Plan.** With the proposed continued data collection, we will have 9 waves of repeated measures data (5 waves from Baseline, 6, 12, 18 and 24-months) and 4 annual waves (3, 4, 5, and 6 years follow-up) for each cohort: GnRHa and GAH. Additional recruitment of a) YOC participants for each cohort and b) assigned male at birth (AMAB) for the GAH cohort, enables the study of changes within and between cohorts for up to 4-year follow-up to inform current medical care models. **Description of each cohort and how they map onto proposed study Aims:** 1) GnRHa cohort (**Aim 1**); 2) GAH cohort (**Aim 2**); and 3) created groups GnRHa + GAH and age- and assigned sex at birth-matched GAH only (**Aim 3**). Analyses concerning **Aim 4:** YOC and non-binary gender identity will be addressed within respective cohort analyses. We will continue with the general data analytical plan for categorical and continuous variables described below and Generalized Linear Models (GLM) (e.g., multiple linear, logistic, Poisson regression) to track and examine cross-sectional associations and changes between waves in key variables of interest, while accounting for key covariates to inform longitudinal analyses). To investigate intra-individual change and inter-individual differences in outcome variables of interest over time, we will employ **Latent Growth Curve Models (LGCM)** and variants (e.g., piecewise LGCM, multiple-group LGCM) within the Structural Equation Modeling framework. The advantages of using LGCM to model longitudinal data include the explicit incorporation of measurement error as a part of model specifications, accounting for autocorrelation among repeated measures, and its flexibility to evaluate and compare complex models.[11] LGCM are also highly flexible in terms of handling missing data, unequally spaced time points, non-normally distributed or discretely scaled measures (e.g., dichotomous outcomes), non-linear trajectories, and multivariate (i.e., parallel) growth processes.[27] Moreover, piecewise LGCM is particularly suited to model changes in outcomes (and predictors of outcomes) that may occur during meaningful transition points. All analytic activities will be conducted with IBM SPSS (v 22) and Mplus (v 7.31). **C8a. Data Checking, Cleaning, and Management.** Data cleaning procedures and descriptive analyses will occur throughout new data collection to ensure high quality. Analyses will describe patterns of correlations. Covariance checks for multicollinearity and singularity of variables of the new datasets will facilitate the identification of multivariate outliers and assumptions of multivariate normality. **C8b. Descriptive Analyses and Data Visualization.** Univariate statistics will characterize the sample, including demographics, physiological parameters, and psychosocial measures for the GnRHa cohort. Scatter plots will help identify underlying trends and patterns in the data, which can help inform longitudinal modeling. Bivariate analyses will also identify potential covariates for inclusion in multivariate models. **C8c. Data Reduction and Psychometric Analyses.** Factor analysis will identify and/or verify scale structure of constructs. Items not loading on hypothesized factors and/or items loading on multiple factors may be excluded. Scale scores will be created as means or sums of unweighted composite scores, or composite scores weighted by factor loadings, as appropriate. Psychometric properties verifying stability of structure of new/adapted scales over time within the latent variable framework will be tracked at each assessment time point for both cohorts to inform analyses and interpretation of results. **C8d. Long Term Effects of Medical Treatments on Development.** Examples include **bone density for GnRHa (Aim 1a) and cardiovascular risk for GAH cohorts (Aim 2a).** Analyses **will examine whether indicators exceed** the clinically safe range.

Safety of medical Interventions in the GnRHa (Aim 1a) and GAH cohorts (Aim 2a)
HYP 1a: Raw bone density scores will remain stable for early-pubertal transgender youth receiving GnRH agonists; however, age-matched z-scores may decrease. **HYP 2a:** Cross-sex hormones will not increase cardiovascular risk factors (obesity, blood pressure and lipids) above clinically safe ranges among transgender youth receiving GAH.

Safety will be assessed cross-sectionally at specific developmental periods using one-sided one-sample t-tests comparing cohort mean scores to the cutoff value. We hypothesize that GnRHa cohort means will be significantly lower than cutoff scores. We will also use repeated measures ANOVA to estimate trajectories of raw and age-matched bone density scores over time among GnRHa youth; analyzing separately by sex assigned at birth. We hypothesize that for raw scores, the linear term will *not* differ significantly from zero, indicating net stability in bone density over time. However, for age-matched z-scores, the linear term may be negative as gender non-conforming GnRHa youth fail to add bone density at a rate comparable to age-matched peers.[14] These analyses

will also take into account dietary calcium intake and weight-bearing exercise as important influences of bone density over time. For **HYP 2a** this analysis approach will be applied to examine cardiovascular risk among GAH cohort youth receiving GAH to examine whether any increases in cardiovascular risk indicators rise to levels above their age matched peers.[7] In addition to cross sectional analyses, we will use repeated measures ANOVA to estimate trajectories of obesity, blood pressure and lipid scores over time; analyzing separately by sex assigned at birth. Analyses will also be performed on GnRHa cohort for youth who have initiated GAH (GnRHa + GAH). We will use the Benjamini-Hochberg procedure [28] to account for inflated family-wise alpha due to multiple comparisons at each time point. **C8e. Latent Growth Curve Models (LGCM) for Psychosocial Outcomes (see Conceptual Model). Although the hypotheses below focus on mental health outcomes, additional analyses using other outcomes from the conceptual model (e.g. quality of life, body esteem) can be performed using this approach as well as examination of risk (e.g. gender minority stress) and protective (e.g. gender minority resilience) factors that may prove to be important (appear or change) within specific developmental stages.**

Psychological well-being/mental health as a function of time since initiation of GnRHa (Aim 1)
HYP 1b: Patients treated with GnRHa's will exhibit decreased symptoms of depression (anxiety, suicidality) over time.
HYP 1c: These trajectories will vary as a function of age of initiation of GnRHa and will differ based on sex assigned at birth (AMAB or AFAB).

To address **HYP 1b** and **HYP 1c** we will use data from the original and newly enrolled GnRHa cohort. To determine the extent to which negative mental health symptoms have decreased over time, we will develop LGCM that estimate trajectories of each of the outcomes across time for the entire sample, existing cohort and newly enrolled (projected N=125 using 83% retention based on current data) by end of wave 6 (36 month follow-up). We will also develop LGCM that estimate trajectories of each of the outcomes across time for the subsample of existing cohort (projected N=79) by end of wave 9 (using 83% retention). The growth profile of an individual is represented by at least two growth parameters: initial status (intercept), and the rate of change/trajectory of the growth (slope). Graphical approaches, which include examination of individual empirical growth plots and comparison to ordinary least square estimated individual trajectories, will assist in evaluating whether the selected model adequately captures the shape of the growth trajectory. If not, we may consider adding an additional parameter to account for quadratic growth rather than linear growth. In addition, the initiation of GAH can potentially create discontinuities in the growth curve (e.g., the negative slope of depression could decline more sharply after GAH initiation or surgery).[29] To characterize these discontinuities more precisely, we may model these treatments' impact as additional time-variant predictors. We will compare progressively more complex models and select the best model utilizing fit statistics (e.g., AIC/BIC, RSMEA, CFI/TLI) and by examining differences in chi-square statistics of nested models.[30] Other time-variant variables (e.g., life stress, gender dysphoria, **non-binary gender identity**, family support, discrimination) and time-invariant variables (e.g., **race/ethnicity**) can be added to the model as predictors (i.e., risk, protective factors) of growth profiles of specific outcomes. Time-variant and time-invariant predictors can also be specified as exerting either time-varying or uniform effects across time. To determine the nature of the impact of these theoretically and potentially statistically important predictors of growth trajectories of interest, we will examine results from descriptive and cross-sectional analyses. We will also plot expected trajectories by levels of predictors to visualize their impact over time. We will consider an alternate approach to modeling these discontinuities by developing a *piece-wise LGCM*, which segments a growth profile into multiple pieces with each piece representing a conceptually meaningful, distinct time period (e.g., prior to GAH, post-GAH) to investigate how these impact psychosocial well-being and mental health over time.[31] Because there is an explicit interest in modeling differences in outcomes between AMAB and AFAB, we will employ *multiple-group LGCM* to investigate differences in growth trajectories between these two groups by imposing equality constraints across AMAB- and AFAB- specific growth parameter estimates. Age of initiation of GnRHa (baseline value) will be added as a time-invariant predictor to the *multiple-group LGCM*, thereby enabling us to examine its potential unique effect for each group on psychological well-being over time. In addition to examining change across waves of data collection, we will also investigate changes in outcomes by *modeling age as time* (aged 8-22 for the GnRHa cohort) spanning up to fourteen years by the time wave 9 ends, using a *cohort-sequential data analytic approach*. With this method, multiple independent cohorts (i.e., age) assessed at staggered but partially overlapping time points are linked to create a common trajectory to determine the common underlying developmental trend.[32,33] An important consideration in a cohort-sequential analysis is to test for assumption of invariance of growth parameters across cohorts – i.e., that outcome trajectory does not vary by age cohort. To do so, we estimate cohort sequential models within a multiple-group framework to impose cross-cohort equality constraints needed to evaluate invariance holding other parameters equal when more than one cohort represents an age. Then we can follow

similar approaches to model general LGCM and its variants as described above to examine trajectories of psychosocial well-being and mental health by age. Partially missing data (e.g., in the lower and higher age range) inherent to using this approach can be addressed by Maximum Likelihood estimation for continuous and normally distributed outcomes or the use of multiple-imputations, which involves pooling of parameter estimates from imputed datasets.

Psychological well-being/mental health as a function of time since initiation of GAH (Aim 2)

HYP 2a: Patients treated with GAH will exhibit decreased symptoms of depression (anxiety, suicidality) over time.
HYP 2b: These trajectories will vary as a function of age of initiation of GAH and will differ based on sex assigned at birth (AMAB or AFAB).

To address **HYP 2a** and **HYP 2b**, we will utilize data from the original and newly enrolled GAH cohort across 6 waves (36 months) (projected N=492 using 83% retention). We will develop LGCM that estimate trajectories of each of the outcomes across time for the subsample of existing cohort (projected N=262) by end of wave 9 (83% retention of existing cohort). We will follow the approach outlined above for **HYP1a** and **HYP1b** to capture the overall trajectory of change in psychological and mental health outcomes of interest over time and inserting significant time-variant (e.g., gender minority stress and resilience) and time-invariant predictors (e.g., getting surgery) to predict how these trajectories change over time. We will explicitly model these trajectories based on sex assigned at birth and age of GAH initiation. We will then move onto examining these changes by age (aged 11 to 27 for GAH cohort) using the cohort-sequential approach, to create a common trajectory to determine the common underlying developmental trend for this cohort, which spans up to sixteen years.

Psychological well-being/mental health as a function of history of GnRHa and age initiating GAH (Aim 3)
HYP 3a: Patients receiving GAH with a history of GnRHa (GnRHa + GAH) will exhibit greater decreased symptoms of depression (anxiety, suicidality) over time compared to those with no prior history of GnRHa (GAH Cohort).
HYP 3b: These trajectories will vary as a function of age of initiation of GAH, and sex assigned at birth.

To address HYP 3a and HYP 3b that are focused on comparing the two age- and sex assigned at birth created groups, we will identify the GnRHa plus GAH group when they initiated GAH from the a) GnRHa participants 13-18 at the time they initiated GAH during up to 36 month follow-up or were b) the 29 existing GAH participants (13-18 years) who were taking GnRHA at the time of study enrollment yielding an estimated combined total sample size of 84. We anticipate adding 21 eligible participants from the newly enrolled GnRHa cohort and GAH cohort for a total of 105 for this GnRHa + GAH group. We will draw GAH only participants (within the ages of 13-18) for matching purposes. Age categories for matching will be defined as 13-15 and 16-18 because these are meaningful distinctions in GAH provision to youth. In addition to age and sex assigned at birth we will examine the distribution of Tanner stage to make the groups more comparable. Once this newly combined dataset (N= 210) is created, we will first develop GLM models that compare psychological well-being and mental health outcomes between the two groups cross-sectionally and between waves. The variable "group", which denotes the GnRHa + GAH vs. GAH-only will be entered into each regression model. We expect the GnRHa + GAH group to exhibit significantly fewer symptoms of depression (anxiety, and incidences of suicidality) compared to the GAH-only group, after adjusting for significant covariates (i.e., protective and risk factors at each wave). Next, we will investigate cohort differences in psychological well-being and mental health longitudinally with LGCM, modeling age as time (aged between 13 to 21) spanning up to eight years, using the cohort-sequential data analytic approach described above. This approach is particularly helpful to tease out how trajectories might vary between the two cohorts as a function of age of initiation of GAH. **C8f. Site-Clustering Effects.** We will continue to monitor potential site-specific effects by including a group identifier for each participant in the analytic dataset, and the intra-class correlation (ICC) for each outcome will be calculated prior to conducting multivariate analyses. If a significant difference in group-level variance is detected, we will specify a two-level multilevel LGCM within the SEM framework, whereby the three-level clustered longitudinal data is analyzed with a two-level model.[34-36] We can then follow with the analyses specified above for hypotheses testing. **C8g. Power Analysis and Sample Size Estimations for the Use of LGCM.** While GCM has the flexibility to fit models with unbalanced data (i.e., include participants with varying waves of data), we will first estimate power for the most stringent set of hypotheses, which is with the GnRHa cohort (**Aim 1**) that has a projected sample size of 79 by 72 months (wave 9). Estimates of power for the proposed models were generated using Monte Carlo simulations in Mplus (v7.31), keeping in mind that the level of parameter bias, standard error bias, and coverage across estimates are below acceptable cut-off levels.[36,37] Results indicated that with nine waves of data and accounting for missing data patterns based on current data, the power to detect significant effects (ranged from small to medium: Cohen's d=0.18 to 0.35) of covariates on linear change is between 83% to over 99%. For a projected sample size of 262 of the GAH cohort (**Aim 2**) by wave 9, we estimated the power to detect small effect sizes in the range of 0.10

to 0.12 to be 8 3% to 94%. For a sample of 210 (aged-match GnRHa + GAH and GAH-only cohorts) (**Aim 3**), the power to also detect small effects (Cohen's d=0.12 to 0.15) ranged from 81% to 94%.

C9. Potential Problems and Alternative Strategies.C9a. Attrition between baseline enrollment and follow-up visits has been smaller than anticipated, and we have over-enrolled from initial target numbers. However, with extended follow-up (up to six years past enrollment) attrition could impact the validity of results and the power to detect relationships among variables. Older adolescents and young adults are migratory by nature, although continued GnRHa or hormone treatment is a compelling reason to stay engaged in care. Only a few participants have chosen to go off study. This could become more challenging as youth age out of care at any of the sites; however all sites treat youth up to 25 years of age. To date we have only enrolled twelve 19-20 year old GAH participants who could age out of care within 6 years across all four sites. Study investigators fully appreciate the challenges associated with tracking young adults during this period of their lives. We are skilled at successfully retaining participants for follow-up surveys based upon extensive experience tracking young adults in previous studies including many of whom were hard-to-reach due to homelessness, substance use, or other risk behavior. Key retention strategies include: collecting extensive tracking information and verifying contact information at each follow-up visit; storing tracking information in a retrievable Access database; linking each participant to specific staff; conducting brief monthly check-ins via email or text; and training staff on the importance of retention (see Recruitment and Retention Plan for more details). **C9b. Collecting and transmitting data** During the initial grant the 4 sites implemented strong data collection and study protocols which will continue in the new grant. To support cross-site data collection, we have budgeted for a full-time data manager at the data coordinating site (CHLA) responsible for data cleaning, ensuring data are complete, querying study coordinators about problematic data, running analyses, providing data summaries, monitoring enrollment and retention rates, and assisting analysis interpretation. Guided by Dr. Wong and (b)(6) they will continue to respond to requests for data analysis and data sets from the sites' biostatisticians. **C9c. Risk to participants**. While this study will likely cause minimal risk to participants, they could potentially experience distress and/or discomfort when asked questions of a more sensitive nature in the assessments. If participants experience distress or discomfort, as outlined in the Protection of Human Subjects, they will be directed immediately to a licensed mental health clinician for evaluation and counseling.

C10. Benchmarks of Success and Timeline. Benchmarks (see **Study Timeline**) include: 1) Recruitment and enrolling of the selective cohorts (YOC and transfeminine); 2) successful enactment of recruitment protocols; 3) convening of the CAB; 4) multisite protocol team meeting; 5) data collection at each follow-up point; 6) data management and analysis; and 7) published manuscripts and dissemination.

C11. Dissemination. The PIs will present findings to at least one national/international conference per year beginning in Year 1. Data obtained from this study will be presented at national conferences (e.g., Society for Adolescent Health and Medicine, Pediatric Academic Societies, American Psychological Association) and gender-specific conferences (e.g., WPATH, Gender Odyssey). Ongoing peer-reviewed publications will be developed pertaining to cross-sectional hypotheses and longitudinal trajectory questions in Aims 1, 2 and 3.

C12. Future Directions. The continuation of this network of investigators, and ongoing data collection is an essential step in the progress to eradicate health disparity that currently exists for transgender youth. With a newly awarded NIH grant (R01HD09712; PI: Hidalgo). We have extended our investigations to examine gender identity milestones (e.g., gender cognition), mental health, and resiliency among prepubertal TGD children. This current proposal will allow us to continue observation through early adulthood, covering a large spectrum of middle childhood to young adulthood development. This longitudinal outcome research is sorely needed for understanding and optimizing medical interventions for TGD youth. Within this proposal, our network is seeking to answer some of new and unanticipated questions as they have arisen within the context of the previous work. This proposal sets up an ideal framework to continue collecting longitudinal data from the cohorts recruited for this initial work as well as understand the additional complexities of this population.

PROGRESS REPORT PUBLICATION LIST

Our group has been productive during the funding period (8/1/15-6/30/20) of this NICHD/NIH R01 HD 082554 grant. We have 31 publications, 1 paper with revisions under review, and 2 papers submitted for review demonstrating our substantial progress on all of the original aims. We have used this R01 as a platform for mentoring (* indicates author is a mentee), reflecting the commitment of the principal investigators and co-investigators to mentor early stage investigators.

Cohort Publications

1. (b)(4)

2. (b)(4)

3. **Chen, D.**, Lash, B., Kim, E. **Hidalgo, M.A.**, Muldoon, A.L., Liu, E., Jensen, J., Grabert, R., **Chan, Y.M.**, **Garofalo, R.**, & **Tishelman, A.** (Under review). A comparison of psychosocial characteristics between transgender youth enrolling versus not enrolling in a multisite research study. Under review at *LGBT Health*

4. **Olson-Kennedy J**, **Chan YM**, **Garofalo R**, Spack N, **Chen D**, **Clark L**, **Ehrensaft D**, **Hidalgo M**, **Tishelman A**, **Rosenthal S**. Impact of Early Medical Treatment for Transgender Youth: Protocol for the Longitudinal, Observational Trans Youth Care Study. *JMIR Res Protoc* 2019;8(7):e14434. PMCID: 6647755

5. **Olson-Kennedy J, Chan YM, Rosenthal S, Hidalgo MA, Chen D, Clark L, Ehrensaft D, Tishelman A, Garofalo R.** Creating the Trans Youth Research Network: A Collaborative Research Endeavor. *Transgend Health*. 2019 Nov 1;4(1):304-312. PMCID: PMC6830532.

Shared Resource Publications (grant supported time and effort)

6. **Hidalgo MA**, Petras H, **Chen D**, Chodzen G*. (2019) The Gender Minority Stress and Resilience Measure: Psychometric validity of an adolescent extension. *Clinical Practice in Pediatric Psychology, 7*, 278-290.

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PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001 and 0925-0002

Expiration Date: 03/31/2020

Are Human Subjects Involved	● Yes ○ No
Is the Project Exempt from Federal regulations?	○ Yes ● No
Exemption Number	❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8
Other Requested Information	

Human Subject Studies

Study#	Study Title	Clinical Trial?
1	The Impact of Early Medical Treatment in Transgender Youth	No

Section 1 - Basic Information (Study 1)

OMB Number: 0925-0001 and 0925-0002

Expiration Date: 03/31/2020

1.1. Study Title *

The Impact of Early Medical Treatment in Transgender Youth

1.2. Is this study exempt from Federal Regulations * ❍ Yes ● No

1.3. Exemption Number ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8

1.4. Clinical Trial Questionnaire *

1.4.a. Does the study involve human participants?	● Yes	❍ No
1.4.b. Are the participants prospectively assigned to an intervention?	❍ Yes	● No
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?	❍ Yes	● No
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?	❍ Yes	● No

1.5. Provide the ClinicalTrials.gov Identifier (e.g. NCT87654321) for this trial, if applicable

Section 2 - Study Population Characteristics (Study 1)

2.1. Conditions or Focus of Study

- Gender Dysphoria

2.2. Eligibility Criteria

GnRHa YOUTH COHORT
Inclusion Criteria
- Presence of gender dysphoria as determined by a clinician;
- Tanner stage 2, 3, or 4 of sexual development
- Appropriate to undergo puberty suppression with GnRH agonists;
- Ages 8 through 16 years inclusive;
- Ability to read and understand English;
- Receiving or planning to receive services at a study site clinic; and
- Willing and able to provide informed assent.

Additional Inclusion Criteria for New Enrollments in the Renewal Period
- Youth of color with an emphasis on non-Hispanic/Latinx youth

Exclusion Criteria
- Prior utilization of GnRH agonists;
- Precocious puberty (natal males younger than 9 years or natal females younger than 8 years);
- Pre-existing osteoporosis;
- Presence of serious psychiatric symptoms (e.g., active hallucinations, thought disorder) that would impair the individual's ability to provide true informed consent or participate in the baseline survey;
- Visibly distraught (e.g., suicidal, homicidal, exhibiting violent behavior) at the time of consent or the baseline survey; or Intoxicated or under the influence of alcohol or other substances to such an extent that in the opinion of the study staff, the ability to give true informed consent or to understand and answer the questions is impaired.

GnRHa PARENT/CAREGIVER COHORT
Inclusion Criteria
- Parent or caregiver of a child who meets the GnRHa Youth Cohort inclusion/exclusion criteria;
- Ages 18 and above;
- Ability to read and understand English; and
- Willing and able to provide signed informed consent.

Exclusion Criteria
- Presence of serious psychiatric symptoms (e.g., active hallucinations, thought disorder) that would impair the individual's ability to provide true informed consent or participate in the baseline survey;
- Visibly distraught (e.g., suicidal, homicidal, exhibiting violent behavior) at the time of consent or the baseline survey; or
- Intoxicated or under the influence of alcohol or other substances to such an extent that in the opinion of the study staff, the ability to give true informed consent or to understand and answer the questions is impaired.

GENDER-AFFIRMING HORMONE COHORT
Inclusion Criteria
- The presence for gender dysphoria as determined by a clinician;
- Appropriate for initiating phenotypic gender change with gender-affirming hormones;
- Ages 8 through 20 years inclusive;
- Ability to read and understand English;
- Receiving or planning to receive services at a study clinic; and
- Willing and able to provide signed informed consent or assent.

Additional Inclusion Criteria for New Enrollments in the Renewal Period
- Transmasculine participants - identify as a youth of color with an emphasis on non-Hispanic/Latinx youth
- Transfeminine participants - no race or ethnicity requirements

Exclusion Criteria
- Prior utilization of gender-affirming hormones;
- Previously or currently enrolled in the GnRHa cohort;
- Presence of serious psychiatric symptoms (e.g., active hallucinations, thought disorder) that would impair the individual's ability to provide true informed consent or participate in the baseline survey;
- Visibly distraught (e.g., suicidal, homicidal, exhibiting violent behavior) at the time of consent or the baseline survey; or
- Intoxicated or under the influence of alcohol or other substances to such an extent that in the opinion of the study staff, the ability to give true informed consent or to understand and answer the questions is impaired.

2.3. Age Limits Min Age: 8 Years Max Age: N/A (No limit)

2.4. Inclusion of Women, Minorities, and Children Inclusion_of_Women_Minorities_and_Children.pdf

2.5. Recruitment and Retention Plan	Recruitment_and_Retention_Plan.pdf	
2.6. Recruitment Status	Enrolling by invitation	
2.7. Study Timeline	Study_Timeline.pdf	
2.8. Enrollment of First Subject	07/25/2016	Actual

INCLUSION OF WOMEN, MINORITIES, AND CHILDREN

Inclusion of Women and Minorities

This project meets standards for inclusion of women and minorities.

As a study of transgender children, youth, and young adults, potential participants who identify with a gender that is incongruent with the sex they were assigned at birth may be eligible to be enrolled in this study. These individuals will be recruited to participate in the proposed study and may identify with any number of gender identity labels including, but not limited to transgender, gender fluid, nonbinary, genderqueer, female, transgender female, male, and transgender male. The goal of the study is to have equal numbers of transfeminine and transmasculine participants in the youth cohorts. Currently, the gender identity percentages are relatively similar within the GnRHa cohort with 43.2% identifying as transmasculine; 47.4% transfeminine; and 9.6% nonbinary, genderqueer, or gender fluid (48% assigned female at birth and 52% assigned male at birth). However, within the gender-affirming hormone cohort, the participants are 60.3% transmasculine; 33.1% transfeminine; 5% nonbinary, genderqueer, or gender fluid; and 1.2% other (65% assigned female at birth and 35% assigned male at birth). Therefore, in the gender-affirming cohort, we are not limiting the recruitment of transfeminine youth to the specific race and ethnicity requirements that were implemented with the GnRHa cohort discussed below.

Initially, all racial and ethnic categories were eligible to enroll in the study during the first grant period; however, it became evident that the percentage of white youth enrolling in the study was higher than expected, reflecting the rates of youth in care at all four of the sites. To address the lack of racial/ethnic diversity, the MPIs decided at the protocol team meeting in late 2018 to restrict new transmasculine participant enrollments in the gender-affirming hormone cohort to participants of color, with an emphasis on non-Hispanic/Latinx youth. In the GnRHa cohort, enrollment was also restricted to youth of color, with an emphasis on non-Hispanic/Latinx youth. Due to the need to recruit and enroll more transfeminine youth in the gender-affirming hormone cohort, there were no race or ethnicity restrictions implemented. In our current cohorts, the gender-affirming hormone youth cohort is (b)(4); (b)(6). The GnRHa youth cohort is (b)(4); (b)(6) (b)(4);.

Inclusion of Children

This project meets standards for inclusion of children.

The research conducted thus far and during the renewal grant period will include coded data from early and late pubertal gender dysphoric children, adolescents, and young adults to understand the impact of hormone therapy to suppress puberty and assist in phenotypic transition. In the initial grant period, youth participants have ranged in age from 8 to 20, with a mean age of 11 years in the GnRHa cohort and 16 years in the gender-affirming hormone cohort at enrollment. Data will be collected from their medical charts as well as surveys and interviews; however, all data collection will be coded to help ensure confidentiality. Children and adolescents will be asked to complete surveys at baseline and every six months through the month-24 visit and annually thereafter for seven years. As described in the Research Plan, the Principal Investigator, research staff, and collaborating partners have a long history of providing care for and conducting research with transgender children and adolescents.

Parent/Caregiver participants must be at least 18 years of age; this is required due to self-consent requirements for participating in the study. It is not expected that we would have a potential participant under age 18 as the minimum age for the youth participants is 8 years.

The investigative team of MPIs and Co-Is has extensive expertise in providing medical and psychosocial care to children, adolescents, and young adults. The four study sites are children's hospitals with strong academic partnerships. The research space in the four children's hospital sites is age-appropriate, and the facilities are ideal for conducting research with children. The majority of the members of the PI and Co-I teams are active clinicians in addition to their research endeavors as university faculty.

Involvement of children in this study will be in compliance with all applicable subparts of 45 CFR 46, Subpart D – Additional Protections for Children Involved as Subjects in Research, as well as other pertinent Federal and State laws/regulations.

RECRUITMENT AND RETENTION PLAN

Recruitment is conducted through the clinics at the four study sites as inclusion criteria require that participants access care at the study site in order for the study to obtain observational data on the medical impact of a GnRHa to prevent progression beyond early puberty or gender-affirming hormones for phenotypic transition. In addition, these four clinic sites are some of the largest providers of transgender pediatric care in the country.

During the original grant period, our team noted that the diversity of the enrolled study population needed to be improved. This led to the launching of a selective recruitment strategy specifically to increase participation of youth of color with an emphasis on non-Hispanic/Latinx youth in the GnRHa cohort. In the gender-affirming hormone cohort, the same emphasis was placed on transmasculine participant recruitment; however, due to the smaller number of transfeminine participants in the GAH cohort, a focus on youth of color was not implemented. During the tenure of the first grant period, UCSF opened a second site at Benioff Children's Hospital Oakland that began providing gender care for that geographic region and is located in a more ethnically diverse neighborhood. Recruitment from this site, in addition to selective recruitment at the other sites, has provided additional diversity to the study population. In order to assist with identifying additional recruitment strategies, Dr. Asa Radix has joined the protocol team as a co-investigator. In addition, Dr. Olson-Kennedy at Children's Hospital Los Angeles obtained CTSI funding and IRB approval to conduct qualitative focus groups with transgender and gender diverse young adults of color to gather data about the challenges youth of color face in accessing care. The first three focus groups have been conducted, and funding has been sought to support additional focus groups. These strategies form the backbone of recruitment efforts to diversify the study population.

Our study coordinators who identify as transgender, non-binary, or genderqueer at each of the study sites provide unique recruitment and enrollment support. Having a study coordinator with whom the participants have a shared experience is of unquestionable value to the youth and parent/caregiver participants, especially when answering questions during the recruitment, informed consent, and enrollment processes. We have found this to also greatly benefit retention efforts as the youth appreciate this shared experience when they are responding to measures related to their gender identity and during the debrief at the end of each study visit.

Retention of participants at study follow-up visits is facilitated by the fact that study visits correspond to clinically-required medical follow-up visits. Additionally, we provide compensation to the participants to acknowledge the time required of them to participate in study visits. Currently, incentive amounts vary based on the type of study visit. For example, 6- and 18-month visits are shorter than baseline, month 12, and month 24 visits, and therefore, we provide less compensation for shorter visits than longer visits. During the renewal period, to strengthen retention, we will increase the incentives provided to participants over time to incentivize remaining in the study without providing an incentive so large as to be considered coercive. We also provide transportation assistance via ridesharing (e.g., Lyft), parking validations, or mileage reimbursement to assist participants in attending study visits.

Retention rates for the GnRHa cohort are as follows: 6 month: 83% (100% visits complete); 12 month: 78% (96% visits complete); 18 month: 73% (86% visits complete); 24 month: 89% (55% visits complete), and for the GAH cohort: 6 month: 92% (100% visits complete); 12 month: 83% (97% visits complete); 18 month: 73% (93% visits complete); 24 month: 80% (79% visits complete). We believe that through the efforts described above, we will continue to maintain a high retention rate throughout the study renewal period.

During the renewal grant period, retention efforts will be increased as study visits will decrease in frequency to be annual rather than every six months after month 24. In addition, as some participants may be on gender-affirming hormones for three or more years, their medical care visits may also be further spaced apart. Study coordinators will utilize retention strategies such as phone calls to participants, sending birthday cards, and providing small tokens of appreciation that will remind them of the study. As pediatric institutions, we recognize that some participants will age out of services during the seven-year extended follow-up period. To assist with retention, we will transition the survey to a web-based platform (REDCap) so that participants who no longer live close to the study site may be able to complete some study visits remotely. Also, we will continue to retain these participants through strategies such as scheduling study visits during trips home from college and obtaining

release of information forms to access medical data from other care providers. We update locator information at all visits, and we contact participants between study visits to correct and update contact information.

Retention will also be maintained through timely dissemination of data analysis to participants (youth and parents/caregivers) in a meaningful and digestible manner. In addition, presentations of study data are not limited to academic conferences and settings; we will continue to present at meetings that are attended by the community, which study participants and their family may be attending.

STUDY TIMELINE

	Year 1				Year 2				Year 3				Year 4				Year 5			
Quarters (Q1-Q4) Per Yr	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Multisite Protocol Team Meeting		■				■				■				■				■		
Convene CAB	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Recruit and Enroll New Cohort	■	■	■	■	■	■	■	■												
1-Year Follow-Up New Cohort					■	■	■	■	■	■	■	■								
2-Year Follow-Up Original/New Cohort	■	■	■	■					■	■	■	■	■	■	■	■				
3-Year Follow-Up Original/New Cohort	■	■	■	■	■	■	■	■					■	■	■	■	■	■	■	■
4-Year Follow-Up Original/New Cohort	■	■	■	■	■	■	■	■	■	■	■	■					■	■	■	■
5-Year Follow-Up Original Cohort					■	■	■	■	■	■	■	■	■	■	■	■				
6-Year Follow-Up Original Cohort									■	■	■	■	■	■	■	■	■	■	■	■
Data Management, Cleaning, and Analysis	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Renewal Aim 1 Analyses & Papers										■	■	■	■	■	■	■				
Renewal Aim 2 Analyses & Papers												■	■	■	■	■	■	■	■	■
Renewal Aim 3 Analyses & Papers																		■	■	■
Conference Presentations				■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■

Inclusion Enrollment Reports

IER ID#	Enrollment Location Type	Enrollment Location
Study 1, IER 1	Domestic	Ann & Robert H. Lurie Children's Hospital of Chicago Boston Children's Hospital Children's Hospital Los Angeles UCSF Benioff Children's Hospital Oakland UCSF Benioff Children's Hospital San Francisco
Study 1, IER 2	Domestic	Ann & Robert H. Lurie Children's Hospital of Chicago Boston Children's Hospital Children's Hospital Los Angeles UCSF Benioff Children's Hospital Oakland UCSF Benioff Children's Hospital San Francisco
Study 1, IER 3	Domestic	Ann & Robert H. Lurie Children's Hospital of Chicago Boston Children's Hospital Children's Hospital Los Angeles UCSF Benioff Children's Hospital Oakland UCSF Benioff Children's Hospital San Francisco

Inclusion Enrollment Report 1

Using an Existing Dataset or Resource* : ● Yes ○ No

Enrollment Location Type* : ● Domestic ○ Foreign

Enrollment Country(ies): USA: UNITED STATES

Enrollment Location(s): Ann & Robert H. Lurie Children's Hospital of Chicago
Boston Children's Hospital
Children's Hospital Los Angeles
UCSF Benioff Children's Hospital Oakland
UCSF Benioff Children's Hospital San Francisco

Comments: GnRHa (BLOCKER)YOUTH COHORT PLANNED AND CUMULATIVE ENROLLMENT FOR THE CURRENT GRANT
Cumulative (Actual) data below are for youth and parent/caregiver participants enrolled in the current study through 2/29/20 based on identity reported in the baseline visit.
Data below are reported by sex assigned at birth, not gender identity.
UCSF Benioff Children's Hospital Oakland was added as a site during the initial grant period to improve racial and ethnic diversity in the study population.

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	(b)(4); (b)(6)				
Asian					
Native Hawaiian or Other Pacific Islander					
Black or African American					
White					
More than One Race					
Total					

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	(b)(4); (b)(6)									
Asian										
Native Hawaiian or Other Pacific Islander										
Black or African American										
White										
More than One Race										

Unknown or Not Reported	(b)(4); (b)(6)
Total	

Inclusion Enrollment Report 2

Using an Existing Dataset or Resource* : ● Yes ○ No

Enrollment Location Type* : ● Domestic ○ Foreign

Enrollment Country(ies): USA: UNITED STATES

Enrollment Location(s): Ann & Robert H. Lurie Children's Hospital of Chicago
Boston Children's Hospital
Children's Hospital Los Angeles
UCSF Benioff Children's Hospital Oakland
UCSF Benioff Children's Hospital San Francisco

Comments: GnRHa (BLOCKER) PARENT/CAREGIVER COHORT PLANNED AND CUMULATIVE ENROLLMENT FOR THE CURRENT GRANT
Cumulative (Actual) data below are for youth and parent/caregiver participants enrolled in the current study through 2/29/20 based on identity reported in the baseline visit.
Data below are reported by sex assigned at birth, not gender identity.
UCSF Benioff Children's Hospital Oakland was added as a site during the initial grant period to improve racial and ethnic diversity in the study population

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	(b)(4); (b)(6)				
Asian					
Native Hawaiian or Other Pacific Islander					
Black or African American					
White					
More than One Race					
Total					

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	(b)(4); (b)(6)									
Asian										
Native Hawaiian or Other Pacific Islander										
Black or African American										
White										
More than One Race										

Unknown or Not Reported	(b)(4); (b)(6)
Total	

Inclusion Enrollment Report 3

Using an Existing Dataset or Resource* : ● Yes ○ No

Enrollment Location Type* : ● Domestic ○ Foreign

Enrollment Country(ies): USA: UNITED STATES

Enrollment Location(s): Ann & Robert H. Lurie Children's Hospital of Chicago
Boston Children's Hospital
Children's Hospital Los Angeles
UCSF Benioff Children's Hospital Oakland
UCSF Benioff Children's Hospital San Francisco

Comments: GENDER AFFIRMING HORMONE (GAH) COHORT PLANNED AND CUMULATIVE ENROLLMENT FOR THE CURRENT GRANT
Cumulative (Actual) data below are for youth and parent/caregiver participants enrolled in the current study through 2/29/20 based on identity reported in the baseline visit.
Data below are reported by sex assigned at birth, not gender identity.
UCSF Benioff Children's Hospital Oakland was added as a site during the initial grant period to improve racial and ethnic diversity in the study population.

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	(b)(4); (b)(6)				
Asian					
Native Hawaiian or Other Pacific Islander					
Black or African American					
White					
More than One Race					
Total					

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	(b)(4); (b)(6)									
Asian										
Native Hawaiian or Other Pacific Islander										
Black or African American										
White										
More than One Race										

Unknown or Not Reported	(b)(4); (b)(6)
Total	

Section 3 - Protection and Monitoring Plans (Study 1)

3.1. Protection of Human Subjects	Protection_of_Human_Subjects.pdf
3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?	● Yes ○ No ○ N/A
If yes, describe the single IRB plan	Single_IRB_Plan.pdf
3.3. Data and Safety Monitoring Plan	Data_and_Safety_Monitoring_Plan.pdf
3.4. Will a Data and Safety Monitoring Board be appointed for this study?	○ Yes ● No
3.5. Overall structure of the study team	Overall_Structure_of_the_Study_Team.pdf

PROTECTION OF HUMAN SUBJECTS

Risks to Human Subjects

a. Human Subjects Involvement, Characteristics and Design

The primary objective of this observational, longitudinal, multicenter renewal study is to extend the initial 2-year follow-up period for an additional 4 years to evaluate the longer-term physiological and psychological impact of early medical treatment in two cohorts of dysphoric youth: 1) Those treated with puberty suppression initiated in early puberty who go on to receive gender-affirming hormones (estrogen or testosterone), and 2) those treated initially in later puberty with gender-affirming hormones. The sample of children, adolescents, and young adults will be recruited from patients presenting for care at any of the four sites along with one parent/primary caregiver for the children and youth accessing a GnRHa.

We will enroll 138 early pubertal youth participants in the GnRHa cohort (an additional 43 participants) who will meet the following inclusion and exclusion criteria:

Inclusion Criteria

- Presence of gender dysphoria as determined by a clinician;
- Tanner stage 2, 3, or 4 of sexual development
- Appropriate to undergo puberty suppression with GnRH agonists;
- Ages 8 through 16 years inclusive;
- Ability to read and understand English;
- Receiving or planning to receive services at a study site clinic; and
- Willing and able to provide informed assent.

Additional Inclusion Criteria for New Enrollments in the Renewal Period

- Youth of color with an emphasis on non-Hispanic/Latinx youth

Exclusion Criteria

- Prior utilization of GnRH agonists;
- Precocious puberty (natal males younger than 9 years or natal females younger than 8 years);
- Pre-existing osteoporosis;
- Presence of serious psychiatric symptoms (e.g., active hallucinations, thought disorder) that would impair the individual's ability to provide true informed consent or participate in the baseline survey;
- Visibly distraught (e.g., suicidal, homicidal, exhibiting violent behavior) at the time of consent or the baseline survey;
- or Intoxicated or under the influence of alcohol or other substances to such an extent that in the opinion of the study staff, the ability to give true informed consent or to understand and answer the questions is impaired.

We will enroll as study participants 138 parents or caregivers (an additional 43 participants) of the early pubertal participants who will meet the following inclusion and exclusion criteria:

Inclusion Criteria

- Parent or caregiver of a child who meets the GnRHa Youth Cohort inclusion/exclusion criteria;
- Ages 18 and above;
- Ability to read and understand English; and
- Willing and able to provide signed informed consent.

Exclusion Criteria

- Presence of serious psychiatric symptoms (e.g., active hallucinations, thought disorder) that would impair the individual's ability to provide true informed consent or participate in the baseline survey;
- Visibly distraught (e.g., suicidal, homicidal, exhibiting violent behavior) at the time of consent or the baseline survey; or
- Intoxicated or under the influence of alcohol or other substances to such an extent that in the opinion of the study staff, the ability to give true informed consent or to understand and answer the questions is impaired.

We will enroll 472 late pubertal cohort participants in the GAH cohort (an additional 156 participants) who will meet the following inclusion and exclusion criteria:

Inclusion Criteria

- The presence for gender dysphoria as determined by a clinician;
- Appropriate for initiating phenotypic gender change with gender-affirming hormones;
- Ages 8 through 20 years inclusive;
- Ability to read and understand English;
- Receiving or planning to receive services at a study clinic; and
- Willing and able to provide signed informed consent or assent.

Additional Inclusion Criteria for New Enrollments in the Renewal Period

- Transmasculine participants – identify as a youth of color with an emphasis on non-Hispanic/Latinx youth
- Transfeminine participants – no race or ethnicity requirements

Exclusion Criteria

- Prior utilization of gender-affirming hormones;
- Previously or currently enrolled in the GnRHa cohort;
- Presence of serious psychiatric symptoms (e.g., active hallucinations, thought disorder) that would impair the individual's ability to provide true informed consent or participate in the baseline survey;
- Visibly distraught (e.g., suicidal, homicidal, exhibiting violent behavior) at the time of consent or the baseline survey; or
- Intoxicated or under the influence of alcohol or other substances to such an extent that in the opinion of the study staff, the ability to give true informed consent or to understand and answer the questions is impaired.

The research is being conducted at Children's Hospital Los Angeles (CHLA), Ann & Robert H. Lurie Children's Hospital of Chicago, Boston Children's Hospital, and University of California San Francisco Benioff Children's Hospitals San Francisco and Oakland. These four academic hospitals are situated strategically across the country and have dedicated transgender youth clinics. They are considered the national leaders in the care of transgender children, adolescents, and young adults. All four sites employ a similar model for care that includes medical and mental health professionals and represent some of the most experienced providers in the country doing this work.

The four collaborating sites will recruit and enroll child and parent/caregiver participants, conduct study activities, and provide data to the data core at CHLA. The principal investigators will oversee all aspects of the study process and will monitor implementation of study activities. They will maintain ongoing communication through conference calls in order to be responsive to any issues that may arise and will modify the protocol if needed.

b. Study Procedures, Materials, and Potential Risks

Data will be collected directly from participants and their parents or caregiver via a computerized survey or by interview to minimize concerns about confidentiality, encourage honest responses to sensitive issues, and allow completion of the survey at the participants' own pace. Demographic data collected will include items such as age, ethnicity, educational level and birth city/country, as well as data specific to the transgender population, such as age parents realized their child's transgender identity, age of youth participant first living in the desired gender role, and contexts in which the child is living in their desired gender role, if any. The computerized survey will also collect information from the parents and youth regarding data such as physical activity and dietary calcium intake and psychosocial assessments such as the degree of social gender transition, parental support for gender diversity, parenting stress, quality of life, resiliency, anxiety, self-harm, social connectedness, etc. Interviews will be used for obtaining mental health diagnosis information through the use of the MINI and MINI Kid and for obtaining information regarding diagnoses and medications that may not be detailed in the electronic health record. In addition, case report forms (CRFs) will be used for items such as tracking the Modified Ferriman-Gallwey score, Tanner staging, medication information, diagnoses, etc.

Only site-specific research staff and local institution IRB personnel conducting quality assurance activities will have access to individually identifiable private information about the participants. The CHLA coordinating

center staff may have access to individually identifiable private information about the participants when providing on-site technical assistance for study implementation and quality assurance activities.

No personal identifying information (e.g., name, tracking information, etc.) will be placed on any of the CRFs or collected within the computerized survey. All study-specific records will be identified by a coded number only, to maintain confidentiality. Only the research staff will have access to the database linking the participant's unique ID code and name in a secure network, password-protected file or in a secure location under double-lock when not in use and with restricted access during work hours and/or when unattended.

For the computerized baseline and follow-up surveys each participant will be assigned a code and their surveys will be linked via this code. A master list of the codes assigned to participants will be kept in a secure, password protected file at each site or in a secured location under double-lock when not in use and with restricted access during work hours and/or when unattended. The coordinating center staff will not have access to the sites' key to the codes.

Computerized data will be collected via QDS software and web-based services (e.g., REDCap, ASEBA) at the collaborating sites. Upon transfer of the encrypted data to CHLA, the data will be stored on CHLA's secured network (with firewall protection), which cannot be accessed by anyone outside of CHLA. All case report forms (CRFs) will be entered into password protected databases at the site and be transmitted securely with an ID to CHLA. A password will be used to access survey data and will be made accessible only to the MPIs and study staff. These data will be archived in a password-protected database on the local network on a daily basis. The data coordination staff, housed at CHLA, will support all PIs with the generation of a cross-site protocol for data collection and templates. Study-wide data management procedures, including integration and verification of multi-site data, will take place at CHLA.

The potential risks of participation in this study are minimal and are not greater than those that would be accepted by other persons not participating in the study. Participants are expected to be exposed only to minimal risk based on questions asked and the confidential system of data collection. While all safeguards will be in place to protect their identity, there is also potential risk that identifying information collected could be accessed by someone other than the research team. A number of precautions and safeguards have been developed in order to protect the confidentiality of individuals who participate in the study. No personal identifying information will be used on the CRFs or surveys. Consent forms will be filed and stored separate from the raw data in a secured location under double-lock when not in use and with restricted access during work hours and/or when unattended.

As this is an observational study, there are no alternative treatments or procedures.

Adequacy of Protection against Risks
a. Informed Consent and Assent
Study team members will recruit participants for the study by speaking with patients and their parents/legally authorized representatives face-to-face or by telephone. Information regarding the study will be provided and interest in participation will be assessed.

If potential participants are interested in enrolling in the study, staff members from Children's Hospital Los Angeles, Lurie Children's Hospital of Chicago, Boston Children's Hospital, and University of California at San Francisco who have received IRB certification will consent participants. All research participants will review and sign an informed consent/permission/assent form. The informed consent/permission/assent form covers information about the overall purpose of the study, what the study entails, potential risks, potential benefits to participating individuals and society, the confidentiality of data, and contact information for the site Principal Investigator and the IRB. A waiver of some or all of the elements of informed consent will not be sought.

For child participants aged 8 to 17 years old, the participant will sign an assent form and the parent/legally authorized representative will sign a parental permission form. Young adult participants 18 and older will sign a consent form. If a youth participant turns 18 while on the study, they will sign a consent addendum. All

parent/caregiver participants will provide written consent for their own participation in the study. Informed consent, assent, permission will be obtained before any research activities are conducted.

Once informed consent/permission/assent has been obtained, the research staff will have the form reviewed by a fellow research team member, who will confirm that it is fully completed before it is filed in a secure location under double-lock when not in use and with restricted access during work hours and/or when unattended.

Project staff will inform participants that they have the right to skip any questions during the computerized survey or face-to-face interview that make them feel uncomfortable. Participants will be informed that participation is completely voluntary and that they are free to stop their involvement in the study at any time without any negative consequences. They will be informed of their rights to privacy and confidentiality and will be told that their answers to the survey will be kept confidential and not shared with others outside of the research staff. They will be informed that no information about them or provided by them during the research will be disclosed to others without their written permission, except if necessary to protect their rights or welfare (for example, if they are injured and need emergency care) or if required by law (i.e., child or elder abuse, harm to self or others, or reports of certain infectious diseases).

b. Protection Against Risk

A number of precautions and safeguards have been developed in order to protect the confidentiality of individuals who participate in the study.

No personal identifying information (e.g., names or medical record numbers) of the participants will appear in any computer or paper files associated with this research project in any location. Participants will be assigned a unique identification number code. A key file that matches the ID number to the participant and organization will be maintained in a secure data repository within the project offices at each of the four sites. Data will be kept strictly confidential, except as required by law, and stored on a secure network, with password protection such that only authorized users will have access to the file server. All computers will be located in locked facilities, and consent forms will be filed and stored separate from the raw data in a secured location under double-lock when not in use and with restricted access during work hours and/or when unattended. Any temporary data files kept on removable storage devices, as well as printouts derived from data analysis, will be stored in a locked compartment when not in use.

Data will remain on the CHLA server or secure, HIPAA compliant web applications (REDCap and ASEBA) during data collection, verification, cleaning, and analysis. CHLA will continue to serve as the repository for intact versions of the study's comprehensive data sets. The most up-to-date data set (as well as site-specific data), including scored measures and created scales, will be made readily available to all PIs. To meet NIH obligations for data sharing, other investigators not affiliated with the study will also have access de-identified study data pursuant to a signed Data Use Agreement. The Contact PI (Dr. Olson-Kennedy of CHLA) will be responsible for maintaining Data Use Agreement records and secure transmission of data to outside investigators.

As this is an observational study, adverse events are not anticipated. However, there is some risk that answering questions about some of the topics may be uncomfortable or upsetting. In the event of discomfort or upset, there are medical and psychological professionals on the research team who can provide ongoing support as needed. All of the sites have licensed psychologists who provide clinical care to transgender and gender nonconforming children. Participants do not have to answer any question in the computerized or face-to-face interview that they do not want to answer. Furthermore, participants will be informed that at any point, they may stop if they do not wish to continue the questionnaire. In the event of an adverse event, it will be reported to the IRB as per protocol to ensure the safety of participants.

A possible adverse event that is anticipated includes the need to violate participant confidentiality due to risk of harm to self or child abuse. Study personnel will be trained regarding the limits of confidentiality. This training will include reviewing possible scenarios and knowledge of key questions to assess risk. We will train staff to err on the side of caution and to contact a supervisor as needed. Supervisors will be available by

phone 24 hours a day should staff need to consult regarding an emergency. In this situation, we will train staff members to leave participants in the company of study personnel and immediately contact supervisors before participants leave. Under the guidance of supervisors, staff will be trained either to ensure the safety of participants (i.e. call the police, or if appropriate, to escort participants to the emergency room).

Unanticipated adverse events will be brought to the attention of the MPIs and reported immediately to all relevant IRBs. The IRBs will determine whether it is appropriate to stop the study protocol temporarily or will provide suggestions/modifications to the study procedures. Any recommendations from local IRBs will be communicated to the IRB of Record at CHLA. Possible modifications include adding these possible adverse events to the consent form and re-consenting all study participants. The PI will be responsible for monitoring participant safety on a monthly basis at regularly scheduled research meetings. They will keep a written log of all adverse events and ensure that the IRB is contacted immediately. They will also keep a log of the outcome of IRB decisions regarding adverse events and apprise the research team of any changes that need to be made as a result of IRB decisions.

c. Vulnerable Subjects

This proposal involves children, a vulnerable subject population. The protocol will be certified through the IRB of Record, which is located at a children's hospital, and the research staff will be certified through the local IRB at each of the four sites to conduct research on human subjects, especially as related to children. This observational study is 46.404, research not involving greater than minimal risk, and 46.408 requirements for permission by parents or legally authorized representatives and for assent by children will be followed. All HHS Subpart D – Additional Protections for Children will be followed. Within the first two months of funding, the project staff will submit an application to the single IRB for protocol approval. Throughout the project, staff will continue to work with the IRB to protect the rights and confidentiality of all individuals who participate in data collection.

Potential Benefits of the Proposed Research to Research Participants and Others

While there are no potential direct benefits to the research participants, possible risks (i.e. discomfort answering questions, potential confidentiality breeches) are minimal and are outweighed by the anticipated societal benefits.

Importance of the Knowledge to be Gained

The proposed research provides the opportunity to obtain a better understanding of transgender youth, improve their care, and share information on a local and national level about how to provide care and hormone therapy for gender dysphoric children and adolescents. The information that is learned from this project will support innovative approaches to identifying, understanding, and providing optimal care for early pubertal and late pubertal, multi-ethnic transgender youth.

SINGLE IRB PLAN

During the current grant cycle, the study has been reviewed and approved by all of the four institutional IRBs. For the renewal grant period, the study will transition to a single Institutional Review Board (sIRB), and Children's Hospital Los Angeles (CHLA) will fulfill the role of IRB of Record for this study. CHLA has extensive experience as a single IRB (sIRB) and as an IRB of record for pediatric research consortia. It obtained accreditation from the Association for the Accreditation of Human Research Protection Programs, Inc., in 2012, recognizing its commitment to the protection of human research participants through the highest ethical standards. CHLA sIRB activities are supported through the CHLA Human Subjects Protection Program, which follows all regulatory requirements including those from the Department of Health and Human Services (DHHS) at 45 CFR 46, the Food and Drug Administration (FDA) at 21 CFR 50 and 56, the Health Insurance Portability and Accountability Act (HIPAA) at 45 CFR 160 and 64 and any and all other regulatory requirements affecting research with humans including local and state laws and ordinances. The CHLA IRB is well qualified to meet the Final NIH Policy on the Use of a Single Institution Review Board for Multi-Site Research.

All sites have agreed that the Children's Hospital Los Angeles IRB will serve as the sIRB of record and to rely on the proposed sIRB. If an additional site was to be added after award, it will rely on the sIRB.

Communication between sites and the sIRB will be conducted at two levels. The Director of the Human Subjects Protection Program at CHLA and the sites will communicate to establish a reliance agreement. All sites are members of the SMART IRB Reliance platform, which will facilitate communication during the reliance process. The CHLA Clinical Research Manager will communicate with each site's study coordinator/research associate regarding information that needs to be relayed to the local IRB or vice versa. Communication will support the local context for research, ensuring that the research teams follow local laws and regulations where they will be conducting research. In addition, information may be needed regarding local customs and literacy. Documentation will be provided to the relying sites of all amendments to the protocol to ensure that all sites are implementing the protocol with fidelity and that relying IRBs have accurate information regarding research activities being conducted at their institution. Locally-relevant reportable events (such a serious adverse events or protocol deviations) will be submitted to both the local IRB and the CHLA sIRB. CHLA and the sites are experienced in this relationship as CHLA is the coordinating center for the current multi-site R01HD097122, A Longitudinal Study of Gender Nonconformity in Prepubescent Children.

All participating sites will, prior to initiating the study, sign an authorization/reliance agreement that will clarify the roles and responsibilities of the sIRB and participating sites.

CHLA will maintain records of the authorization/reliance agreements and of the communication plan.

DATA AND SAFETY MONITORING PLAN

This study is a minimal risk, observational study and does not meet the NIH definition of a clinical trial. Nevertheless, there still remains a risk of an adverse event. The most likely occurrence would be related to answering or responding to questions about sensitive topics that may be uncomfortable or upsetting. In the event of said situation, the study coordinators are trained to contact a licensed clinician to respond to the situation immediately. Any adverse events or unanticipated problems are reported to the coordinating center clinical research manager in order for them to be reported to the IRB of record. In addition, as a DSMB is not required of this study, any unanticipated problem or adverse events are discussed on the monthly MPI call to ensure awareness and oversight.

Data monitoring is conducted by the data manager and the data analyst at the Coordinating Center. Data that are submitted by the sites are reviewed for completeness and accuracy and to ensure incoming data are of high quality. The data analyst will run ongoing analyses as the cohorts move through the data points. If any data items are unclear or of concern, the data analyst sends a query to the study coordinator and tracks the query until the response is complete. The data manager provides updates regarding the data and analyses being conducted to the MPIs during the monthly MPI calls, and if a concern was found during an analysis of the observational, clinical data, it would be reported to the MPIs for safety discussions.

OVERALL STRUCTURE OF THE STUDY TEAM

The overall structure of the study team is as follows. Also, please reference the Multiple Principal Investigator Leadership Plan.

Four Study Sites

- Principal Investigator – responsible for all study activities occurring at the site and for coordinating with the other MPIs for overall study communication regarding: human subjects protection, NIH reporting, study implementation, data analysis, and publication. Please see the MPI Leadership Plan for more detail.
- Co-Investigator – collaborate with the Co-Is at the other sites to obtain meaningful mental health information form the youth, young adult, and parent/caregiver participants; conduct data analysis; and disseminate results.
- Study Coordinator – recruit and enroll study participants, conduct informed consent conferences, conduct study activities, accurately obtain and record data, participate in monthly study coordinator calls, report concerns to the site PI.
- Biostatician – collaborate with the PIs and Co-Is to conduct analyses of the medical and mental health data for publication.

Coordinating Center & Subaward Site

- Contact Principal Investigator – responsible for coordination of the MPIs and overseeing the coordinating center.
- Co-Investigators – responsible for making final decisions regarding instruments and data collection tools; oversee and direct quantitative data management and analysis and provide advanced statistical consultation to the project, including developing and executing analytical plans and advising the data team on appropriate longitudinal data analysis methods and procedures. Work closely with the biostaticians to ensure clear communication and coordination between sites on analytical and data-related issues. Provide guidance regarding strategies to diversify the study population.
- Data Analyst – conduct activities such as data cleaning, ensuring that data are complete, querying the study coordinators about problematic data, running analyses, providing data to the protocol team, and assisting with interpretation of analysis results.
- Research Manager – oversees the data management system, data cleaning and merging, and data analysis activities; coordinates the Data Coordination Committee.
- Clinical Research Manager – responsible for all activities related to the sIRB; amends the protocol as needed; communicates with all of the study coordinators regarding the study protocol through facilitating monthly calls; provides technical assistance; conducts quality assurance activities.
- Database Manager – maintains and updates the database that collects participant clinical data and creates reports to support study implementation and data analysis.

Section 4 - Protocol Synopsis (Study 1)

4.1. Brief Summary

4.2. Study Design

4.2.a. Narrative Study Description

4.2.b. Primary Purpose

4.2.c. Interventions

Type	Name	Description

4.2.d. Study Phase

Is this an NIH-defined Phase III Clinical Trial? ❍ Yes ❍ No

4.2.e. Intervention Model

4.2.f. Masking ❍ Yes ❍ No

❑ Participant ❑ Care Provider ❑ Investigator ❑ Outcomes Assessor

4.2.g. Allocation

4.3. Outcome Measures

Type	Name	Time Frame	Brief Description

4.4. Statistical Design and Power

4.5. Subject Participation Duration

4.6. Will the study use an FDA-regulated intervention? ❍ Yes ❍ No

4.6.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/ Investigational Device Exemption (IDE) status

4.7. Dissemination Plan

Delayed Onset Studies

Delayed Onset Study#	Study Title	Anticipated Clinical Trial?	Justification
The form does not have any delayed onset studies			

MULTIPLE PI/PD LEADERSHIP PLAN

Rationale

Johanna Olson-Kennedy, M.D., Robert Garofalo M.D., M.P.H., Stephen Rosenthal, M.D., and Dr. Yee-Ming Chan, M.D., Ph.D. will continue to serve as the Multiple Principal Investigator team on this study. Each PI is responsible and accountable to the National Institutes of Health (NIH) for the proper conduct of the research. The rationale for the decision to act as a multiple PI team was based on the fact that these four investigators bring unique experiences and knowledge that have complemented one another in the implementation of this project. We believe that continuing the MPI structure is a strength because it ensures a PI at each site, which is highly beneficial and particularly important because each site operates independently from the others, with each embedded differently within very large academic-hospital systems. PIs at each site, with institutional and community knowledge particular to their site, have effectively (and efficiently) managed the intricacies of study protocol implementation within each of these unique sites and regions. In addition, the MPIs have carefully developed trusted partnerships with local community-based organizations (CBOs) that serve transgender youth, and their MPI status has largely benefitted engagement of these CBOs in referral/promotion efforts. Our four sites are proposing to continue our collaboration for the proposed study due to our successful collaboration to date, as well as the possibility of enrolling a larger sample size than could be collected by a single site for the proposed research endeavor seeking to understand an uncommon experience in an understudied population.

Dr. Johanna Olson-Kennedy, M.D. (Pediatrics and Adolescent and Young Adult Medicine), is the Medical Director of the Center for Transyouth Health and Development at Children's Hospital Los Angeles (University of Southern California). She and her team based at CHLA, including Co-Is (b)(6) and Marco Hidalgo, Ph.D., lead the largest transgender youth program in the United States. Dr. Hidalgo is the Contact PI of a recently-funded NICHD study (R01HD097122). This study is the first of its kind to establish a US national cohort of prepubertal TGNC children. The primary objective of this longitudinal, multisite, observational study is to provide empirical evidence to inform clinical care by characterizing developmental patterns of gender identity and gender-role behavior, mental health outcomes at baseline and over time, and the impact of social gender transition (when present) in a cohort of prepubertal TGNC children. (b)(6) has extensive experience in multi-site and multi-partner studies as PI or Co-investigator including the 13 site Community Intervention Trial for Youth (CITY Project CDC PI), HIV couples testing in two African Capitols (NIH Co-I), Project AIM in 3 School Districts (CDC overall PI), Project Legacy for Homeless Youth and those at-risk for homelessness (Los Angeles, San Diego (HHS PI), and provision of start-up support for the NICHD funded ATN Connect to Protect Project ((b)(4). The combined expertise of this team provides both comprehensive clinical knowledge and extensive research expertise in the area of transgender adolescents.

Dr. Yee-Ming Chan, M.D. (Pediatric Endocrinology) is Director of the Boston Children's Hospital Pediatric Reproductive Hormone (PReproHormone) Program, which provides clinical care to patients with disorders of puberty, patients with differences of sex development, and transgender youth and conducts clinical and translational research in these areas. The BCH PReproHormone Program houses the Gender Management Service (GeMS), which opened in 2007 and was the first pediatric academic program in the western hemisphere to treat pubescent teens. Three-quarters of GeMS patients come from a 150-mile radius of Boston; the rest come from throughout the US and the world. Co-I (b)(6) is a clinical psychologist with significant expertise in the scholarship and clinical realms; before joining the GeMS team, she was the Director of Child Protection Clinical Services at Boston Children's Hospital and subsequently Director of Training and Research for that program. (b)(6) has decades of experience evaluating children and families and is a recognized expert in the area of trauma and interpersonal violence with an interest in helping vulnerable children and adolescents.

Dr. Robert Garofalo, M.D., M.P.H. (Pediatrics and Adolescent and Young Adult Medicine), is Co-Director of the Gender and Sex Development Program, Division Head of Adolescent Medicine at Ann & Robert H. Lurie Children's Hospital of Chicago, and Associate Professor of Pediatrics at Northwestern University's Feinberg School of Medicine. He will serve as the PI for the Chicago site. He and his team, including Co-I Diane Chen, Ph.D., bring a wealth of expertise caring for and conducting research in adolescent populations, with particular

focus on transgender and other sexual minority youth. The Chicago team has been providing clinical services to gender non-conforming youth for more than a decade. Their multidisciplinary program for gender non-conforming youth and transgender youth undergoing medical suppression of puberty or initiating cross-sex hormone therapy brings together experts in pediatrics/adolescent care, endocrinology, psychology and child development, psychiatry, surgical subspecialties, and medical ethics. The team has extensive experience conducting NIH- funded multisite clinical and behavioral research with marginalized populations of youth.

Dr. Stephen M. Rosenthal, M.D. (Pediatric Endocrinology), Professor of Pediatrics, has served as Program Director for Pediatric Endocrinology and Co-Director of the Disorders of Sex Development Clinic, and currently serves as co-founder and Medical Director of the Child and Adolescent Gender Center (CAGC) at the University of California San Francisco (UCSF) Benioff Children's Hospital. Dr. Rosenthal is an established clinical investigator with 40 years of experience in child and adolescent endocrinology. He will serve as PI for the UCSF site. His Co-Investigator, Diane Ehrensaft, Ph.D., Associate Professor of Pediatrics and Mental Health Director of the UCSF CAGC, is an internationally recognized child psychologist/gender specialist. The UCSF CAGC has been providing multi-disciplinary care for gender non-conforming/transgender youth and adolescents for the past 10 years. The UCSF CAGC is the only such multi-disciplinary gender program in Northern California and attracts patients not only from California, but from as far away as Florida and Egypt.

Primary Roles and Areas of Responsibility for Each PI

Administrative

- Upon successful funding, the award will be made to Children's Hospital Los Angeles (CHLA). All participants will be enrolled at one of the four study sites – The Center for Transyouth Health and Development (CHLA), The Child and Adolescent Gender Center (University of California San Francisco), The Gender, Sexuality and HIV Prevention Center (Ann & Robert H. Lurie Children's Hospital of Chicago), or the Gender Management Service (Boston Children's Hospital). Drs. Olson-Kennedy, Garofalo, Rosenthal, and Chan will work collaboratively to prepare reports and other requirements for submission to the NIH. Each will oversee the administrative responsibilities at each of their respective institutions.
- Although not expected, if any PI should move to a new institution or step down (such as the retirement of Dr. Spack during the current grant period), the department at the relevant institution or one of the MPIs will nominate a candidate. The candidate would need to be democratically approved by the other MPIs.

Technical

- Dr. Olson-Kennedy, given her experience overseeing the CHLA coordinating center for the current project, will work with Drs. Rosenthal, Chan, Garofalo and the Co-Is to revise the study protocol reflecting the aging of the cohort and the extended data collection period.
- All four PIs will finalize protocols for each cohort in the study. Each site will continue to adhere to study implementation protocols to ensure that all sites conduct the research in the same manner.
- Data will be collected systematically, with identical operating procedures including CRFs, survey programming, and data flow sheets to facilitate the creation of a data repository that is suitable for analysis and available for all four sites to explore. The data will be owned equally by each of the four participating sites.
- All PIs and Co-Is at each site, will direct recruitment, retention, and data collection, with support from the project team at each of their respective sites. Data will be directly entered into a HIPAA-compliant, web-based database or stored at each site and safely transferred via secure protocols to CHLA for cleaning and merging.
- Dr. Olson-Kennedy, (b)(6), and the CHLA Data Core will direct data management, including integration and verification at CHLA.
- PIs, Co-Is, and biostaticians will direct data analysis at their site or request data analysis from the data core.
- PIs and Co-Is will be involved in data interpretation and dissemination.

Governance/Structure

Communication plan

- These four sites are strategically positioned across the U.S., necessitating synchronization of the cross-site protocol and dissemination plans via on-site, face-to-face meetings and structured ongoing communication via regular teleconferencing. The investigators have budgeted for annual protocol meetings in which all of the teams meet at the CHLA site. This allows the protocol teams, including the study coordinators, to review study progress, discuss protocol changes that may be needed, determine data analysis priorities, conduct rich interpretation dialogs, and support manuscript writing and dissemination activities.
- The MPIs and Co-Is meet monthly by phone with the Data Core Manager and the Coordinating Center Clinical Research Manager to discuss scientific issues, recruitment, study implementation, completion of study manuscripts, dissemination activities, etc. Additional meetings will be scheduled with members of the study team as needed.
- The Study Coordinators meet monthly by phone or videoconference to discuss study implementation, challenges, and helpful hints to successfully implement the study activities.
- Decisions on scientific direction will be made during the monthly MPI phone meetings. Dr. Olson-Kennedy will make final decisions on the implementation of the study protocol, whereas (b)(6) will make final decisions regarding instruments, data collection tools, and the statistical analyses for manuscript preparation.

Procedures for Resolving Conflicts

We do not anticipate unresolvable disagreements among the MPIs as they have several years of working together under the current grant; however, if consensus is not reached for protocol implementation issues, Dr. Garofalo, the senior investigator on the investigative team, will facilitate resolution among the MPIs, and if needed, refer the issues of conflict to third party arbitration consisting of Division Chiefs or Department Chairs of the four institutions. The four sites have determined that the following domains may require third party arbitration in the event of conflict that is not resolved through discussion amongst the sites:

- Authorship dispute – Issues of conflict will be heard by an objective observer from the WPATH executive board.
- Scientific dispute – Scientific conflict will be arbitrated by a pediatric endocrinologist faculty member at Children's Hospital of Pennsylvania.

Distribution of Resources to Four Sites

CHLA will be the primary institution for the receipt of the award and the three other sites will be supported through subcontracts from CHLA. Primary responsibility for administration at the CHLA site is (b)(6) (b)(6) (Division Head), along with financial administrator (b)(6). This team has extensive experience with financial administration of multiple site projects.

To ensure all sites maintain sufficient enrollment, enrollment progress will be assessed by all MPIs every 6 months. If a site is unable to meet its enrollment goals, MPIs may decide to reallocate funds to assist other sites in over-sampling to meet the overall study sample size. This decision will be informed the site's likelihood of meeting its target enrollment, informed by the site's sample size, degree of responsiveness regarding recruitment strategies, and its rate of enrollment to date. The MPIs will democratically reach an agreement on any reallocation of funds, relying on third party arbitrations (see Procedures for Resolving Conflicts above) should this process result in a conflict that requires resolution.

Dissemination

In order to share process and outcome data from this project with the broader scientific community, abstracts will be submitted for presentation to at least one scientific conference per year. Conferences where data may be presented include annual meetings of the Society for Adolescent Health and Medicine, The American Academy of Pediatrics, The World Professional Association of Transgender Health, Pediatric Academic Societies, The Endocrine Society, The American Public Health Association, The American Psychological

Association, The American Psychiatric Association, and others. Manuscripts are planned on the following topics:

- Description of the sample and preliminary results
- Description of the intervention
- Primary outcomes

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15. Guss CE, Williams DN, Reisner SL, Austin SB, Katz-Wise SL. Disordered Weight Management Behaviors, Nonprescription Steroid Use, and Weight Perception in Transgender Youth. *J Adolesc Health.* 2017;60(1):17-22.
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Consortium/Contractual Arrangements

PA-18-729 Research on the Health of Transgender and Gender Nonconforming Populations (R01)
Due Date: March 5, 2020
Earliest Start Date if funded: September 1, 2020
Duration of Project Period: Five years
Project Title: The Impact of Early Medical Treatment in Transgender Youth
Primary Applicant: Children's Hospital Los Angeles
Contact Principal Investigator: Johanna Olson-Kennedy, M.D.

The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the agency's consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.

Programmatic & Administrative Arrangements:

Children's Hospital Los Angeles
Children's Hospital Los Angeles (CHLA) will be the primary institution for the receipt of the award and the four partner sites will be supported through subcontracts from Children's Hospital Los Angeles. The Contact Principal Investigator, Johanna Olson-Kennedy, M.D., will take primary responsibility for all study related activities. CHLA will act as the data center or core for the project, and the CHLA research team will have the primary responsibility for creating data protocols in partnership with the other sites and will be the IRB of Record. Programming of changes to the computer survey, modifications of CRFs, and data management, cleaning, and analysis will occur at CHLA.

Boston Children's Hospital
The Principal Investigator, Yee-Ming Chan, M.D., Ph.D., will take primary responsibility for the implementation of the scientific aims of this project at Boston Children's Hospital. Dr. Chan will take primary responsibility for the implementation of the scientific aims of this project at Boston Children's Hospital and will collaborate in the analysis, interpretation, and dissemination of findings. The key personnel at Boston Children's Hospital will collaborate with the partner sites to submit abstracts for presentation at scientific conferences and in co-authorship of publications to disseminate important research findings as a result of this study.

Ann & Robert H. Lurie's Children's Hospital of Chicago
The Principal Investigator, Robert Garofalo, M.D., will take primary responsibility for the implementation of the scientific aims of this project at Lurie Children's Hospital. Dr. Garofalo will take primary responsibility for the implementation of the scientific aims of this project at Lurie Children's Hospital of Chicago and will collaborate in the analysis, interpretation, and dissemination of findings. The key personnel at Lurie Children's Hospital will collaborate with the partner sites to submit abstracts for presentation at scientific conferences and in co-authorship of publications to disseminate important research findings as a result of this study.

University of California San Francisco
The Principal Investigator, Stephen Rosenthal, M.D., will take primary responsibility for the implementation of the scientific aims of this project at the University of California, San Francisco (UCSF). Dr. Rosenthal will take primary responsibility for the implementation of the scientific aims of this project at UCSF and will collaborate in the analysis, interpretation, and dissemination of findings. The key personnel at UCSF will collaborate with the partner sites to submit abstracts for presentation at scientific conferences and in co-authorship of publications to disseminate important research findings as a result of this study.

Callen-Lorde Community Health Center

The Co-Investigator, Asa Radix, M.D., will provide scientific insight and perspective as an experienced clinician researcher as well as a (b)(6). This expansion of our team positions us to have enhanced community engagement, ongoing evaluation of measures, and recommendations for enriched analytic approaches. He will collaborate with the MPIs and Co-Is in the analysis, interpretation, and dissemination of findings. He will also collaborate with the partner sites to submit abstracts for presentation at scientific conferences and in co-authorship of publications to disseminate important research findings as a result of this study.

Fiscal Arrangements

Children's Hospital Los Angeles: includes full project costs (CHLA site costs and consortium and subaward site costs and F&A)

	Direct	Indirect	TOTAL Per Year
Year 1	$ (b)(4)	$ (b)(4)	$ (b)(4)
Year 2	$	$	$
Year 3	$	$	$
Year 4	$	$	$
Year 5	$	$	$
TOTAL	$	$	$

Boston Children's Hospital

	Direct	Indirect	TOTAL Per Year
Year 1	$ (b)(4)	$ (b)(4)	$ (b)(4)
Year 2	$	$	$
Year 3	$	$	$
Year 4	$	$	$
Year 5	$	$	$
TOTAL	$	$	$

Ann & Robert H. Lurie Children's Hospital of Chicago

	Direct	Indirect	TOTAL Per Year
Year 1	$ (b)(4)	$ (b)(4)	$ (b)(4)
Year 2	$	$	$
Year 3	$	$	$
Year 4	$	$	$
Year 5	$	$	$
TOTAL	$	$	$

University of California San Francisco

	Direct	Indirect	TOTAL Per Year
Year 1	$ (b)(5)	$ (b)(4)	$ (b)(4)
Year 2	$	$	$
Year 3	$	$	$
Year 4	$	$	$
Year 5	$	$	$
TOTAL	$	$	$

Callen-Lorde Community Health Center

	Direct	Indirect	TOTAL Per Year
Year 1	$ (b)(4)	$ (b)(4)	$ (b)(4)
Year 2	$	$	$
Year 3	$	$	$
Year 4	$	$	$
Year 5	$	$	$
TOTAL	$	$	$

Letters of Support

Authors of the attached letters of support were approached for use of their letter for this resubmission, which they approved.

Multiple PI and Co-I Letters

1. University of California San Francisco/Benioff Children's Hospital San Francisco and Oakland (Rosenthal, MPI)
2. Boston Children's Hospital/Harvard University (Chan, MPI)
3. Boston Children's Hospital/Harvard University ((b)(6))
4. Ann & Robert H. Lurie Children's Hospital of Chicago/Northwestern University (Garofalo, MPI, and Chen, Co-I)
5. Callen-Lorde, New York, NY (Radix, Co-I)*

Clinical and Translational Science Institute (CTSI) Leadership

6. Southern California Clinical and Translational Science Institute, University of Southern California ((b)(6))
7. University of California San Francisco, Clinical and Translational Science Institute ((b)(6))
8. Northwestern University Clinical and Translational Sciences Institute ((b)(6))

Academic Medical Centers with Multidisciplinary Services for Transgender Youth

9. University of Minnesota's Program in Human Sexuality, Minneapolis, MN ((b)(6))*
10. Children's National Medical Center, Gender Development Program, Washington, DC ((b)(6))
11. MetroHealth Medical Center/Case Western Reserve University, Cleveland, OH ((b)(6))
12. Gender & Sexuality Development Clinic, Children's Hospital of Philadelphia, Philadelphia, PA ((b)(6)) ((b)(6))
13. Rady Children's Hospital/University of California San Diego, San Diego, CA ((b)(6))
14. Hasbro Children's Hospital/Brown University (Forcier), Providence, Rhode Island ((b)(6))
15. University of California San Francisco's Dimensions Clinic, San Francisco, CA ((b)(6))

Community Health Centers with Health Services for Transgender Youth

16. El Rio Health Center, Tuscon, AZ ((b)(6))

Organizations Focused on Policy and Health Advocacy Impacting Transgender Youth

17. Human Rights Campaign, Youth and Families Program, Washington, DC ((b)(6))
18. The Trevor Project, West Hollywood, CA ((b)(6))
19. Gender Spectrum, San Leandro, CA ((b)(6))

Public Health Researchers

20. Boston Children's Hospital/Harvard T.H. Chan School of Public Health, Boston, MA ((b)(6))*
21. Boston Children's Hospital/Harvard Medical School, Boston, MA ((b)(6))

Community-based Groups

22. Mind the Gap Trans Youth Mental Health Consortium, Oakland, CA ((b)(6))
23. Parents of Transgender Individuals Chicago/PFLAG, Chicago, IL ((b)(6))

***Co-Chair of Revision Committee, World Professional Association for Transgender Health (WPATH) Standards of Care**

University of California
San Francisco

Department of Pediatrics
Division of Endocrinology

Maya B. Lodish, M.D., MHSc
Gina Capodanno, M.D.
Brian J. Feldman, M.D., Ph.D.
Stephen E. Gitelman, M.D.
Roger K. Long, M.D.
Robert H. Lustig, M.D.
Walter L. Miller, M.D.
Stephen M. Rosenthal, M.D.
Srinath Sanda, M.D.
Shylaja Srinivasan, M.D.
Jenise C. Wong, M.D., Ph.D.

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June 19, 2019

Johanna Olson-Kennedy, MD, MPH
Associate Professor of Clinical Pediatrics
Division of Adolescent Medicine
Medical Director, Center for Transyouth Health and Development
Children's Hospital Los Angeles
5000 W. Sunset Blvd., 4th Floor
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Dear Dr. Olson:

We are delighted to continue our collaboration with you and the other members of our Multiple Principal Investigator-led teams for the continuation of the project entitled "The Impact of Early Medical Treatment in Transgender Youth" (1R01HD082554) in response to PA-18-729: Research on the Health of Transgender and Gender Nonconforming Populations. Our site, the UCSF Child and Adolescent Gender Center (CAGC) has thus far enrolled more than 100 subjects into our combined 4-site database, and, in particular we have exceeded our enrollment targets for the early pubertal cohort treated with pubertal blockers. While we will complete 24-month follow-up on our study subjects at the end of the current grant period (June, 2020), it is clear that longer-term outcomes studies beyond 24 months are essential to meaningfully assess the physiologic and mental health impact of current clinical practice guidelines for transgender youth.

For this renewal, the following key personnel will work with you and the other investigators in the long-term follow-up of the impact of early medical treatment in transgender youth:

Stephen M. Rosenthal, MD, Site Principal Investigator, will continue to take primary responsibility for the implementation of the scientific aims of this project at UCSF Benioff Children's Hospital, as well as collaborate to disseminate findings.

Diane Ehrensaft, PhD, Site Co-Investigator, will share responsibility for the scientific and fiscal integrity of the project. As a Clinical Psychologist, Dr. Ehrensaft will assist in the implementation of the scientific aims, data collection, data analysis, preparation of manuscripts, and dissemination of findings at scientific meetings. She will also assist Dr. Rosenthal with IRB submissions, and will assist in developing and overseeing recruitment strategies.

Our collaborative proposal has the potential to provide much needed outcomes studies to inform and optimize care for a population of youth that has been often marginalized and poorly understood. We continue to be deeply committed to this work, and seeing it reach its fruition.

Sincerely,

(b)(6)

Stephen M. Rosenthal, MD
Professor of Pediatrics
Division of Pediatric Endocrinology
Medical Director, Child and Adolescent Gender Center

Director, Endocrine Society
Past President, Pediatric Endocrine Society

Boston Children's Hospital
Department of Pediatrics
Division of Endocrinology

Harvard Medical School
Department of Pediatrics

Yee-Ming Chan, M.D., Ph.D.
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300 Longwood Avenue
Boston, Massachusetts 02115
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June 10, 2019

Dear Jo, Rob, and Steve,

My colleagues at Boston Children's Hospital and I are delighted to continue our collaboration on the Trans Youth Care (TYC) Study. We have much to be proud of: developing a solid research infrastructure to study gender-diverse youth at our four sites, exceeding our recruitment targets, thoughtfully revising our data collection methods to be responsive to the needs of our diverse study cohort, and most of all creating a network of medical providers, mental health providers, and research staff for vibrant scientific exchange. We have been avidly analyzing the baseline data from our study, we are excited to start analyzing the follow-up data emerging from our study, and we are most excited about the prospect of following our cohorts for another five years as they reach key milestones for their physical and psychosocial development.

I anticipate many more years of productive and stimulating collaboration as we continue our vital work to enhance the health and well-being of our gender-diverse patients.

Sincerely,

(b)(6)

Yee-Ming Chan, M.D., Ph.D.

Boston Children's Hospital

HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

June 9, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I write this letter in support of our research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow us and our collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents (TGNC) beyond a 24-month period. The ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood. We also propose to expand the current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of this study.

I am a (b)(6) at Boston Children's Hospital, which serves TGNC children, adolescents and young adults. I am also on the (b)(6) child and adolescent committee and am a (b)(6). As a (b)(6) I am very aware of how necessary it is to move the field forward with research that will directly affect the care practices and well-being of transgender adolescents and youth, currently a high risk population. I anticipate that this unique and much needed research will disseminate information of high scientific and clinical value to demonstrate the diverse impacts of medical treatments on TGNC youth and young adults, and how to facilitate resilience and better outcomes in this population. Should you be awarded NIH funding, I am certain that our research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria. Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6).

Sincerely,

(b)(6)

(b)(6)

Assistant Professor
Harvard Medical School

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

Ann & Robert H. Lurie
Children's Hospital of Chicago™

July 3, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Robert Garofalo MD, MPH
Division Head
Adolescent Medicine

Faculty
Diane Chen, PhD
Claire Coyne, PhD
Cherie Priya Dhar, MD
Amy K. Johnson, PhD, MSW
Lisa Kuhns, PhD, MPH
Maria Rahmander, MD
Lisa Simons, MD
Raina Voss, MD

Clinical Staff
Sarah Cohen, LCSW
Lindsey Eilers, LCSW
Katharine Greeley, LSW
Jennifer Jensen, APN
Janay Joyce-Ward, LCSW
Joseph Ronda, LCSW
D. Javier Thompson, LCSW

Dear Dr. Olson-Kennedy,

We are delighted to continue our collaboration with you and the other members of our Multiple Principal Investigator-led teams for the continuation of the project entitled "The Impact of Early Medical Treatment in Transgender Youth" (1R01HD082554) in response to PA-18-729: Research on the Health of Transgender and Gender Nonconforming Populations. Our site, the Ann & Robert H. Lurie Children's Hospital of Chicago Gender & Sex Development Program (GSDP) has thus far enrolled more than 100 subjects into our combined 4-site database. While we will complete 24-month follow-up on our study subjects at the end of the current grant period (June, 2020), it is clear that longer-term outcomes studies beyond 24 months are essential to meaningfully assess the physiologic and mental health impact of current clinical practice guidelines for transgender youth.

For this renewal, the following key personnel will work with you and the other investigators in the long-term follow-up of the impact of early medical treatment in transgender youth:

Rob Garofalo, MD, MPH, Site Principal Investigator, will continue to take primary responsibility for the implementation of the scientific aims of this project at Lurie Children's, as well as collaborate to disseminate findings.

Diane Chen, PhD, Site Co-Investigator, will share responsibility for the scientific and fiscal integrity of the project. As a Pediatric Psychologist, Dr. Chen will assist in the implementation of the scientific aims, data collection, data analysis, preparation of manuscripts, and dissemination of findings at scientific meetings. She will also assist Dr. Garofalo with IRB submissions, and will assist in developing and overseeing recruitment strategies.

Our collaborative proposal has the potential to provide much needed outcomes studies to inform and optimize care for a population of youth that has been often marginalized and poorly understood. We continue to be deeply committed to this work, and seeing it reach its fruition.

Ann & Robert H. Lurie
Children's Hospital of Chicago™

Sincerely,

(b)(6)

Rob Garofalo, MD, MPH
Division Chief, Potocsnak Family Division of Adolescent and Young Adult Medicine
Director, Adolescent HIV Services
Director, Center for Gender Sexuality and HIV Prevention
Co-Director, Gender & Sex Development Program
Ann & Robert H. Lurie Children's Hospital of Chicago
Professor of Pediatrics and Preventive Medicine
Northwestern University Feinberg School of Medicine

(b)(6)

Diane Chen, PhD
Pediatric Psychologist
Behavioral Health Director, Potocsnak Family Division of Adolescent and Young Adult Medicine
Ann & Robert H. Lurie Children's Hospital of Chicago
Assistant Professor of Psychiatry and Behavioral Sciences, and Pediatrics
Northwestern University Feinberg School of Medicine

CALLEN-LORDE

6/12/2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood.

You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study.

My background is in internal medicine and infectious diseases, with specific training in epidemiology and public health. I am very familiar with the medical and bio-psychosocial issues affecting transgender communities. I am currently the co-chair the World Professional Association of Transgender Health Stands of Care Revision Committee as well as serving on the WPATH board. I am very familiar with the gaps in research, especially for transgender children and adolescents. The results of this study will result in much needed information to inform clinical standards. It has high scientific and clinical value. Although similar studies are underway in Europe, this is the first to be conducted in racially and ethnically diverse communities and is therefore likely to have much greater impact for the global community.

Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6).

Sincerely,

(b)(6)

Asa Radix, MD, MPH, FACP
Senior Director of Research and Education

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

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Thea Spyer Center
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Bronx, NY 10451
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Southern California
Clinical and Translational Science Institute
Translating Science into Solutions for Better Health

Thomas Buchanan, M.D.
Director, SC CTSI

Michele Kipke, Ph.D.
Co-Director, SC CTSI; Director, Community Engagement

April Armstrong, M.D., M.P.H.
Director, Clinical Research Support

John Wood, M.D., Ph.D.
Co-Director, Clinical Research Support

Katrina Kubicek, M.A.
Director, Evaluation and Improvement

Sarah Hamm-Alvarez, Ph.D.
Director, Research Development

Quinnie Le, MBA
Director, Operations and Finance

Wendy Mack, Ph.D.
Director, Biostatistics

Daniella Meeker, Ph.D.
Director, Clinical Research Informatics

Juan Espinoza, M.D.
Co-Director, Clinical Research Informatics

Allison Orechwa, Ph.D.
Director, Programmatic Development

Eunjoo Pacifici, Ph.D.
Director, Regulatory Knowledge and Support

Katja Reuter, Ph.D.
Director, Digital Innovation and Communication

Cecilia Patino-Sutton, MD, MeD, PhD
Director, Workforce Development/Co-Director, KL2 Program

Steven Siegel, MD, PhD
Director, KL2 Program

June 14, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

As (b)(6) of the Southern California Clinical and Translational Science Institute (SC CTSI) and (b)(6) in the Department of Pediatrics at Children's Hospital Los Angeles (CHLA), it is with enormous enthusiasm that I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood. You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study. To be sure, your proposed research is highly significant, innovative, and timely, and you have my full and enthusiastic support.

The University of Southern California (USC) and Children's Hospital Los Angeles (CHLA) have a large Clinical and Translational Science Award from the National Institutes of Health, called the Southern California Clinical and Translational Science Institute (SC CTSI). The SC CTSI has built an organization devoted entirely to improving the success of translational science with diverse populations, using an array of tools and programs that support researchers and their work. The SC CTSI has emerged as a valuable, multifaceted resource for pre-clinical, clinical and community-partnered translational research at USC, CHLA, and throughout Southern California. To date the SC CTSI has supported more than 900 investigators in their quest to create and apply new diagnostic and therapeutic advances, medical procedures, and behavioral interventions to improve clinical care and the health of individuals and the public.

Southern California Clinical and Translational Science Institute | University of Southern California
2250 Alcazar Street, Suite 200, Los Angeles, CA 90033-9074 | Tel: 323.442.4032 | Fax: 323.442.2082 | info@sc-ctsi.org | www.sc-ctsi.org

I assure you that you and your entire team here at CHLA will continue to have the full support of our SC CTSI, which may include the availability of additional resources such as statistical support, community engagement, and any assistance needed for implementing the highest quality clinical trials and clinical and translational research. We will work with your research team to disseminate necessary scientific findings that improve the delivery of health care and medical intervention to youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6).

Sincerely,

(b)(6)

University of Southern California
2250 Alcazar Street, Suite 200, Los Angeles CA 90033

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

University of California
San Francisco

UCSF

Department of Family & Community Medicine

(b)(6)

Mailing address:
(b)(6)
Tel: (b)(6)
Fax: (b)(6)
Email: (b)(6)

June 20, 2019

Stephen M. Rosenthal, MD
Medical Director, Child and Adolescent Gender Center
UCSF Benioff Children's Hospital
Mission Hall, Global Health & Clinical Sciences
550 – 16th Street, 4th Floor
San Francisco, CA 94143

Dear Dr. Rosenthal,

I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood. You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study.

As a (b)(6)
(b)(6)
Program, I recognize the tremendous value of the research you are conducting. Clinicians, patients, and families desperately need more scientific evidence on the long-term outcomes of gender-affirming health care to guide clinical practice and shared decision making by patients and families. Critical to the success of this research is engaging the transgender and broader LGBTQ community as partners in participatory research. Our Community Engagement Program looks forward to working with you and your multicenter research team to optimize stakeholder engagement in your proposed study. I assure you that, should you be awarded NIH funding, you and your entire team here at UCSF will have the full backing and support of our CTSI, as needed. We will work with your research team to disseminate

scientific findings that improve the delivery of health care and medical intervention to youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic.

Sincerely,

(b)(6)

Cc: Johanna Olson-Kennedy, MD, Robert Garofalo MD, Yee-Ming Chan MD, Asa Radix MD

Northwestern Medicine

NUCATS Clinical and Translational Sciences Institute

(b)(6)

(b)(6)
Tel: (b)(6)
Fax: (b)(6)
Email: (b)(6)

(date)

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

The Northwestern University Clinical and Translational Science Institute and the Stanley Manne Research Institute of Ann & Robert H. Lurie Children's Hospital of Chicago enthusiastically support your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." This funding will extend current research conducted at Lurie Children's Hospital] under the leadership of Dr. Robert Garofalo, allowing you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently funded by the NICHD) for an additional 5-year period, allowing your team to continue to examine both short and longer-term physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond your originally proposed 24-month period. As this is the only U.S cohort study of its kind, the ability to extend observation of this sample over time is imperative and will yield much-needed information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood. You research will also begin to elucidate critically important questions previously unexplored in the literature about the clinical care decisions and paradigms and as such is of considerable public health significance.

Your proposal to expand your current work and sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of adds significantly to its innovation and clinical/public health significance. Dr. Garofalo is uniquely positioned to be the PI of the proposed research here at Northwestern University Feinberg School of Medicine and Lurie Children's. He has 20 years of clinical experience working with transgender populations. He started and co-directs the Lurie Children's Gender & Sex Development Program and is considered to leader in the emerging academic discipline that is transgender health. He is the Editor-in-Chief of the journal Transgender Health. Dr. Garofalo also has extensive experience leading and conducting NIH funded research. He has been the PI on 13 NIH research grants and a Co-I on an additional 18 research projects funded by the NIH.

I assure you that Dr. Garofalo and his entire team here at Lurie Children's Hospital and Northwestern University will have the full backing and support of NUCATS and the Manne Institute, including but not limited to statistical support, community engagement, and any assistance required for the conduct of the highest quality clinical and translational research. With this NIH funding, we will work with your research team to disseminate necessary scientific findings that improve the delivery of health care and medical intervention to youth with gender dysphoria.

The Clinical and Translational Research Program of the Manne Children's Research Institute is a partner of the Northwestern University Clinical and Translational Sciences (NUCATS) Institute. NUCATS was launched in 2007 to create an integrated hub supporting and accelerating clinical and translational science (CTS) across Northwestern University (NU; including 6 schools), our 3 nationally-renowned clinical partners, our Chicago community and stakeholders, and across the broad consortium of CTSA-funded institutions. NU is a leading national research university affiliated with Ann & Robert H. Lurie Children's Hospital of Chicago, Northwestern Memorial HealthCare Corp., and the Shirley Ryan Ability Lab (formerly the Rehabilitation Institute of Chicago), each of which is ranked in the top 10 among its peer hospitals nationally. NUCATS was designed to leverage and advance the strengths of NU researchers and all of our partners to enhance CTS, and has been supported continuously since 2008 by ~$60 million in CTSA award funding from NIH and ~$75 million in financial and in-kind support from NU and its partners. This proposal is strongly aligned with the NUCATS and Lurie Children's mission and goals, including our strong commitments to populations underrepresented in biomedical research, and has our unqualified support.

Sincerely,

(b)(6)

(b)(6)

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Program in Human Sexuality
Department of Family Medicine and Community Health
Medical School

1300 South 2nd Street, Suite 180
Minneapolis, MN 55454
Office: (b)(6)
Fax: (b)(6)

June 17, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood.

You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study.

As (b)(6) at the University of Minnesota Medical School and have been working in the field of transgender health for 40 years, I applaud this effort recognizing the critical need for further research in this area. Also as (b)(6) (b)(6) I appreciate how valuable the findings of this research for advancing best practices of gender-affirming medical care among adolescence. This is an area that is woefully under researched.

Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact (b)(6) .

(b)(6)

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD

Johanna Olson-Kennedy, MD
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles CA 90027

June 20th, 2019

Dear Dr. Olson-Kennedy:

I am writing to express my strong support for your proposal to the National Institutes of Health entitled, "The Impact of Early Medical Treatment in Transgender Youth." I am aware that this proposal extends the assessment period of the original Trans Youth Care Study. The field of youth gender care has struggled due to a lack of research and an over-focus on cross-sectional (single time point) designs. The few existing "outcome" studies of transgender youth have included extremely small samples and two or three time-points. I am confident that your proposed study will be a major contribution to the field given its: rich sampling of youth over multiple time-points and extended assessment period into later adolescence and young adulthood. Because you have already curated one of the largest and most diverse samples of well-characterized transgender youth, your current proposal to continue to follow them over time is clearly feasible. Further, your plan to expand sampling across your four sites to better represent the growing ethnic/racial diversity of adolescents seeking gender-affirming care is critical given the limited generalizability of previous gender-care studies due to mono-cultural recruitments.

As you know, I am the (b)(6) Children's National Medical Center in Washington, DC. The Gender Development Program is one of the first founded pediatric gender programs nationally, and serves the large and diverse Washington, DC metropolitan area. Findings from the Trans Youth Care Study and its proposed extension are needed to inform and refine clinical care such as that provided in our program, as the number of transgender and gender diverse youth presenting for gender care continues to increase. We must better understand both the physiological and psychosocial outcomes of gender-affirming medical intervention over time, as current care standards are understudied. Your ability to extend observation of your sample into later adolescence and young adulthood will provide key information regarding longer-term safety and side effects of gender-affirming medical care. Should your proposal be funded, I am hopeful that your group will continue to share scientific findings with the broad community to optimize the safe and effective delivery of medical care to transgender youth. Please keep me informed of ways that I may support your important work.

Sincerely,

(b)(6)

Children's National Medical Center (Washington, DC)

Cc: Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD, Robert Garofalo MD

June 6, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

This letter is in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood.

I am pleased that you also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study.

I cannot emphasize enough how critical it is that we systematically measure the long-term outcomes in this study. As a psychologist involved with research and clinical services for gender-diverse youth since 2008, I am confident this study would provide much-needed data with high scientific and clinical value.

Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6) or (b)(6).

Sincerely,

(b)(6)

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

The MetroHealth System
2500 MetroHealth Drive, Cleveland, Ohio 44109-1998
216 - 778 - 7800

Children's Hospital of Philadelphia
3401 Civic Center Blvd. • Philadelphia, PA 19104 • (b)(6) • chop.edu

PolicyLab

June 18, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood.

You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study.

As the (b)(6) Development we now care for more than 1300 transgender and gender-diverse children and adolescents. We each have more than 10 years of experience providing clinical care and conducting research with transgender youth. In light of our experience in the field of pediatric transgender health we find your proposed study to be of high scientific and clinical value as we have a paucity of long term data to guide clinical management.

Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6).

Sincerely,

(b)(6)

The Children's Hospital of Philadelphia
3550 Market Street, (b)(6)
Philadelphia, PA, 19104

(b)(6)

The Children's Hospital of Philadelphia
3550 Market Street, (b)(6)
Philadelphia, PA, 19104

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

Rady Children's Specialists of San Diego
A Medical Foundation

UC San Diego
SCHOOL OF MEDICINE

Advancing the future of pediatric healthcare...together.

Pediatric Endocrinology and Diabetes

Attending:
Michael Gottschalk, MD, PhD
Division Chief
Laura Barba, RNC, MS, NNP
Patricia Clark, MD
Giana Consiglieri, PNP
Carla Demeterco, MD, PhD
Kenneth L. Jones, MD
Thomas G. Kelly, MD
Jane J. Kim, MD
Karen Klein, MD
Maja Marinkovic, MD
Ron Newfield, MD
Susan Phillips, MD

Fellows:
Abigail Fruzza, MD
Audrey Briscoe, MD
Hiba Al-Zubeidi, MD

Nurses:
Karen Haddad, RN, MS, CPNP
Andrea Huber, RN, CDE
Beth McFeely, RN, CDE
Kim McNamara, RN, BSN
Emalie Sherrell, RN
Emily Spangenberg, RN, BSN

Dietician:
Vanessa Aldaz, MPH, RD, CDE
Lisa Ameer, MSNH, RD, CDE

Social Worker:
Eleanor Lazarow, LCSW
Renee Price, LCSW

Mailing Address:
3020 Children's Way
Mail Code (b)(6)
San Diego, CA 92123

(b)(6) Fax

Regional Offices:
Encinitas
Escondido
Murrieta
Oceanside

www.RCSSD.org

June 20, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood.

You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study.

As a (b)(6) who has been providing care to transgender/gender nonconforming (TGNC) youth since 2012, I have a deep understanding of the importance of the research that you and your colleagues are conducting. In the field of transgender medicine, the long-term outcome data relevant to pediatric and adolescent population are very scarce. Therefore, it is of utmost importance for researchers such as Dr. Olson-Kennedy and colleagues to continue their work on prospective data gathering. This will enable them to provide valuable information on safety, efficacy, possible side effects and other relevant data from large and diverse cohorts.

Rady Children's Specialists of San Diego
A Medical Foundation

UC San Diego
SCHOOL OF MEDICINE

Advancing the future of pediatric healthcare...together.

Pediatric Endocrinology and Diabetes

Attending:
Michael Gottschalk, MD, PhD
Division Chief
Laura Barba, RNC, MS, NNP
Patricia Clark, MD
Giana Consiglieri, PNP
Carla Demeterco, MD, PhD
Kenneth L. Jones, MD
Thomas G. Kelly, MD
Jane J. Kim, MD
Karen Klein, MD
Maja Marinkovic, MD
Ron Newfield, MD
Susan Phillips, MD
Fellows:
Abigail Fruzza, MD
Audrey Briscoe, MD
Hiba Al-Zubeidi, MD
Nurses:
Karen Haddad, RN, MS, CPNP
Andrea Huber, RN, CDE
Beth McFeely, RN, CDE
Kim McNamara, RN, BSN
Emalie Sherrell, RN
Emily Spangenberg, RN, BSN
Dietician:
Vanessa Aldaz, MPH, RD, CDE
Lisa Ameer, MSNH, RD, CDE
Social Worker:
Eleanor Lazarow, LCSW
Renee Price, LCSW

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Regional Offices:
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Escondido
Murrieta
Oceanside

www.RCSSD.org

Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6).

Sincerely,

(b)(6)

(b)(6)
Rady Children's Hospital
3030 Childrens Way
San Diego, CA 92123
Office: (b)(6)
FAX: (b)(6)

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

Rhode Island Hospital
Hasbro Children's Hospital
A Lifespan Partner

June 20 2019

Department of Pediatrics
Division of Adolescent Medicine

593 Eddy Street
Providence, RI 02903
Academic Office
Tel
Fax (b)(6)

Adolescent Clinic
3055 Coro West 1 Hoppin St
Providence RI 02903
Tel
Fax (b)(6)

Abigail A. Donaldson, MD
Patricia Flanagan, MD
Michelle Forcier, MD MPH
Sherry Gagnon, NP
Unab Khan, MD
Margaret Kozel, MD
Suzanne Palinski, MD
Jack Rusley, MD

Medicine Pediatrics Clinic
245 Chapman St
Providence RI 02903

Department of Pediatrics
The Warren Alpert Medical School of Brown University

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood. You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study.

Our clinic is a high volume academic center in New England that care for pediatric, adolescent, adult patients of all ages. We serve over 500 gender diverse patients and collaborate with a variety of training residency programs and students (medical and nurse practitioner) in Rhode Island and Massachusetts. Your research is approached with scientific integrity, attention to patient needs, and has great ongoing scientific and clinical value. We fully and strongly support continued and increased funding for this very necessary project.

Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at [PHONE].

Sincerely,

(b)(6)

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

University of California
San Francisco

Department of Psychiatry
School of Medicine

San Francisco General Hospital
1001 Potrero Avenue
San Francisco, CA 94110
tel: (b)(6)
fax: (b)(6)

June 15, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood.

You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study.

I have been working in transgender health at UCSF for over 25 years, and for the last 16 years have worked as the (b)(6) a multiagency collaborative funded by the San Francisco Department of Public Health to care for trans youth. As a coauthor of (b)(6) and a (b)(6), I know the high scientific and clinical importance of longitudinal data on the healthcare of transgender youth. I am aware of the work that you and your collaborators of doing and I believe the continuation of this work, and the information to be derived from it, is of critical importance to guide healthcare providers and researchers in doing our work.

Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6) or (b)(6).

Sincerely,

(b)(6)

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

EL RIO
COMMUNITY HEALTH CENTER

06/18/2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood.

You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study. This would be very helpful for us, as our population in Arizona is predominantly Hispanic, a population that has not been thoroughly studied for gender-affirming care.

I am the (b)(6). Our center provides care for approximately 175 youth ages 4-21 (we also have an adult program that cares for about 300 adult transgender patients). We provide age appropriate primary care as well as puberty blockers and gender-affirming hormone therapy.

Our program would not exist without this research. The high scientific and clinical value of your study cannot be overstated. When we first started our program, we used your research published to date as well as presentations you have done to explain why we needed to provide this service to our patients and to show that what we were doing was not experimental. Your research has shown us that we save lives by intervening early in the care of transgender youth.

Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6)

Sincerely,

(b)(6)

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

El Pueblo Clinic El Rio Health Center
(b)(6)
101 W Irvington Rd
Tucson, AZ 857143050

June 6, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood.

You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study.

In my role as the (b)(6), I provide national leadership and expertise in public education and advocacy efforts on behalf of LGBTQ youth and families. I speak frequently at national and regional conferences and provide training and consultation for child welfare professionals, educators, and healthcare providers. Prior to joining HRC, I (b)(6) (b)(6), and supervisor of a behavioral health program for people with HIV. I am well aware of the urgent need for affirming care for transgender youth; the proposed study is of high scientific and clinical value, and I believe with great conviction that this work saves lives.

Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6).

(b)(6)

Human Rights Campaign Foundation

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD

June 8, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I am happy to write this letter on behalf of The Trevor Project's Research Department in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The data your team is collecting via the Trans Youth Care (TYC) Study examining physiological and psychosocial outcomes of gender-affirming medical intervention among transgender and non-binary adolescents is critical for improving our understanding of these innovative and life-saving treatments. Your ability to extend observation of this sample beyond a 24-month period will vastly improve the field's understanding of longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they continue to mature into young adulthood.

Additionally, your proposal to improve representation of transgender and non-binary youth of color presenting for gender-affirming medical care will be enormously valuable. At The Trevor Project, we value culturally relevant evidence-based care in mental health and medicine. We also recognize that intersectional identities such as race, ethnicity, gender identity, and sexual orientation may be differently impacted by changes experienced as a result of gender-affirming medical care.

Based on my expertise in implementation of evidence-based care for youth and specifically for LGBTQ youth at elevated risk for suicide, I view this research as crucial to improving our understanding of youth's experience of this care.

I look forward to the opportunity to continue learning from the valuable work of your research team to maximize safe and effective delivery of medical intervention for transgender and non-binary youth with gender dysphoria. Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6).

Sincerely,

(b)(6)

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

gender spectrum

June 12, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I enthusiastically write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood.

Your proposal to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study is also very important. We know from first-hand experience with thousands of youth and their families that race, ethnicity and regional sense of place all factor into the determination of effective care for youth.

Your research is desperately needed. Every day in our work at Gender Spectrum we see the challenges families and clinicians have as they struggle to effectively meet the health care needs of transgender and other gender non-conforming youth. The lack of data, especially longitudinal data, leaves many providers without clear guidance regarding how to best meet the needs of those in their care. Your study has both high research and clinical significance and will allow youth across the country to receive more effective treatment.

Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me by phone at (b)(6), or by email at (b)(6).

Sincerely,

(b)(6)

Gender Spectrum

gender spectrum

1271 Washington Ave.
San Leandro, CA 94577

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD

Boston Children's Hospital
Until every child is well

HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

6/14/19

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood.

You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study.

As an (b)(6), my research focuses on health disparities and inequities in transgender and gender non-binary communities. I am an (b)(6) at Boston Children's Hospital / Harvard Medical School, and (b)(6) at Harvard T.H. Chan School of Public Health I am also (b)(6) (b)(6), a local Boston-area community health center serving more than 3,500 transgender patients. I offer my full support of this proposal with high scientific and clinical value.

Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6).

Sincerely,

(b)(6)

Division of General Pediatrics, Boston Children's Hospital

(b)(6)

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD

Boston Children's Hospital
Until every child is well

Division of Adolescent/Young Adult Medicine
300 Longwood Avenue
Boston, Massachusetts 02115
Phone (b)(6)
Fax (b)(6)

June 7, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the ongoing Trans Youth Care (TYC) Study to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study. Your ability to extend observation of this sample over time and expand your sample to increase racial/ethnic diversity will yield greater information on the longer-term safety and side effects of gender-affirming medical care with a diverse group of understudied youth as they develop over adolescence and into young adulthood.

I am a researcher with over 10 years of experience working with the transgender community. One of my primary areas of research is psychosocial functioning of transgender youth and their families. I recently finished data collection for a NIH-funded community-based longitudinal mixed methods study of transgender teens and their families to understand how the family environment is related to transgender and non-binary teens' health and well-being across two years. The field of transgender youths' health has been limited in the lack of research on the longitudinal effects of gender-affirming medical care. Findings from the proposed research will significantly contribute to both knowledge about and clinical care with transgender youth. Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to transgender/gender-nonconforming youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6) or (b)(6).

Sincerely,

(b)(6)

(b)(6)

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

Mind the Gap

trans youth mental health consortium
Child and Adolescent Gender Center
(b)(6)

Oakland, California 94610

June 15, 2019

Stephen Rosenthal, MD
Pediatric Endocrinology
Child and Adolescent Gender Center
Division of Pediatrics
University of California San Francisco
San Francisco, CA 94118

Dear Dr. Rosenthal:

We write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender, gender creative, and gender-nonconforming adolescents beyond a 24-month period. Your opportunity to extend observation of this sample over time will yield greater information on the long term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood. The field of transgender healthcare needs this data to inform best practices with youth.

You and your colleagues also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study. We applaud this expansion.

Your study is ground breaking and critically needed to advance the science and develop the standards of practice for clinical work with transgender, gender creative, and gender-nonconfroming youth. The 300+ youth serving health professionals represented by our group **Mind the Gap** are practicing state of the art evaluation and treatment for the youth being studied. Our group represents the majority of mental health clinicians involved in the community with the patients of the Child and Adolescent Gender Clinic at UCSF. Many of our members are nationally known contributors to the care for these youth and we are devoted to excellence and evidence based practice. Through the various organizations in which we collectively are involved we are deeply involved in building capacity in caring for these special young people and their families.

Mind the gap support page 2

Should you be awarded NIH funding, we are hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep us posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6) and (b)(6)

(b)(6)

Mind the Gap

Cc: Robert Garofalo MD, Johanna Olson-Kennedy, MD, Yee-Ming Chan MD, Asa Radix MD

Parents of Transgender Individuals Support Group

June 20, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood.

You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study.

As an organization that cares about young TGNC people and their families we at PTI Chicago value the importance of this proposed study that will be of high scientific and clinical significance and will add to the knowledge base of those professionals that care for our children.

Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6)

Sincerely,

(b)(6)

Parents of Transgender Individuals Chicago

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

DATA SHARING PLAN

The proposed research will include data from 316 transgender youth in the gender-affirming hormone (GAH) cohort and 95 in the puberty blocker (GnRHa) cohort that will include survey data and lab data for bone densitometry, hormone levels, and other physiologic and anthropometric parameters collected from four participating sites at baseline through up to seven years. It will also include data from the 95 parents/caregivers of the GnRHa participants seeking puberty suppression. New enrollees (n=202) from selected demographics will have data from baseline through up to four years following initiation of either a GnRHa or GAH. The final datasets will include self-reported demographic and behavioral data from surveys with the participants and laboratory data from specimens provided for routine care of transgender youth. The dataset for the GnRHa cohort will also include demographic and behavioral and mental health data about the youth provided by the parent/caregiver.

We wish to make our results available to the transgender community, mental and medical health providers, public health practitioners, and scientists interested in studying the provision of competent mental and medical healthcare for transgender youth and young adults. Thus, we will submit the data to the NICHD Data and Specimen Hub (DASH) as rapidly as possible. Our plan also includes sharing study findings through multiple presentations at meetings of both community audiences (such as the World Professional Association of Transgender Health, GLMA, Gender Odyssey, Gender Spectrum, Gender Infinity) and national pediatric and transgender health conferences (such as American Academy of Pediatrics, Society for Adolescent Health and Medicine, U.S. Professional Association of Transgender Health, Pediatric Academic Societies).

PI: **Olson, Johanna**	Title: The Impact of Early Medical Treatment in Transgender Youth	
Received: 11/05/2014	Opportunity: PA-12-111	Council: 05/2015
Competition ID: FORMS-C	FOA Title: RESEARCH ON THE HEALTH OF LGBTI POPULATIONS [R01]	
1R01HD082554-01A1	Dual: MH	Accession Number: 3760705
IPF: 1520001	Organization: CHILDREN'S HOSPITAL OF LOS ANGELES	
Former Number:	Department: Pediatrics	
IRG/SRG: CHHD-M	AIDS: N	Expedited: N
Subtotal Direct Costs (excludes consortium F&A) Year 1: (b)(4) Year 2: (b)(4) Year 3: (b)(4) Year 4: (b)(4) Year 5: (b)(4)	Animals: N Humans: Y Clinical Trial: N Current HS Code: (b)(4) HESC: N	New Investigator: N Early Stage Investigator: N
Senior/Key Personnel:	*Organization:*	*Role Category:*
Johanna Olson M.D.	Children's Hospital Los Angeles	PD/PI
Marvin Belzer M.D.	Children's Hospital Los Angeles	Co-Investigator
(b)(6)	(b)(6)	Co-Investigator
Sheree Schrager Ph.D	Children's Hospital Los Angeles	Co-Investigator
Norman Spack M.D.	Boston Children's Hospital	MPI
Daniel Shumer M.D.	Boston Children's Hospital	Co-Investigator
(b)(6)	(b)(6)	Co-Investigator
Robert Garofalo M.D.	Lurie Children's Hospital of Chicago	MPI
Lisa Simons M.D.	Lurie Children's Hospital of Chicago	Co-Investigator
Marco Hidalgo Ph.D	Lurie Children's Hospital of Chicago	Co-Investigator
Scott Leibowitz M.D.	Lurie Children's Hospital of Chicago	Co-Investigator
Courtney Finlayson M.D.	Lurie Children's Hospital of Chicago	Co-Investigator
Joel Frader M.D.	Lurie Children's Hospital of Chicago	Other (Specify)-Ethicist
Stephen Rosenthal M.D.	University of California at San Francisco	MPI
Diane Ehrensaft Ph.D	University of California at San Francisco	Co-Investigator
David Glidden Ph.D	University of California at San Francisco	Co-Investigator

Appendices

Appx b consent permission assent forms,Appx c early pubertal cohort tg specific measures,Appx d late pubertal cohort tg specific measures,Appx a wpath and endocrine society letters

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE | **State Application Identifier**

1. TYPE OF SUBMISSION*

❍ Pre-application ❍ Application ● Changed/Corrected Application

4.a. Federal Identifier
HD082554

b. Agency Routing Number

2. DATE SUBMITTED | **Application Identifier**

c. Previous Grants.gov Tracking Number
Grant11778312

5. APPLICANT INFORMATION **Organizational DUNS*:** 052277936

Legal Name*: Children's Hospital Los Angeles
Department: Sponsored Projects Office
Division: The Saban Research Institute
Street1*: 4650 Sunset Blvd., MS #97
Street2:
City*: Los Angeles
County: Los Angeles
State*: CA: California
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 90027-6062

Person to be contacted on matters involving this application
Prefix: (b)(6) First Name*: (b)(6) Middle Name: (b)(6) Last Name*: (b)(6) Suffix:
Position/Title: (b)(6)
Street1*: 4650 Sunset Boulevard, Mailstop #97
Street2:
City*: Los Angeles
County:
State*: CA: California
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 90027-6062
Phone Number*: (b)(6) Fax Number: 323-361-8054 Email: chlaawards@chla.usc.edu

6. EMPLOYER IDENTIFICATION NUMBER *(EIN) or (TIN)** 95-1690977

7. TYPE OF APPLICANT* M: Nonprofit with 501C3 IRS Status (Other than Institution of Higher Education)

Other (Specify):
Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

8. TYPE OF APPLICATION*
❍ New ● Resubmission
❍ Renewal ❍ Continuation ❍ Revision

If Revision, mark appropriate box(es).
❍ A. Increase Award ❍ B. Decrease Award ❍ C. Increase Duration
❍ D. Decrease Duration ❍ E. Other *(specify)* :

Is this application being submitted to other agencies?* ❍Yes ●No What other Agencies?

9. NAME OF FEDERAL AGENCY*
National Institutes of Health

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER
TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
The Impact of Early Medical Treatment in Transgender Youth

12. PROPOSED PROJECT
Start Date* 07/01/2015
Ending Date* 06/30/2020

13. CONGRESSIONAL DISTRICTS OF APPLICANT
CA-028

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: Dr. First Name*: Johanna Middle Name: Last Name*: Olson Suffix: M.D.

Position/Title: Assistant Professor
Organization Name*: Children's Hospital Los Angeles
Department: Pediatrics
Division: Adolescent Medicine
Street1*: 4650 Sunset Blvd., MS#2
Street2:
City*: Los Angeles
County: Los Angeles
State*: CA: California
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 90027-6062
Phone Number*: (b)(6) Fax Number: 323-913-3614 Email*: jolson@chla.usc.edu

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested*	$ (b)(4)
b. Total Non-Federal Funds*	$0.00
c. Total Federal & Non-Federal Funds*	$ (b)(4)
d. Estimated Program Income*	$0.00

16.IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?*

a. YES ○ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE:

b. NO ● PROGRAM IS NOT COVERED BY E.O. 12372; OR

○ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

● I agree*

** The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

18. SFLLL or OTHER EXPLANATORY DOCUMENTATION File Name:

19. AUTHORIZED REPRESENTATIVE

Prefix: (b)(6) First Name*: (b)(6) Middle Name: (b)(6) Last Name*: (b)(6) Suffix:

Position/Title*: (b)(6)
Organization Name*: Children's Hospital Los Angeles
Department: Sponsored Projects Office
Division: The Saban Research Institute
Street1*: 4650 Sunset Blvd., MS #97
Street2:
City*: Los Angeles
County: Los Angeles
State*: CA: California
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 90027-6062
Phone Number*: (b)(6) Fax Number: 323-361-8054 Email*: chlaawards@chla.usc.edu

Signature of Authorized Representative* (b)(6)

Date Signed* 11/05/2014

20. PRE-APPLICATION File Name:

21. COVER LETTER ATTACHMENT File Name:1235-Cover Letter.pdf

424 R&R and PHS-398 Specific
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OMB Number: 4040-0010
Expiration Date: 06/30/2016

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	Children's Hospital Los Angeles
Duns Number:	0522779360000
Street1*:	4650 Sunset Blvd., MS #97
Street2:	
City*:	Los Angeles
County:	Los Angeles
State*:	CA: California
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	90027-6062
Project/Performance Site Congressional District*:	CA-028

Project/Performance Site Location 1

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	Boston Children's Hospital
DUNS Number:	0765937220000
Street1*:	300 Longwood Avenue
Street2:	
City*:	Boston
County:	Suffolk
State*:	MA: Massachusetts
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	02115-5724
Project/Performance Site Congressional District*:	MA-007

Project/Performance Site Location 2

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	Lurie Children's Hospital of Chicago
DUNS Number:	0744387550000
Street1*:	225 East Chicago Avenue
Street2:	
City*:	Chicago
County:	Cook County
State*:	IL: Illinois
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	60614-3393
Project/Performance Site Congressional District*:	IL-005

Project/Performance Site Location 3

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	University of California at San Francisco
DUNS Number:	0948783370000
Street1*:	400 Parnassus Ave, Second Floor
Street2:	
City*:	San Francisco
County:	San Francisco
State*:	CA: California
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	94143-0296
Project/Performance Site Congressional District*:	CA-012

File Name

Additional Location(s)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ○ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ○ Yes ● No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6

If NO, is the IRB review Pending? ● **Yes** ○ **No**

IRB Approval Date:

Human Subject Assurance Number 00001914

2. Are Vertebrate Animals Used?* ○ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ○ Yes ○ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ○ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ○ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ○ Yes ○ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ○ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ○ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	1236-Project Summary Abstract.pdf
8. Project Narrative*	1237-Project Narrative.pdf
9. Bibliography & References Cited	1238-References.pdf
10.Facilities & Other Resources	1239-Facilities and Resources.pdf
11.Equipment	
12. Other Attachments	1240-LargeGrantWaiverApproval.pdf

PROJECT SUMMARY/ABSTRACT

Transgender children and adolescents are a poorly understood and a distinctly understudied population in the United States. The limited available data suggest that transgender youth who are gender dysphoric (persistently distressed about gender incongruence) are at increased risk for negative mental and medical health outcomes including anxiety, depression, HIV acquisition, suicide, and substance use compared to their peers. Therefore, medical intervention is aimed at alleviating gender dysphoria and ameliorating potential negative outcomes. Existing strategies for treating transgender youth depend on the developmental stage at which these youth present for care. For those transgender youth that present for care in the early stages of pubertal development, treatment is aimed at suppressing their endogenous puberty in order to avoid the development of undesired secondary sexual characteristics that intensify the distress associated with gender incongruence. For those youth in later stages of puberty, the goal of treatment is to use cross-sex hormones in order to induce the development of desired secondary sexual characteristics that bring the body into closer alignment with the youth's internal sense of gender. In 2011, the Institute of Medicine emphasized a clear need for the development of evidence-based and rigorous research aimed at understanding the health implications of hormone use in transgender individuals. The proposed study networks four academic sites around the country (Children's Hospital Los Angeles/University of Southern California, Boston Children's Hospital, Lurie Children's Hospital of Chicago/Northwestern University, and University of California San Francisco) with dedicated transgender youth clinics to conduct a multi-site observational study examining the physiological and psychosocial outcomes of existing medical treatment protocols for transgender youth with gender dysphoria. The study will include two groups of gender dysphoric youth: one in the earliest stages of pubertal development to assess the impact of puberty suppression, and one in later stages of pubertal development to assess the impact of cross-sex hormones for gender transition. Specifically, in the earlier pubertal cohort (Tanner stages 2-3; n=80) the study will evaluate the impact on mental health, psychological well-being, physiologic parameters and bone health as well as document safety of GnRH agonists administered for puberty suppression. In the later pubertal cohort (Tanner stages 4-5; n=200) the study will evaluate the impact on mental health, psychological well-being, and metabolic/physiologic parameters, as well as document the safety of cross-sex hormones administered for gender transition. This multi-center study will be the first in the U.S. to evaluate longitudinal outcomes of medical treatment for transgender youth and will provide essential evidence-based data on the physiological and psychosocial effects and safety of treatments currently used for transgender youth.

PROJECT NARRATIVE

The Institute of Medicine's 2011 report "The Health of Lesbian, Gay, Bisexual, and Transgender (LGBT) People," calls for the development of evidence-based and rigorous research aimed at understanding the health implications of hormone use in transgender individuals. The goal of the proposed research is to conduct a multi-site observational study examining the physiological and psychosocial outcomes of existing medical treatment protocols for gender dysphoria in two cohorts: early pubertal and late pubertal transgender youth.

FACILITIES AND RESOURCES

Children's Hospital Los Angeles

Children's Hospital Los Angeles (CHLA)
Located at 4650 Sunset Boulevard in the Hollywood/Wilshire Health District of Service Planning Area 4 of Los Angeles County, Children's Hospital Los Angeles (CHLA) is the largest pediatric facility in the western United States and is the principal pediatric center in Southern California. Founded in 1901, CHLA has been dedicated to serving the needs of critically and chronically ill children with compassion, dedication, and excellence. As a community-based medical center with an international impact, CHLA provides specialized, multi-disciplinary treatment and prevention services for more than 104,000 children and youth each year. Guided by a century of medical care, its mission is "to create hope and build healthier futures." In 1932, CHLA and the University of Southern California (USC) signed an affiliation agreement that made CHLA the principal pediatric teaching facility for the Keck School of Medicine. Full time physicians (176) at CHLA have appointments in the Departments of Pediatrics, Surgery, Pathology, Neurology, and Radiology at the Keck School of Medicine, while the full time basic science faculty (36) holds appointments in the Departments of Biochemistry, Cell Biology, Microbiology, and Physiology.

CHLA is unique because few pediatric hospitals in the world combine a freestanding clinical center with an on-campus research facility – the CHLA Saban Research Institute, one of the largest and most productive pediatric research facilities in the United States. This link offers the ability within a single institution to rapidly move discoveries from the research laboratories to the bedside of children suffering from complex and life-threatening disease. Dedicated to advancing the limits of knowledge, the researchers at CHLA seek solutions for childhood cancer, infections, genetic disease, development disabilities, and healthcare success.

Saban Research Institute at CHLA
Established in 1992, the Saban Research Institute is the umbrella under which research is conducted at CHLA. Its mission is to foster an environment of scientific excellence where research will lead to discoveries involving the molecular and clinical understanding of childhood development and implementation of procedures to diagnose, treat, and prevent pediatric diseases and promote child health. The Saban Research Institute ranks fifth among 26 major pediatric research institutions across the country, and principal investigators utilize more than 150,000-square-feet of research space in the Saban Research Building, the Smith Research Tower, within the hospital, and in the community. Researchers are involved in more than 200 active studies and projects, many of which are funded by NIH. The Research Institute and faculty are affiliated with USC, and at any given time, more than 120 graduate students and post-doctoral fellows are in training.

The Clinical Investigation Center and the Clinical Trials Unit support clinical research while the Office of Research Advancement and Administration provides centralized support for all aspects of research. The Department of Research Administration provides a centralized administrative system that ensures that research is maintained at the highest quality and safety levels. It includes sponsored-research award administration, the Office of Technology Transfer, the Office of Operation and Facilities, and satellite offices for Human Resources, Accounts Payable, Purchasing, and Marketing Communications.

Extramural funding for research totaled $37,412,898 at the end of FY 2009, including $23,345,012 in NIH funding. These research activities reflect a very significant expansion of the Saban Research Institute over the past years. Extramural funding has increased from $20.5 MM (total costs) in 1998 to $37.4 MM in 2009, while NIH funding increased from $10.3 MM in 1998 to $26 MM in 2009. At the same time, institutional intramural funding for research has increased by 1.8 fold, research restricted endowments by 2.5 fold, and research space by 1.6 fold with the completion of the Saban Research Building in June of 2003, reflecting the strong commitment of CHLA to research. As a result, the Research Institute has been able to actively recruit new research faculty members, increasing the pool of extramurally funded investigators from 69 in 1998 to 100 in 2009. A total of 186 extramurally funded research projects existed in 2009.

Research education is an integral part of the mission of CHLA and a top priority of the Saban Research Institute. The Research Institute has developed a comprehensive approach to training and contributing to the development of the research careers of individuals at various levels of their education. The Saban Research

Institute established in 1997 a High School Outreach Program with Marlborough High School supporting four or five students per year to perform research projects under the guidance of individual principal investigators at the Research Institute. The Saban Research Institute funds graduate students who are enrolled in a USC-based graduate program and are working in the laboratory of a principal investigator located at CHLA. An intramural Research Career Development Fellowship (CHLA-RCDF) was established in 1995 that supports the research and promotes the careers of postdoctoral fellows. The Saban Research Institute also established a mentored Research Career Development Award (RCDA) modeled after the NIH RCDA program that supports the academic careers of junior faculty at CHLA. A total of $2.1 MM has been allocated to support these research education efforts since 1995.

Division of Adolescent and Young Adult Medicine

The proposed research will be conducted under the auspices of the Division of Adolescent and Young Adult Medicine at CHLA and the direction of Principal Investigator Dr. Johanna Olson. The Division of Adolescent and Young Adult Medicine (DAYAM), established in 1963, is known for its innovative service models, leadership in community collaboration, training programs in adolescent health care, and research regarding adolescent issues. The mission of the DAYAM is to advance the health and well-being of adolescents by integrating health care, health promotion and prevention, youth development, professional education, advocacy, and research and evaluation in response to the needs of young people and their communities.

Since the early 1980s, the DAYAM has had a special focus on at-risk youth and has developed model programs to serve targeted groups of vulnerable youth. These youth include homeless and runaway youth, substance-using youth, youth with mental health problems, youth at-risk for and infected with HIV, pregnant teens and teen parents, transgender youth, and youth at-risk for violence. Through these programs, the DAYAM provides health care, mental health and substance abuse treatment, case management, and health education services to over 7,000 youth annually. The DAYAM operates an outpatient clinic for youth ages 10 to 24, and through a mental health contract from the County, provides individual, family, group, and multi-family treatment to over 300 youth annually. Since 1982, the DAYAM has established itself as a leader in needs assessments, epidemiologic and ethnographic studies, and research and evaluation projects focused on adolescents and young adults from diverse communities throughout Los Angeles County and the Southern California region.

The DAYAM has an accredited adolescent medicine fellowship program, one of only two in California, and an American Psychological Association accredited pre-doctoral internship and post-doctoral fellowship program. In fiscal year 2013-14, the DAYAM's total operating budget exceeded 13.9 million dollars of which 3.3 million dollars were dedicated to a wide range of research activities, including research associated with the national Adolescent Trials Network; the development and evaluation of an evidence-based HIV/AIDS prevention intervention that is being adapted for application with youth from middle and high schools and with emerging adults; epidemiologic and intervention research related to substance use and misuse; service needs assessment of homeless and runaway youth; and evaluation research related to DAYAM programs.

The DAYAM's key programs for this research study are:

- **The Center for Transyouth Health and Development** – The Center for Transyouth Health and Development promotes healthy futures for transyouth by providing services, research, training, and capacity building that are developmentally informed, affirmative, compassionate, and holistic for gender non-conforming children and transyouth. The principal investigator (Dr. Olson) is the Medical Director for the Center. The Center includes the nation's largest pediatric clinic for transgender youth and gender non-conforming children. The Center also houses the DAYAM's mental health, health education, research, and capacity building assistance focused on transgender youth and children.
- **The Research and Evaluation Program** – The Research and Evaluation Program conducts mixed and single-method epidemiologic and evaluation research related to issues affecting the health and well-being of adolescents and young adults. Past and current research foci include, but are not limited to, substance use and misuse, HIV/AIDS, reproductive health, relationship violence, transition of youth with chronic illness and special needs to adult care, and service needs of disenfranchised or marginalized youth. The Research and Evaluation Program also develops and conducts research for each DAYAM service program to support the development and document the impact of our prevention and intervention programs and increase our understanding of the youth utilizing DAYAM services.

Additional programs include:

- **The Teenage and Young Adult Health Center** – health care for youth with complex medical and psychosocial problems. In addition to the health care services offered through the health center, we provide health care at the Los Angeles and Long Beach Job Corps and in community clinics;
- **The Risk Reduction Program** – specialty health care, mental health counseling, case management, and support for HIV positive youth and HIV prevention services for transgender youth and young gay men. The DAYAM has a harm reduction program for transgender youth offering hormone treatment, case management, mental health services, and youth leadership opportunities. The Risk Reduction Program participates in a multicenter research network funded by the NIH to explore promising behavioral and therapeutic interventions for HIV-infected and at-risk adolescents;
- **The Behavioral Health Program** – mental health services for youth 12-21 including assessment; individual, family, and group counseling; and case management services funded by Medi-Cal and under the auspice of the Department of Mental Health;
- **The High Risk Youth Program** – health care, mental health counseling, case management and support for homeless youth. The project is a member of the six agency Hollywood Homeless Youth Partnership and the countywide LA Coalition to End Youth Homelessness.
- **Adolescent Transition Clinic** – in collaboration with CHLA sub-specialty clinics, the Adolescent Transition Team caters to teens and young adults with special health issues and their families to facilitate transition into adulthood and adult healthcare. Provides comprehensive, individualized mental, physical, and social evaluation and planning that emphasizes empowering each young adult to take control of his/her own health issues to ensure successful transition. Tools include health passports, interactive web programs, financial counseling, individual therapy, and peer support.
- **The Gang Reduction/Youth Development Program** – violence prevention services for youth 10-15 years old and their families in the Cypress Park/Glassell Park areas, focused on keeping youth away from gangs, supporting families, and building healthy communities;
- **Project NATEEN** – case management and support for pregnant and parenting teens and young adults with an on-site school, a special employment and life skills program for young parents, and specialized services for young fathers; and
- **The Substance Abuse Prevention and Treatment** – no-cost outpatient services for youth ages 10-25. Services include walk-in screenings and short and long-term individual, family, and group sessions.

Division Director Marvin Belzer, MD, serves as the Principal Investigator of all Los Angeles-based research related to the Adolescent Trials Network (ATN), an NIH-supported national consortium of 14 academic institutions throughout the US. The ATN has put forth a broad research agenda calling for "interventional studies, conducted collaboratively and independently when needed, aimed at the primary, secondary, and tertiary prevention of HIV infection in pre-adolescents, adolescents, and young adults at the trial units in the network." CHLA, the only ATN site on the West Coast, has been engaged in dozens of ATN studies over the past 15 years as a primary or collaborative research site.

While the Division Director oversees all divisional activities, the DAYAM operates with a 20-member Management Team that includes the managers of each of the community based programs, medical directors, the Director of Behavioral Health, the Director of Research, the Fiscal Administrator, the Associate Director, and the Division Director. A seven person senior management team provides oversight for clinical, research, and training activities, as well as finance and administration, and includes the Director, Associate Director, Fiscal Administrator, Director of Research, and Director of Behavioral Health Services.

Community, Health Outcomes, and Intervention Research (CHOIR) Program

Many of the DAYAM's faculty are part of the institution-wide Community, Health Outcomes, and Intervention Research (CHOIR) Program of the Saban Research Institute, an assembly of faculty and other CHLA investigators conducting health services/outcomes, social, behavioral, and community-focused research to promote the health and wellbeing of children, adolescents, and families. In an urban, densely populated area such as Los Angeles, there are numerous opportunities to reduce health disparities and address barriers to healthy living for children and adolescents. Our researchers seek to prevent illness, injury and reduce barriers to health care by conducting innovative research, implementing effective interventions, and working to ensure that all children and adolescents receive the high-quality healthcare that they need. Research plays a critical

role in understanding why some children are at greater risk for poorer health than others and how best to intervene to improve health and health outcomes. CHOIR members conduct research that is interdisciplinary, collaborative, cumulative, applied, and closely linked to policy and practice. Moreover, CHOIR's work emphasizes the importance of adopting a developmental framework that focuses attention on the differing needs, circumstances, and key transitions that children, adolescents, and young adults experience as they grow and develop. Whenever possible, CHOIR works closely with faculty and staff across the various Departments and Divisions at CHLA and USC to ensure that there are clear and tangible linkages among research, clinical care, and program development. Finally, considerable effort is made to disseminate the research findings widely and strategically to key stakeholder groups (e.g., federal, state, and local policy makers, health providers, advocacy groups, the media, and parents).

Members of the CHOIR program also participate in a range of formal and informal staff support, research, and technical training meetings convened on a regular basis. These include weekly staff meetings, regular and ongoing seminars convened by researchers who are conducting children's health services and behavioral and social science research as part of several funded research projects, and ongoing technical support and training meetings. Qualitative and quantitative researchers meet regularly to discuss their work, analytic approaches used for various types of research, and mathematical models that can be used and applied to advance our work.

Clinic

The clinical space for outpatient medical services is 3,314 square feet. Clinical space includes eight exam rooms, two laboratories for collection of lab specimens and a utility room containing storage for immunizations and lab collection materials. Access to radiologic services is located at the main campus of CHLA approximately one-half mile from the DAYAM.

Lab

The Department of Pathology and Laboratory Medicine at Children's Hospital Los Angeles provides a full array of laboratory services that draw on both established and state-of-the-art diagnostic techniques. The department, one of the most comprehensive pediatric pathology programs nationwide, is staffed by board-certified pediatric pathologists including several pathologists with sub-specialty expertise. The department directs the operations of the main Clinical Laboratory, Surgical Pathology, and Autopsy Service, as well as phlebotomy services, point-of-care testing, and a laboratory outreach program. In addition, the department is responsible for the Blood Bank, Blood Donor Programs, and Transfusion Medicine. The department's service functions are complemented by an active educational program, with a certified pediatric pathology residency program and a State of California certified education program for Clinical Laboratory Scientists, plus various learning opportunities for hospital and community physicians. The full-service Clinical Laboratory at Children's Hospital Los Angeles provides a broad spectrum of clinical chemistry analyses, including routine chemistry, therapeutic drug monitoring, thyroid testing, transplant immunosuppressive drug monitoring, qualitative drugs-of-abuse screening and blood gas analysis. The hematology laboratory has extensive experience in the diagnosis of a variety of hematological disorders and coagulationopathies. The histocompatibility laboratory supports the extensive programs in bone marrow and solid organ transplantation. Microbiology services are oriented to common pediatric infectious diseases as well as infections in immunocompromised patients. The Special Chemistry laboratory aids in the diagnosis and treatment of metabolic disorders. Many of these services are available around the clock, every day of the year. Special services to meet the needs of the hospital's pediatric population include a comprehensive cytogenetics laboratory (COG certified); catecholamine (vanillymendelic acid and homovanillic acid) testing; and blood lead testing. Appropriate pediatric reference values are included with each laboratory report. The CHLA Laboratories are CLIA Certified, State of California Department of Public Health Licensed, College of American Pathologists Accredited, and hold other relevant certifications and accreditations. Our experienced staff is comprised of American Society for Clinical Pathology-certified technologists who are licensed by the State of California as Clinical Laboratory Scientists.

Computer

CHLA research investigators have access to research computing facilities at their workstations in their offices and at PC work stations in the Biostatistics lab located at CHLA. A computer lab is designated for data entry, management, and statistical support staff. The DAYAM and CHOIR provide statistical database, spreadsheet, word-processing, desktop publishing, accounting, and a variety of utility software programs to all platforms. E-mail and internet access is provided to all staff. In addition, the USC University Computing Services provides a

comprehensive computing environment to support instructional and research goals of the University and its affiliated campuses, including CHLA. Facilities and services include campus-wide networking, a variety of central host systems, public user rooms, and support for distributed systems, hardware maintenance, and user support services. It provides support for and access to departmental and shared campus computing resources, library information systems, and regional, national, and international information resources. USC utilizes the most up-to-date hardware equipment and supports a variety of communication and scientific hardware and software systems. CHLA is connected to USC's health sciences network. Every research faculty and staff member has a computer on his or her desk for database and statistical analysis, simulation, spreadsheet work, and text processing and has the capability to communicate electronically.

Office
CHLA is located in the Los Angeles community known as East Hollywood, approximately eight miles from the USC Health Sciences Campus and the Keck School of Medicine. The Co-Investigators and research staff will be located at the offices in the Division of Adolescent and Young Adult Medicine. The DAYAM's main administrative offices and comprehensive ambulatory health clinic, the Teenage and Young Adult Health Center, are located at 5000 Sunset Blvd., in a seven-story office building several blocks from the main campus of CHLA. The Division occupies 20,233 square feet on three floors. Offices are equipped with computers and broadband connections to the internet. There are two large multi-purpose rooms. One is 560 square feet on the fourth floor, and the other is 400 square feet on the fifth floor. Four smaller conference rooms are also available on the fourth and seventh floors.

Other
The Children's Hospital Health Sciences Library provides resources and services to CHLA staff. In addition to its collection of 3,500 print books and 170+ current print journal subscriptions, the library supplies access to over 200 electronic books and 2,000 electronic journals. Online access is available anywhere in the hospital or from remote computers that connect to the USC network. In addition to books and journals, the library also provides local and remote access to journal article databases including: Ovid MEDLINE, Ovid CINAHL, PubMed, PsycINFO, Science Citation Index, and Journal Citation Reports. The library's book and journal catalog, as well as that of the USC Norris Medical Library with whom the CHLA library has reciprocal borrowing agreements, is searchable online as well. Library services include mediated literature searching (searches conducted by a librarian), interlibrary loan borrowing (for obtaining materials that the CHLA library does not own), Ovid AutoAlerts (a current awareness service that delivers weekly citations that match a researcher's predefined topic), and HouseCalls (one-one-one, time-of-need meetings where the librarian can instruct users on a variety of topics including database searching, PowerPoint, or EndNote).

Ann & Robert H. Lurie Children's Hospital of Chicago

Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's; formerly known as Children's Memorial Hospital)
Located at new state of the art facilities at 225 E. Chicago Avenue in Chicago, is a 288 bed pediatric facility with over 1,100 pediatric/adolescent specialists focusing on 70 medical specialties. Lurie Children's provides care to more young people than any other Chicago-area hospital or medical center with more than 330,000 outpatient visits each year and more than 9,000 inpatient visits. Lurie is accredited by the Joint Commission on Accreditation of Healthcare Organization (JCAHO) and has a fully equipped ambulatory adolescent and HIV clinic located at its Clark/Deming building designed to be culturally appropriate for adolescents and young adults specifically. This adolescent specific space has four exam rooms, team meeting space, provider office space and touchdown areas for nursing and social work.

Laboratory
The clinical mass spectrometry lab is located in the Deming Building, room 3043 at Ann & Robert H. Lurie Children's Hospital of Chicago Outpatient Center. The clinical LC-MS/MS laboratory at Lurie Children's Hospital Outpatient Center is an 1100 ft^2 laboratory and is comprised of 5 rooms and is under the direct supervision of Shannon Haymond, Ph.D., a clinical and analytical chemist. The laboratory is CLIA-certified by the College of American Pathologists and performs testing for clinical and research purposes. The processes and procedures used for research samples during the pre-analytical, analytical, and post-analytical phases of

testing are aligned and compliant with CLIA quality regulations for clinical testing. It is staffed by a manager and four technologists/scientists with dedicated training in HPLC and tandem mass spectrometry, in addition to general clinical laboratory functions (e.g., specimen processing, lab information system function, electronic medical record function). The main lab area contains two HPLC, two UPLC, three tandem mass spectrometers (LC-MS/MS) and one graphite furnace atomic absorption spectrometer as well as an automated pipetting system, fume hoods, refrigerator, freezers, evaporators, flammable and acid/base storage cabinets, reverse osmosis water filtration system, sinks, lab benches, storage units, and five technologist PC workstations. Therefore, this room is used for glassware washing, sample preparation, analysis, and documentation. The second room is specifically separated from the main area of the lab to prevent contamination from carryover during analysis as it is used to precisely and accurately weigh the standard compounds used to prepare the calibrators, quality control materials, and other concentrated stock solutions required for the various assays. This room contains a lab bench, sink, freezer, a fume hood, flammable storage cabinet, and analytical balance with balance enclosure situated atop a marble table. The third room contains a nitrogen generator system that supplies high purity nitrogen gas required for operation of the mass spectrometers. It comprises an air compressor, storage tank, dryer unit, and nitrogen generator. Nitrogen cylinders that are connected to an automatic switch over system serve as backup in case of nitrogen generator system failure. The fourth room is the tank room containing 4 high purity argon cylinders to supply gas to the mass spectrometers and the atomic absorption spectrometer. Reagents and stock solutions are stored in -20º C freezers and/or refrigerator located throughout the lab rooms. Specimens are stored at -70° C until ready for analysis. Two dedicated -70° C freezers are located in the final room. Freezer and refrigerator temperatures are monitored and recorded by an automated building alarm system.

The clinical chemistry laboratory is located on the 8th floor of the Ann & Robert H. Lurie Children's Hospital of Chicago. It is included within the 'core' laboratory and is under the direct supervision of Shannon Haymond, Ph.D., a clinical and analytical chemist. This laboratory is CLIA-certified by the College of American Pathologists and performs testing for clinical and research purposes. The processes and procedures used for research samples during the pre-analytical, analytical, and post-analytical phases of testing are aligned and compliant with CLIA quality regulations for clinical testing. It is staffed by a manager, three coordinators and over 30 technologists/scientists to maintain the 24/7 operation necessary to support inpatient and outpatient activity in a tertiary care pediatric facility. Policies, procedures, training, and competency documents detailing research services are maintained by the laboratory management and a dedicated coordinator. All laboratory personnel responsible for shipping samples are IATA certified to package and ship biohazardous goods.

All entry points to the laboratory are secure and require badge access. The laboratory receipt and processing area has a window opening to the hallway where specimens are dropped off and picked up by couriers and hospital staff. Next to the window is the tube system where specimens are sent from inpatient units and onsite outpatient centers. The specimen processing areas equipped with all items (e.g. centrifuge, racks, decant tubes, label printer, workstation) necessary to prepare the specimen for testing, storage and shipment. The automated testing area includes Chemistry, Hematology, Coagulation, and Urinalysis. After necessary processing, samples are manually delivered to the performing instrument or laboratory. Specimens are tracked throughout the process using a barcoded specimen management system.

Hematology has three Advia 2120 analyzers. Coagulation has two BCS XP Coagulation analyzers. Urinalysis has two Clinitek Advantus analyzers. Chemistry has two Cobas 6000 analyzers and one Immulite 2000 analyzer and one Nova 8 analyzer. There is a manual testing bench for testing of specialty markers. The laboratory research services utilize two -70° C freezers, 4° C refrigerator, and room temperature storage space. Freezer and refrigerator temperatures are monitored and recorded by an automated building alarm system. Monthly reports are reviewed and approved by the manager of the laboratory receiving and processing area. In the event of failure, samples will be moved to a back-up -70° C freezer that is also monitored and maintained by the Department of Pathology and Laboratory Medicine. A departmental policy contains the details of the temperature monitoring, freezer maintenance, and backup plan.

Computer

Lurie Children's maintains excellent computer support staff for general faculty services (i.e. internet access, purchasing, hardware support) and provides staff with full access to the computer resources. PCs are

connected to secure Intranet, allowing for coordination of data entry and management. The PI will have full access to computers and support staff for technical assistance.

Office
Research personnel have adequate office space at Lurie Children's satellite office in the Uptown neighborhood on the north side of Chicago, housed in the Center for Gender, Sexuality and HIV Prevention. The Center has two floors in this location of approximately 4,800 square feet with five private and shared offices, 20 workstations, and six interview rooms on two floors. Each workstation or office is equipped with a computer networked to Lurie Children's main server.

Other
The Stanley Manne Children's Research Institute (CRI) is one of 13 interdisciplinary research centers and institutes of Northwestern University's Feinberg School of Medicine. All principal investigators at the institute are full-time faculty members at Feinberg. The institute is the research arm of Lurie Children's, which is the primary pediatric teaching hospital for the Feinberg School of Medicine. CRI is one of five institutions in the United States dedicated exclusively to pediatric research. The main laboratory of the institute is the Children's Research Center, a 71,000 square-foot facility that opened in 1995. A subdivision of CRI, the Child Health Research Core focuses on population-based research, including multidisciplinary investigations of children in their families and communities. As the research institute affiliated with Lurie Children's, CRI has a long history of successfully managing large federal research projects and is an ideal site for this project because it complements the 3 missions of the hospital: (1) providing culturally relevant child and adolescent health care services; (2) doing research into the prevention, causes and treatment of diseases that affect children and adolescents; and (3) advocacy for the general well-being of all children/adolescents.

The Gender, Sexuality and HIV Prevention Center, at Research Center of excellence at CHCRC, directed by Dr. Garofalo, examines a broad range of multidisciplinary academic subjects including sexual health, gender, sexuality, HIV prevention and health disparities affecting adolescent and young adult populations at risk of acquiring HIV. The Center works to make the lives of high-risk adolescent populations healthier through clinical care, education and evaluation as well as professional training, research and public health advocacy. These populations include but are not limited to homeless, lesbian, gay, bisexual, transgender, and questioning (LGBTQ) youth. The Center strives to partner with like-minded organizations creating an environment where clinicians, academics, and scientists can collaborate to design projects with public health significance. Currently the Center is involved as primary awardee or subcontractor on nine government-funded research projects and programs focusing on the Center's target populations.

Boston Children's Hospital

Boston Children's Hospital
Clinical Recruitment: Patients will be recruited from Boston Children's Hospital, a 395-bed comprehensive center for pediatric health care located at 300 Longwood Avenue in Boston, MA. Boston Children's Hospital has approximately 25,000 inpatient admissions per year and 500,000 annual outpatient visits to 240 specialized clinical programs.

Department of Medicine, Endocrine Division – GeMS Program
Boston Children's Hospital's Division of Endocrinology operates one of the nation's most extensive research programs focused on pediatric endocrine disorders with more than 50 basic science and clinical researchers. The research enterprise addresses an array of endocrine disorders that affect the health and quality of life of children.

The Gender Management (GeMS) Service of Boston Children's Hospital
In 2007, with the support of the hospital administration and clinical leadership of the Division of Endocrinology and the Dept of Pediatrics, the Gender Management Service was inaugurated to serve both transgender adolescents and children, and adolescents with Disorders of Sex Development. The Service was co-directed by the Divisions of Endocrinology under Dr. Spack and the Department of Urology under David Diamond, MD. GeMS was the first academic pediatric center in North America to run a program for the evaluation and

medical treatment of transgender youth and to train pediatric trainees, Endocrinology fellows from pediatric and internal medicine departments and Reproductive Endocrinologists-in-training. In the past six years, ten additional centers in the USA and Canada have initiated their own programs for trans youth, in many cases modeled after the GeMS Program and led by former trainees of ours.

In 2012, we reported on the demographics of the first 100 patients seen in GeMS. Similar to the Dutch, we had equal numbers of genotypic males and females, and 10% of our patients were in the autistic spectrum. Our patients were a bit older by almost two years: 14 years for genotypic males and 15 years for females. Despite being brought to us by both parents with a referral from a gender specialist-therapist following at least six months of counseling, 23% of our patients admitted self-harm prior to their first appointment and 9% had attempted suicide. This data was published in the March issue of Pediatrics in the first article ever written on transgender youth in that journal. From July 1, 2007 – October 31, 2014, GeMS clinic has seen 191 new patients, with a marked increase in the number offered GnRHa analogue since 2011, including genotypic males as genitally advanced as Tanner IV but with incomplete virilization of voice, Adam's apple, facial bones, and facial hair. The long-term benefits of the late intervention need to be ascertained. In addition to our testing psychologist and social worker, we have added a research psychologist, and two part-time endocrinologists. With the receipt of a recent hospital award, our social worker has organized seven Saturday conferences on transgenderism over two years for health professionals, parents, and school personnel. Dr. Spack was invited to eight "visiting professorships" and lectureships in North America in 2013 to strategize about the development of new academic clinics or to be involved in launching them.

Office

Dr. Spack has an office at the 333 Longwood Avenue hospital building across the street from the main hospital. Dr. Shumer has office space in 1 Autumn Street a Boston Children's Hospital office building; Dr. Tishelman has an office at 300 Longwood Avenue, the main building. Office space for study staff will be made available. Offices of faculty and staff at Boston Children's Hospital are fully equipped with telephones with conference calling capability, computers, laser printers, fax machines, scanner, and photocopiers. Locked filing cabinets are part of the office space.

Computer

All investigators have a computer with hospital networking and access to an extensive array of communication, word processing, spreadsheet, graphics, and statistical software. The computers are password protected and there are private servers for data storage. Microsoft Office software includes word processing, spreadsheets (Access, Excel), graphics, and PowerPoint. Statistical software such as SAS, STATA, and SPSS are supported by the hospital's research computing department. Children's Hospital's library supports Endnote citation manager and provides access to extensive resource for literature searches.

Other

- Clinical Research Center (CRC) Established in 1998, the Clinical Research Center (CRC) at Boston Children's Hospital is charged with the mission of providing infrastructure for the conduct of clinical research and methodological expertise to the diverse clinical research community. The goal of the CRC is to provide all investigators with access to expertise in clinical research methods, including biostatistics, epidemiology, survey methods, clinical trials methodology, database programming, data management, and quality control. The faculty and staff of the CRC include doctoral level biostatisticians, master's level biostatisticians, survey epidemiologists, project directors/clinical trials managers, informatics professionals, data managers/study coordinators and data entry staff. The network and computing infrastructure of the clinical research enterprise is supported by the Information Systems Department (ISD) and Research Computing facilities.
- The Children's Hospital library has an extensive collection of pediatric journals and books. The librarian, (b)(6), is also available to assist with literature searches and request interlibrary loans.
- The Francis A. Countway Library of Medicine is the largest medial library in the United States with more than 480,000 volumes, 5,000 periodicals, and complete computer searching capabilities.
- The Harvard Catalyst Program allows investigators to perform cutting edge human research and facilitates human interdisciplinary research across the broad spectrum of departments and research areas through

transformation and extension of the prior NIH-funded General Clinical Research Centers. Now referred to as the Clinical and Translational Study Unit, this resource incorporates dedicated inpatient and outpatient clinical research sites, clinical research personnel, and core laboratory services at the following participating Institutions: Beth Israel-Deaconess Medical Center, Brigham and Women's Hospital, Children's Hospital Boston, Massachusetts General Hospital, and Massachusetts Institute of Technology. Each provides resources available to assist investigators within as well as across these Institutions. Selected resources are available in space dedicated to the CTSU and off-site in other areas where patients are located such as the intensive care units, emergency departments, and ambulatory centers.

University of California San Francisco (UCSF) Benioff Children's Hospital

UCSF Benioff Children's Hospital

The University of California, San Francisco (UCSF) is one of the premier medical research institutions in the world. UCSF is consistently ranked as one of the top five medical schools in the US, and received more research funds from the NIH than any other public institution in 2010 (and ranked third among all institutions nationwide). The 107 acre Parnassus campus houses the schools of Medicine, Dentistry, Pharmacy and Nursing, the Graduate Division, the UCSF Medical Center, The UCSF Benioff Children's Hospital and the Langly-Porter Neuropsychiatric Institute. Additional campuses include the Mt. Zion Cancer Center, the Laurel Heights Campus and the new 43 acre Mission Bay Campus, with >1.3 million ft^2 of research space. There are >1200 principal investigators at UCSF, including 4 Nobel laureates, 42 members of the National Academy of Sciences and 75 members of the Institute of Medicine. Research funding for 2010 was ~$950 million/year, including ~$475 million from NIH: our Schools of Dentistry ($20 M), Nursing ($10 M), and Pharmacy ($23 M) each ranked #1 nationally, and the School of Medicine ($422 M) ranked #2 in NIH funding. Thus scientific excellence pervades the campus.

The UCSF Benioff Children's Hospital is presently a 'hospital-within-a-hospital' at UCSF and accounts for about 25% of the total clinical activity at UCSF Medical Center. In its present configuration within the UCSF Medical Center on Parnassus Avenue, the UCSF Benioff Children's Hospital has 183 beds (excluding well baby bassinettes) in the following units: 67 inpatient medical and surgical beds, 16 intensive care beds, 8 cardiac intensive care beds, 7 bone marrow transplant beds, 5 Pediatric Clinical research Center beds, 51 intensive care nursery beds, 29 perinatal beds, and 12 well baby bassinettes. In 2009-10 there were 5,147 (7,289 including OB) admissions to the Children's Hospital. The general pediatric clinics saw 40,590 visits in 2009-10 and the subspecialty clinics saw 19,714 visits; of these, 4,269 were in pediatric endocrinology.

A new 283-bed Children's, Women's and Cancer Hospital is now under construction on a 14.5 acre plot directly adjacent to the 43 acre UCSF Mission Bay Campus, and is scheduled to open in 2015. The Benioff Children's Hospital, assisted by a $100 million gift from Marc and Lynne Benioff, will occupy 189 of these 283 beds. This new Children's Hospital will include state of the art facilities for translational research with faculty fully integrated into the Mission Bay research campus. Plans are also being developed for new ambulatory facilities along with space for faculty offices, which are also intended to accommodate anticipated expansion of laboratory, clinical, and translational research within the Department of Pediatrics. With the administrative offices of the Clinical and Translational Sciences Institute (CTSI) to be located adjacent to Mission Bay, and as UCSF continues with construction of the 43-acre Mission Bay campus, the Benioff Children's Hospital faculty and trainees will be uniquely positioned to take maximum advantage of the UCSF tradition of research collaboration.

The Clinical and Translational Sciences Institute (CTSI)

UCSF was one of the first twelve academic institutions selected to be part of the NIH's national clinical and translational science consortium, resulting in the creation of the Clinical and Translational Sciences Institute (CTSI). The consortium has a charter to transform clinical and translational research to ensure that the best health solutions get to patients as quickly as possible. The UCSF CTSI is a cross-campus institute. The four major goals of the CTSI are to: 1) enhance, support, and integrate existing training programs, thereby increasing the number and quality of programs, and providing trainees from diverse disciplines with the knowledge, skills, and motivation to make significant contributions to clinical and translational research; 2) enhance, support, and integrate existing infrastructure, thereby implementing changes required to foster the

design and conduct of a diverse spectrum of high quality, original clinical investigation and translational research: 3) enhance career development of faculty and trainees involved in clinical investigation and translational research by providing mentoring, providing opportunities to catalyze original research, and changing the academic culture to appropriately reward original, multidisciplinary, collaborative work; and 4) create a "virtual home" for clinical and translational researchers, thereby nurturing communication, encouraging collaboration, fostering original ideas, and catalyzing the successful conduct of clinical investigation and translational research.

The Pediatric Clinical Research Center (PCRC)

The UCSF PCRC, which was continuously funded by the NIH as a free standing Clinical Research Center from 1967 through 2006, is now part of the unified CTSI Clinical Research Centers (CCRC). The UCSF CTSI-PCRC provides resources for investigator initiated and industry-funded clinical research in a 2,000 sq ft facility located in Moffitt Hospital 6th floor. Available research space relevant to our proposed outpatient study includes 2 outpatient exam rooms, additional rooms for psychosocial assessments, and a conference room for discussion and consenting. The facility is in close proximity to Dr. Rosenthal's office in the Pediatric Endocrinology Divisional space. The PCRC currently provides infrastructure for 78 active principal investigators with 125 approved protocols, and in the past fiscal year had 2,159 outpatient visits and 1,510 inpatient days, with 40 resultant publications. All protocols for research conducted in the PCRC are approved both by the Committee on Human Research/UCSF and by the PCRC Advisory Committee. The PCRC is funded by an NIH National Center for Research Resources (NCRR) grant M01 RR01271. It is one of 77 General Clinical Research Centers nationwide and one of only nine discrete Pediatric Clinical Research Centers.

UCSF Child and Adolescent Gender Center (CAGC)

Under the directorship of Dr. Rosenthal, Professor of Pediatrics and Program Director for Pediatric Endocrinology, the UCSF Child and Adolescent Gender Center (CAGC) is one of the leading centers for the multidisciplinary care of transgender youth in the U.S., and serves as the Pediatric/Adolescent clinical arm of the widely recognized UCSF Center of Excellence for Transgender Health. Housed in the Division of Pediatric Endocrinology at the UCSF Benioff Children's Hospital, the CAGC offers patients and their families an integrated and coherent set of services – medical, mental health, educational, legal, and other forms of advocacy – across the span of childhood and young adulthood, empowering families to more effectively plan for the current and future needs of their gender diverse children. Through a unified network of multi-disciplinary professionals, the CAGC serves to develop and provide best clinical practices, create greater acceptance of gender diversity in schools and other institutions, provide advocacy, influence public policy, and conduct research aimed at enhancing the healthy development and wellbeing of transgender children, adolescents, and young adults. In collaboration with Dr. Rosenthal, the UCSF CAGC provides mental health support under the direction of Diane Ehrensaft, PhD, internationally known child psychologist/gender specialist and widely recognized author, and advocacy support by Gender Spectrum, one of the leading national advocacy groups for transgender youth. The CAGC also provides nursing, social work, and legal support. The CAGC is the only such multi-disciplinary gender program in northern California, attracting patients not only from California, but from as far away as Alaska, Florida, and Egypt. A steady increase in referrals (8-10/month) has led to a quadrupling of services in the last two years. Dr. Rosenthal is a nationally and internationally recognized expert in the care of transgender youth, having been appointed as the official representative of the Pediatric Endocrine Society (PES) to the Endocrine Society (ES)'s Clinical Practice Guidelines Revision Task Force for the Care of Transgender Individuals, and was appointed to the World Professional Association for Transgender Health (WPATH) Consensus committee for revisions of the International Classification of Disease (ICD)-11 pertaining to transgender youth and adults. He has authored 7 manuscripts on transgender youth, including a recently in-press "State-of-the-Art" invited review in *Pediatrics* and an in-press invited review in the "Approach to the patient" series in the *Journal of Clinical Endocrinology & Metabolism*. He has been an invited speaker on transgender youth at annual meetings of PES and ES, as well as at the most recent international meeting of WPATH, and has lectured on this subject at academic centers throughout the U.S. Dr. Rosenthal is also the recipient of the 2013 UCSF Chancellor Award for LGBT Leadership in recognition of his work with transgender youth. As a reflection of its national and international impact, the UCSF CAGC is being featured in an upcoming documentary on transgender youth produced by the British Broadcasting Corporation (BBC).

UCSF Transgender Center of Excellence

The UCSF Transgender Center of Excellence (CoE) was established in 2007 with the mission to increase access to comprehensive, effective, and affirming health care services for transgender and gender-variant communities. The CoE combines the unique strengths and resources of a nationally renowned training and capacity-building institution, the Pacific AIDS Education and Training Center (PAETC), and an internationally recognized leader in HIV prevention research, the Center for AIDS Prevention Studies (CAPS), both of which are housed at UCSF. The ultimate CoE goal is to improve the overall health and well-being of transgender individuals by developing and implementing programs in response to community-identified needs. The CoE is currently implementing several programs for the transgender community with support from the U.S. Centers for Disease Control and Prevention (CDC), the California Endowment, and the NIH. These programs include Coalitions in Action for Transgender Community Health (CATCH): Project to increase community capacity to engage in HIV prevention activities; the Transitions Project, focused on training and assistance for programs seeking to implement HIV prevention interventions in transgender communities, particularly transgender communities of color; and the Transgender Evaluation and Technical Assistance Center (TETAC), focused on enhancing engagement and retention in quality HIV care for transgender women of color.

The UCSF Transgender CoE is linked with a range of clinical services which complement the educational, research, and capacity building missions of the CoE. The UCSF CAGC serves as the Pediatric/Adolescent clinical arm of the UCSF Transgender CoE. The multidisciplinary CAGC is complemented by transgender-focused clinical services in adult primary care, psychiatry, gynecology and gynecologic surgery, and urology and urologic surgery.

Laboratory

The Sample Processing Lab/Pediatric Clinical Research Center is a BSL 1 certified lab, occupying 600sqft in the UCSF Benioff Children's Hospital, 6th floor. It is staffed by 2 FTE providing services to UCSF investigators in routine sample processing, shipping and short-term storage for up to 3 months. The PCRC is equipped with two -80 C freezers, centrifuge, liquid nitrogen storage, CO_2 incubator, and bio-safety cabinets. The PCRC currently supports 55 active investigators with routine processing of blood, urine and other body fluids. On average, the PCRC receives up to 25 specimens per day for routine and specialized processing. Routine processing consists of labeling and identification, processing, shipping, and short-term storage. As a short term storage facility the PCRC lab offers specimen labeling with bar-coded freezer labels and tracking in a sample database. Each freezer is alarmed and monitored by the UC police department who notify PCRC staff of temperature fluctuations. The daily freezer temperature range is monitored twice daily and recorded. In the event of freezer malfunction, samples are transferred to PCRC back up freezers on the Adult CRC sample processing lab for investigator retrieval until the non-functioning freezer is repaired.

Office

Dr. Rosenthal has a 150 square foot office in close proximity to his clinical space. His office has a new PC computer and laser printer. His research staff occupies space nearby, and all are within a very short walk of the clinical space. The Department of Pediatrics at UCSF provides general office machines, faxes, photocopying, and office supplies.

Computer

Dr. Rosenthal's computer has word-processing capability, data analysis, and graphics software, and is connected to the Internet through a campus-wide server. Additional Macintosh and PC computers are available in the Division of Pediatric Endocrinology for use by faculty and staff. Computer support personnel are available through the Information Technology Department of UCSF.

Other

The UCSF library, built in 1990, is both a traditional library, containing extensive collections of scientific books and journals relevant to the study of endocrinology, and is also a teaching and database management facility with The Interactive Learning Center and Center for Knowledge Management. The UCSF Digital Library (GALEN II) offers easy access to a broad collection of databases, reference resources, electronic journals and catalogues of local materials. Through the newly created California Digital Library, students, trainees, and faculty are able to view and request materials from the 10 UC campus libraries. The UCSF library has 900,000 volumes including 2,600 current subscriptions. In addition to the journals and books in the library, the

Interactive Learning Centers maintain facilities for computing with PC and Macintosh computers, printers, software, documentation, consulting support, and connections to the internet, and electronic classrooms. The Multimedia Development Lab provides hardware, software, and consulting support for development of curriculum-integrated, educational materials. Education and Consulting Services offers curriculum-integrated instruction and seminars that assist students, fellows, and faculty in the use of databases, internet, and personal file management software. The Center for Knowledge Management develops knowledge bases and on-line tools for the health sciences, pursues applied research projects, and serves as a laboratory for graduate students interested in using new technologies to solve important health sciences information problems.

ARA acceptance: The Impact of Early Medical Treatment in Transgender Youth

Gorham, Vanessa (NIH/NICHD) [E] [gorhamva@mail.nih.gov]
Sent: Tuesday, February 04, 2014 12:26 PM
To: Olson, Jo
Cc: Freund, Lisa (NIH/NICHD) [E] [freundl@mail.nih.gov]; Hayunga, Eugene G. (NIH/NICHD) [E] [ehayunga@mail.nih.gov]; Dupere, Sherry (NIH/NICHD) [E] [duperes@mail.nih.gov]; Ledu, Melani (NIH/NICHD) [E] [LeduM@niaid.nih.gov]; Nguyen, Hien (NIH/NICHD) [C] [nguyenhi@mail.nih.gov]; Underwood, Brenda (NIH/NICHD) [E] [underwob@mail.nih.gov]; Gorham, Vanessa (NIH/NICHD) [E] [gorhamva@mail.nih.gov]

Dear Dr. Olson:

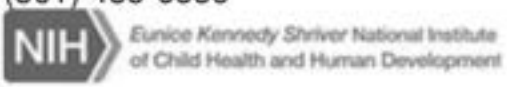
I am pleased to inform you that the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) has approved your request for a waiver of policy and will accept your large grant application for review. We have notified the NIH Center for Scientific Review (CSR) of this decision.

When you submit your application to CSR, please remember to indicate in a cover letter that you have contacted NICHD and that we have agreed to accept this application for review. You may include this letter as an attachment if you wish. Please also remember that all applications requesting $500,000 or more in any budget year are required to include plans for addressing the NIH Policy on Data Sharing (see http://grants.nih.gov/grants/policy/data_sharing/

Acceptance of your application for review does not guarantee that NICHD will fund the application or will fund it at the requested levels, regardless of the outcome of peer review.

Sincerely,

Vanessa Gorham
On behalf of
Eugene Hayunga, PhD
Director, OEP
The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)
Office of Extramural Policy
(301) 435-6856



NIH is in the process of converting to electronic submission of grant applications through Grants.gov, using the SF424 (Research and Related [R&M]) family of forms. Information on the transition plan and on registering for electronic submission is available at http://grants.nih.govkirants/guide/notice-files/NOT-OD-05-067.html Updates **regarding the transition process are at http://era.nih.gov/ElectronicReceipt**. This electronic mail (including any attachments) may contain information that is privileged, confidential, and/or otherwise protected from disclosure to anyone other than its intended recipient(s). Any dissemination or use of this electronic mail or its contents (including any attachments) by persons other than the intended recipient(s) is prohibited. If you have received this message in error, please notify me immediately by reply email so that we may correct our internal records. Please then delete the original message (including any attachments) in its entirety. Thank you.

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: Dr. First Name*: Johanna Middle Name Last Name*: Olson Suffix: M.D.

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Credential, e.g., agency login: (b)(6)

Project Role*: PD/PI Other Project Role Category:

Degree Type: MD Degree Year: 1997

File Name
Attach Biographical Sketch*: 1251-Olson Biosketch.pdf
Attach Current & Pending Support:

PROFILE - Senior/Key Person

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Project Role*: Co-Investigator Other Project Role Category:

Degree Type: MD Degree Year: 1987

File Name
Attach Biographical Sketch*: 1252-Belzer Biosketch.pdf
Attach Current & Pending Support:

PROFILE - Senior/Key Person

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Credential, e.g., agency login: (b)(6)

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: (b)(6) Degree Year: (b)(6)

File Name

Attach Biographical Sketch*: (b)(6)

Attach Current & Pending Support:

PROFILE - Senior/Key Person

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Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year: 2008

File Name

Attach Biographical Sketch*: 1254-Schrager Biosketch.pdf

Attach Current & Pending Support:

PROFILE - Senior/Key Person

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Project Role*: PD/PI Other Project Role Category:

Degree Type: MD Degree Year: 1969

File Name
Attach Biographical Sketch*: 1255-Spack Biosketch.pdf
Attach Current & Pending Support:

PROFILE - Senior/Key Person

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Project Role*: Co-Investigator Other Project Role Category:

Degree Type: MD Degree Year: 2008

File Name
Attach Biographical Sketch*: 1256-Shumer Biosketch.pdf
Attach Current & Pending Support:

PROFILE - Senior/Key Person

Prefix: (b)(6) First Name*: (b)(6) Middle Name (b)(6) Last Name*: (b)(6) Suffix: (b)(6

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County: Suffolk
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Country*: USA: UNITED STATES
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Phone Number*: (b)(6) Fax Number: (b)(6) E-Mail*: (b)(6)

Credential, e.g., agency login: (b)(6)

Project Role*: (b)(6) Other Project Role Category:

Degree Type: (b)(6) Degree Year: (b)(6)

File Name

Attach Biographical Sketch*: (b)(6)

Attach Current & Pending Support:

PROFILE - Senior/Key Person

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Project Role*: PD/PI Other Project Role Category:

Degree Type: MD Degree Year: 1992

File Name

Attach Biographical Sketch*: 1258-Garofalo Biosketch.pdf

Attach Current & Pending Support:

PROFILE - Senior/Key Person

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Project Role*: Co-Investigator Other Project Role Category:

Degree Type: MD Degree Year: 2007

File Name
Attach Biographical Sketch*: 1259-Simons Biosketch.pdf
Attach Current & Pending Support:

PROFILE - Senior/Key Person

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State*: IL: Illinois
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Phone Number*: (b)(6) Fax Number: 312-227-9461 E-Mail*: mhidalgo@luriechildrens.org

Credential, e.g., agency login: (b)(6)

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year: 2011

File Name
Attach Biographical Sketch*: 1260-Hidalgo Biosketch.pdf
Attach Current & Pending Support:

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Scott Middle Name Last Name*: Leibowitz Suffix: M.D.

Position/Title*: Attending Psychiatrist
Organization Name*: Lurie Children's Hospital of Chicago
Department: Pediatrics
Division: Adolescent Medicine
Street1*: 225 East Chicago Avenue, Box 10
Street2:
City*: Chicago
County: Cook
State*: IL: Illinois
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 60611-2605

Phone Number*: (b)(6) Fax Number: 312-227-9659 E-Mail*: SLeibowitz@luriechildrens.org

Credential, e.g., agency login:

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: MD Degree Year: 2004

File Name
Attach Biographical Sketch*: 1261-Leibowitz Biosketch.pdf
Attach Current & Pending Support:

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Courtney Middle Name Anne Last Name*: Finlayson Suffix: M.D.

Position/Title*: Attending Physician
Organization Name*: Lurie Children's Hospital of Chicago
Department: Pediatrics
Division: Adolescent Medicine
Street1*: 225 East Chicago Avenue, Box 54
Street2:
City*: Chicago
County: Cook
State*: IL: Illinois
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 60611-2605

Phone Number*: (b)(6) Fax Number: 312-227-9403 E-Mail*: cfinlayson@luriechildrens.org

Credential, e.g., agency login: (b)(6)

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: MD Degree Year: 2003

File Name
Attach Biographical Sketch*: 1262-Finlayson Biosketch.pdf
Attach Current & Pending Support:

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Joel Middle Name E Last Name*: Frader Suffix: M.D.

Position/Title*: Head, General Pediatrics and Primary Care
Organization Name*: Lurie Children's Hospital of Chicago
Department: Pediatrics
Division: Adolescent Medicine
Street1*: 225 East Chicago Avenue, Box 54
Street2:
City*: Chicago
County: Cook
State*: IL: Illinois
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 60611-2605

Phone Number*: (b)(6) Fax Number: 312-227-9403 E-Mail*: jfrader@northwestern.edu

Credential, e.g., agency login: (b)(6)

Project Role*: Other (Specify) Other Project Role Category: Ethicist

Degree Type: MD Degree Year: 1974

	File Name
Attach Biographical Sketch*:	1263-Frader Biosketch.pdf
Attach Current & Pending Support:	

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Stephen Middle Name M Last Name*: Rosenthal Suffix: M.D.

Position/Title*: Professor of Pediatrics
Organization Name*: University of California at San Francisco
Department: School of Medicine
Division: Pediatric Endocrinology
Street1*: 513 Parnassus Ave
Street2:
City*: San Francisco
County: San Francisco
State*: CA: California
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 94143-0296

Phone Number*: (b)(6) Fax Number: 415-476-8214 E-Mail*: rosenthals@peds.ucsf.edu

Credential, e.g., agency login: (b)(6)

Project Role*: PD/PI Other Project Role Category:

Degree Type: MD Degree Year: 1976

	File Name
Attach Biographical Sketch*:	1264-Rosenthal Biosketch.pdf
Attach Current & Pending Support:	

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Diane Middle Name Last Name*: Ehrensaft Suffix: Ph.D

Position/Title*: Adjunct Associate Professor of Pediatrics
Organization Name*: University of California at San Francisco
Department: School of Medicine
Division: Pediatrics
Street1*: 505 Parnassus Ave, Med Sci Room 696, Box 0110
Street2:
City*: San Francisco
County: San Francisco
State*: CA: California
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 94143-0296

Phone Number*: (b)(6) Fax Number: 510-547-7692 E-Mail*: dehrensaft@earthlink.net

Credential, e.g., agency login: (b)(6)

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year: 1974

File Name
Attach Biographical Sketch*: 1265-Ehrensaft Biosketch.pdf
Attach Current & Pending Support:

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: David Middle Name V Last Name*: Glidden Suffix: Ph.D

Position/Title*: Professor of Biostatistics
Organization Name*: University of California at San Francisco
Department: School of Medicine
Division: Division of Biostatistics
Street1*: 185 Berry Street, Lobby 5, Suite 5700
Street2:
City*: San Francisco
County: San Francisco
State*: CA: California
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 94143-0296

Phone Number*: (b)(6) Fax Number: 415-514-8150 E-Mail*: dave@biostat.ucsf.edu

Credential, e.g., agency login: (b)(6)

Project Role*: Co-Investigator Other Project Role Category:

Degree Type: PhD Degree Year: 1993

File Name
Attach Biographical Sketch*: 1266-Glidden Biosketch.pdf
Attach Current & Pending Support:

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Olson, Johanna L MD	PI/Assistant Professor of Clinical Pediatrics
eRA COMMONS USER NAME (credential, e.g., agency login) (b)(6)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of California San Diego	BA	1992	Animal Physiology
Chicago Medical School	MS	1993	Applied Physiology
Chicago Medical School	MD	1997	Medicine
Children's Hospital Orange County	Internship and Residency	2000	Pediatrics
Children's Hospital Los Angeles	Fellowship	2003	Adolescent Medicine

A. Personal Statement

The goal of the proposed research is to investigate the impact of early medical treatment in transgender children and adolescents presenting for care at four sites across the United States. As a pediatrician and a leading expert in the field of transgender youth care, I am confident that the proposed multi-site study will inform the development of evidence–based practices, thereby leading to improved health outcomes for this understudied and underserved population. I am uniquely suited to actualize the proposed research agenda. As Principal Investigator at the lead site, I will be responsible for overseeing coordination of care services for participants enrolled in the study at the CHLA site, as well as assist in the development of the implementation protocol and contribute to presentations and manuscripts based on study data. While I am early in my career, I am a recognized leader in the development of research and clinical care for transgender and gender non-conforming children and adolescents. I was selected by my colleagues (i.e. R. Garafolo, S. Rosenthal, and N. Spack) to provide leadership on this study in acknowledgement of my overall expertise and experience. I will be provided with mentorship from both my local site mentors (i.e. M. Belzer and L. Clark) as well as the other three site PIs, Drs. Garofalo, Rosenthal and Spack. I have the only active prospective study in the US investigating the impact of treatment of transgender youth. Over the last 4 years, I have developed research protocols, recruited and retained subjects and have initiated data analyses. I have been the recipient of two training grants to pursue research in the gender non-conforming and transgender youth populations; the first, a two year Clinical Research Career Development Award through the Saban Research Institute at CHLA and the second a KL2 translational science award from USC ending in June 2014. I am finishing a Master's Degree in Clinical and Biomedical Investigations at USC, and have two first author papers about transgender youth already published. I am the Medical Director of our Center for Transyouth Health and Development at CHLA. Over the past five years I have expanded the services of the Center to include care and consultative services for gender non-conforming and transgender children and adolescents ages 4 to 24. Over the past five years I have worked tirelessly to successfully quadruple the number of patients served by the Center, with 335 patients actively enrolled in the clinic at this time, making ours the largest transgender youth clinic in the US. Finally, I have made dozens of appearances across the country and on national television over the past 5 years to educate the community, parents and providers about the needs of transgender youth.

B. Positions and Honors

Positions and Employment

2006- USC/ Children's Hospital Los Angeles Assistant Professor of Clinical Pediatrics
2003-2005 University of California Los Angeles – 2003 – 2005

Professional Appointments

2011–present Medical Director of the Center for Transyouth Health and Development
2008-2012 Adolescent Medicine Fellowship Program Director
2003-2006 Pediatric Practice of Zimble/Reinstein
2004–2006 Northeast Valley Health Corporation
2002-2003 Kaiser Permanente, California Sunset

Professional Activity

2014 Medical Expert "A Report on Transgender Children" – CBS The Sunday Morning Show
2013 Medical Expert "Boy to Girl: One Child's Journey" – People Magazine – July 8, 2013
2013 Medical Expert Gender Non-conforming and Transgender Youth – Kids in the House Website
2012 Medical Expert "Trapped in the Wrong Body"– The Ricki Lake Show
2012 Medical Expert "Transgender Childhood" – Dateline
2012 Medical Expert – LA Times
2012 Medical Expert – Bruce Hentsel Show
2012 Medical Expert – Taboo
2012 Medical Expert Transgender Children - Dateline – July 2012
2011 Present Executive Board Member – TransYouth Family Allies
2011 Medical Expert – My Extraordinary Family – Nightline
2011 Medical Expert for the OWN Network – The DOC Club – Rosie O'Donnell/ Transgender Youth
2011 Medical Expert "Adolescents and Bullying"– Dr. Drew show
2009- Executive Board Member – The Champion Fund
2008 Audience Expert for the Dr. Phil Show – "Lost Little Boy"
2007 Medical Expert – "Born in the Wrong Body" – 20/20

Society Memberships

Society for Adolescent Health and Medicine
American Academy of Pediatrics
Los Angeles Pediatric Society
World Professional Association of Transgender Health

Honors

2009 Health Care Advocacy Champion – Democratic Advocates for Disability Issues.
2010 Clinical Research Academic Career Development Award -Saban Research Center TSRI Program: Community Health Outcomes and Intervention
Project: "Treating transgender youth: the impact of a multidisciplinary care team approach".
2012 Extraordinary Service Award – Equality California

C. Selected Peer-Reviewed Publications

Most relevant to the current application

1. **Olson J,** Schrager S M., Clark L F., Dunlap S L., Belzer M. Subcutaneous Testosterone: An Effective Delivery Mechanism for Masculinizing Young Transgender Men, LGBT Health. September 2014, 1(3): 165-167. doi:10.1089/lgbt.2014.0018.
2. **Olson J**, Garofalo R., The peripubertal gender-dysphoric child: puberty suppression and treatment paradigms. Pediatr Ann. 2014 Jun;43(6):e132-7. doi: 10.3928/00904481-20140522-08.
3. Hildago MA, Ehrensaft D, Tishelman AC, Clark LF, Garofalo R, Rosenthal SM, Spack NP, **Olson J.** The gender affirmative model: What we know and what we aim to learn. *Human Development*, 2013, 3: 285-290.
4. Simons L, Schrager S, Clark LF, Belzer M, **Olson J**. Parental support and mental health among transgender adolescents, *J Adol Health*, September 2013 (10.1016/j.jadohealth.2013.07.019).
5. **Olson J**, Clark L, Schrager S, Simons L, Belzer M. Baseline characteristics of transgender youth naïve to cross sex hormone therapy, *J Adol Health*, February 2013 (Vol. 52, Issue 2, Supplement 1, S35-S36.
6. **Olson J**, Forbes C, Belzer M. Management of the transgender adolescent, *Arch Pediatr Adolesc*. 2011;165(2): 171-176.

Additional recent publications of importance to the field (in chronological order)

7. Puccio, JA, Belzer M, **Olson J**, Martinez M, Salata C, Tucker D, Tanaka D. The use of cell phone reminder calls for assisting HIV infected youth to adhere to highly active antiretroviral therapy: A pilot study. *AIDS Patient Care and STDs*. June 1, 2005, 20(6): 438-444. doi:10.1089/apc.2006.20.438.
8. Belzer M, Sanchez K, **Olson J**, Jacobs A, Tucker D. Advance supply of emergency contraception: A Randomized Trial in Adolescent Mothers. *J Ped and Adolesc Gyn*. 2006, 8, 347-354.
9. Belzer ME, **Olson J.** Adherence in adolescents: A review of the literature. Adolescent Medicine: State of the Art Reviews. Evaluation and Management of Adolescent Issues. *Amer Acad of Peds* 2008:1999-117.
10. Belzer M, Naar-King S, **Olson J,** Kohana S, Mussa S, Thornton S, Gaur A, Clark LF. The use of cell phone support for non-adherent HIV-infected youth and young adults: A randomized and controlled intervention trial. *AIDS and Behav* 2013.

D. Research Support

Ongoing Research Support

KL2 Mentored Career Research Development Program of the Center for Education, Training and Career Development under the SC CTSI
The Impact of Hormone Blockers on the Physiologic and Psychosocial Development of Gender Non-Conforming Peri-Pubertal Youth
Role: PI

Treating Transgender Youth Olson (PI)
Examine the impact of a multidisciplinary treatment model on transgender youth starting cross sex hormones.
Role: PI

Descriptive Study of Transgender Patients at Children's Hospital Los Angeles
This study is a retrospective chart review of transgender patients treated for around one year with cross sex hormones to assess safety of treatment.
Role: Co-PI

U01HD040474 Korelitz (PI) 03/01/11-02/28/16
Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN)
The primary mission of the ATN is to conduct research, both independently and in collaboration with existing research networks and individual investigators, in HIV-infected and HIV-at-risk pre-adolescents, adolescents, and young adults up to age 25 years.
Role: Co-Investigator

Completed Research Support

N01-DK-8-0001 Belzer (Site PI) 12/16/07-08/31/14
IMPAACT, P1076: Impact of oral alendronate therapy on bone mineral density in HIV-infected children and adolescents with low bone mineral density.
Role: Co-Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Belzer, Marvin E. M.D.	Professor of Pediatrics and Medicine
eRA COMMONS USER NAME (credential, e.g., agency login) (b)(6)	

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.*)

INSTITUTION AND LOCATION	DEGREE (*if applicable*)	MM/YY	FIELD OF STUDY
University of California, Davis	BS	1981	Zoology
University of Southern California	MD	1986	Medicine
University of California Irvine Medical Center	Intern & Residency	1989	Internal Medicine
Children's Hospital Los Angeles	Fellowship	1991	Adolescent Medicine

A. Personal Statement

I am currently the Director of the Division of Adolescent and Young Adult Medicine at Children's Hospital Los Angeles and an Adolescent Medicine specialist since 1991. I began caring for transgender youth in 1991 and helped develop the first and largest youth-focused, transgender clinic in the United States. I have conducted several research studies looking at risks for female transyouth. I co-chaired the NICHD sponsored study of high risk transgender youth for the Adolescent Trials Network, which included mentoring the protocol chair (Erin Wilson, DrPH) while she was working on her DrPH at UC Berkeley. I have been a site PI In the NICHD supported REACH and ATN Networks for the past 20 years and the PACTG/IMPAACT Network for 15 years. I was the chair of the ATN clinical PI's for a total of 7.5 years and now the ATP representative to the Behavioral Leadership Group. I have extensive experience managing clinical trials and will assist Dr. Olson in managing this complex, 4-site, observational trial of transgender youth. I have been Dr. Olson's primary mentor for her transyouth research over the past 4 years (currently on year 2 of her CTSI KL2 award from the University of Southern California) and well positioned to provide her the support required to ensure this project is successful.

B. Positions and Honors

Positions and Employment

1991- Assistant Professor of Pediatrics and Medicine-University of Southern California
2003- Associate Professor of Pediatrics and Medicine-University of Southern California
2011- Professor of Pediatrics and Medicine-University of Southern California

Professional Appointments

1991- Medical Director, Risk Reduction HIV Program-Division of Adolescent Medicine, CHLA
1995-2006 Medical Director, Teenage Health Center-Division of Adolescent Medicine, CHLA
2006-2008 Associate Director of Research-Division of Adolescent Medicine, CHLA
2008- Director/Division Head-Division of Adolescent Medicine, CHLA

Other Experience and Professional Memberships

1991-2004 Chairman, Adolescent HIV Consortium, County of Los Angeles, California
1992-1993 Member, Adolescent Scientific Committee for AIDS Clinical Trials
1993-1994 Member, Pediatric Primary Therapy Working Group for AIDS Clinical Trials
1994-2001 Principal Investigator from Los Angeles for the Medicine HIV/AIDS Research Network (NIAID/NICHD/HIRSA/NIDA Funded) Clinical Science Group Chair, Steering/Executive Committee Member
1996-1999 Advisory Board Member, Redefining Actions and Decisions. Carbondale, Colorado
2002- Principal Investigator for the Los Angeles Site of the Adolescent Trials Network for HIV/AIDS
2002-2009 Adolescent HIV Trials Network, Chair Clinical PI's, Executive Committee member,

2011-2013	Site Performance Committee
2002-2006	Member Board of Directors, Los Angeles Physicians AIDS Forum
2002-	Journal Review Panel Member for Journal of Adolescent Health, Archives of Pediatric and Adolescent Medicine, Psychology, Public Policy and Law
2003-	American Academy of HIV Medicine Education Committee
2003-2008	AIDS Project Los Angeles IRB Member
2002-2010	American Board of Internal Medicine Representative to Adolescent Medicine Subboard Committee
2009-2010	American Board of Pediatrics Adolescent Medicine Subboard Chair
2014-	American Board of Pediatrics Adolescent Subboard Medical Editor
2005-2007	HRSA Web-based HIV Care, Education Project (Advisory Committee Member)
2005-2007	Member Los Angeles County Office of AIDS Programs and Policy Standards of Care Task Force
2006-	Children's Hospital Los Angeles GCRC/CTSI Local Advisory Committee
2007-	Children's Hospital Los Angeles GCRC/CTSI Local Advisory Committee Chair
2007-2009	Vice-chair of the Adolescent Trials Network Executive Committee

Society Memberships

Society for Adolescent Medicine-Fellow
American College of Physicians-Fellow
American Academy of HIV Medicine-HIV Specialist
World Professional Association for Transgender Health

C. Selected Peer-Reviewed Publications (Selected from 37 peer-reviewed publications)

Most relevant to the current application

1. Johanna Olson, Sheree M. Schrager, Leslie F. Clark, Shannon L Dunlap and **Marvin Belzer*.** Subcutaneous Testosterone: An Effective Delivery Mechanism For Masculinizing Transgender Men." LGBT Health. 2014;1:1-3. DOI:10.1089/LGBT.2014.0018
2. Simons L, Schrager SM, Clark LF, **Belzer M**, Olson J. Parental support and mental Health among transgender adolescents. *Journal of Adolesc Health.* 2013:53:791– 793.
3. Wilson EC, Iverson E, Garofalo R, Belzer M. Parental support and condom use among transgender female youth. J Assoc Nurses AIDS Care. 2012;23(4): 306-17.
4. Brennan J, Kuhns LM, Johnson AK, **Belzer M,** Wilson EC, Garofalo R. Syndemic theory and HIV-related risk among young transgender women: the role of multiple, co-occurring health problems and social marginalization. *American Journal of Public Health.* 2012;102:1751-7.
5. Olson J, Forbes C, **Belzer M**. Management of the transgender adolescent. *Arch Pediatr Adolesc.* 2011;165(2): 171-176.
6. Wilson EC, Garofalo R, Harris DR, **Belzer M**. Sexual risk taking among transgender male-to-female youths with different partner types. *American Journal of Public Health.* 2010:100:1500-1505.
7. Wilson, EC, Garofalo R, Harris RH, Herrick A, Martinez M, **Belzer M**. Transgender female youth and sex work: HIV risk and a comparison of life factors related to engagement in sex work. *AIDS Behavior*, 2009. DOI 10.1007/s10461-008-9508-8.

Additional recent publications of importance to the field (in reverse chronological order)

8. Schrager SM, Olson J, Beharry M, **Belzer M,** Goldsich K, Desai M, Clark LF. Young men and the morning after: a missed opportunity for emergency contraception provision? *J Fam Plann Reprod Health Care.* Jan 24, 2014. [Epub ahead of print].
9. **Belzer ME**, Naar-King S, Olson J, Sarr M, Thornton S, Kahana SY, Gaur A, Clark L. The use of cell phone support for non-adherent HIV-Infected youth and young adults: An initial randomized and controlled intervention trial. *AIDS and Behav.* 2013 DOI 10.1007/s10461-012-0661-3.
10. Garvie P, Flynn P, **Belzer M**, Britto P, Hu C, Grahm B, Neely M, McSherry G, Spector SA, Guar AH. Psychological Factors, beliefs about medication, and adherence of youth with HIV-1 in a multisite directly observed therapy (DOT) Pilot Study. *Journal of Adolescent Health.*2011:48;637-640.

11. Nugent NR, Brown LK, **Belzer M**, Harper GW, Naar-king S, Nachman S. Youth living with HIV and problem substance use: Elevated distress Is associated with nonadherence and sexual risk. *Journal of the International Association of Physicians in AIDS Care.* Online First, Feb 4, 2010 as doi:10.1177/1545109709709357472.
12. **Belzer ME**, Olson J. Adherence in adolescents: A review of the literature. Adolescent Medicine: State of the art reviews. Evaluation and management of adolescent issues. *Amer Acad of Peds.* 2008;1999-117.
13. Puccio JA, **Belzer M,** Olson J, Martinez M, Salata C, Tucker D, Tanaka D. The use of cell phone reminder calls for assisting HIV-Infected adolescents and young adults to adhere to HAART: A Pilot Study. *AIDS Patient Care and STDs.* 2006;20:438-444.
14. **Belzer MB**, Sanchez K, Olson J, Jacobs A, Tucker D. Use of advance supply of emergency contraception: a randomized trial in adolescent mothers. *J Adol Pediatr Adol Gyn.* 2005;18.
15. Murphy DA, **Belzer ME**, Durako SJ, Sarr M, Wilson CM, Muenz LR. Longitudinal antiretroviral adherence among adolescents infected with human immunodeficiency *virus. Arch Pediatr Adolesc Med.* 2005:159:764-770.

D. Research Support

Ongoing Research Support

U01HD040463 (Belzer), NIH/NICHD **04/16/01-02/29/16**
Adolescent Medicine Trials Network for HIV/AIDS Interventions

U01HD040533 **Wilson (PI)** **04/26/01-02/28/16**
NIH/NICHD via University of Alabama at Birmingham
ATN Coordinating Center
Role: Site PI

U01HD040474 **Korelitz (PI)** **04/01-02/28/16**
NIH/NICHD via Westat
Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN)
The primary mission of the ATN is to conduct research, both independently and in collaboration with existing research networks and individual investigators, in HIV-infected and HIV-at-risk pre-adolescents, adolescents, and young adults up to age 25 years.
Role: Site PI

CPIMP141084-01-00 **Martinez (Grantee Project Director)** **09/30/14-08/30/17**
Office of Minority Health
HIV/AIDS Initiative for Minority Men (AIMM)

Completed Research Support

N01-DK-8-0001 **Belzer (Site PI)** **12/16/07-08/31/14**
NICHD International and Domestic Pediatric and Maternal HIV Studies Coordinating Center
The International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network is a global collaboration of investigators, institutions, community representatives and other partners organized for the purpose of evaluating interventions to treat and prevent HIV infection and its consequences in infants, children, adolescents and pregnant/postpartum women through the conduct of high quality clinical trials.
Role: Site PI

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
(b)(6)	(b)(6)
eRA COMMONS USER NAME (credential, e.g., agency login)	
(b)(6)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
(b)(6)	(b)(6)	(b)(6)	(b)(6)

A. Personal Statement

(b)(6)

B. Positions and Honors

(b)(6)

(b)(6)

C. Selected Peer-reviewed Publications (b)(6)

(b)(6)

D. Research Support

(b)(6)

(b)(6)

(b)(6)

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Schrager, Sheree Michelle	Director of Research
eRA COMMONS USER NAME (credential, e.g., agency login)	
(b)(6)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Wellesley College, Wellesley, MA	BA	05/02	Mathematics, Psychology
University of Wisconsin – Madison, Madison, WI	MS	12/03	Psychology
University of Wisconsin – Madison, Madison, WI	MS	12/06	Statistics
University of Wisconsin – Madison, Madison, WI	PhD	05/08	Psychology

A. Personal Statement

As Co-Investigator, I will 1) advise the study core responsible for establishing standard procedures, merging collected data, and managing, analyzing, and reporting on data from all four study sites and 2) collaborate with the project PIs and Co-Is to provide scientific leadership and direction, particularly related to psychological variable measurement and operationalization. Specifically, I will provide direction to the CHLA site study coordinator, data collection staff, data manager, and biostatistician responsible for data management, cleaning, and analysis. I will also assist with survey development and constructing the protocols that will standardize our data collection and merging procedures; oversee the programming of final data collection instruments and pilot testing of ACASI programming logic; and provide advanced statistical consultation to the project, including diagnosing data problems, developing and executing analytical plans, and advising the analytic team on appropriate longitudinal data analysis methods and procedures. I maintain a similar role as Co-Investigator on a current longitudinal study of adolescent and young adult medical marijuana users (R01DA034067-01A1; PI: Lankenau), which is now successfully finishing its first year of data collection. I have several years' experience working productively with members of the CHLA study team (PI Olson, Co-Is Belzer and Clark), most recently on the PI's KL2 Mentored Research Career Development award, and I was a research mentor to a Co-I (Simons) at the Chicago site during her fellowship at CHLA. My history of NIH funding, extensive research and statistical training and experience, and progressive research management experience have prepared me well for the role of Co-Investigator on this study. As the Director of Research for Hospital Medicine at CHLA, my primary work is to develop the research skills of hospital-affiliated faculty and research staff in all aspects of quantitative research methodology, including experimental and non-experimental study design, survey development, study protocols, and data analysis and reporting, with a particular focus on advanced statistical methods. My primary research area has been the health, functioning, and risk behavior of adolescents and young adults, particularly sexual minority and transgender adolescents, which has allowed me to develop considerable expertise in the methods proposed in this R01 application. Specific areas of focus include psychometric analysis, multivariate statistics, and general linear models with corresponding expertise in a variety of analytic software packages. I am also an IRB member and experienced research project manager whose responsibilities include hiring and managing project staff; assisting with IRB protocol development; designing research protocols and instruments; ensuring compliance with IRB and funding source requirements; documenting research processes, including intervention, process, and evaluation data; and leading and participating in project-specific and general management training and meetings. This leadership experience will support me to facilitate the conduct of rigorous, collaborative, and productive research by the project team.

B. Positions and Honors

Positions and Employment

2002-2008 Graduate Research Fellow, University of Wisconsin – Madison, Madison, WI
2008-2009 Biostatistician, Children's Hospital Los Angeles, Los Angeles, CA
2008-2011 Consultant, Agile Mind, San Francisco, CA
2010-2012 Sr. Research Manager, Children's Hospital Los Angeles, Los Angeles, CA

2011-2013	Consultant, Children and Family Futures, Irvine, CA
2012-2013	Behavioral Research Administrator, Children's Hospital Los Angeles, Los Angeles, CA
2012-	Consultant, University of Southern California School of Social Work, Los Angeles, CA
2014-	Director of Research, Children's Hospital Los Angeles, Los Angeles, CA

Honors

2002	Wellesley College: Summa Cum Laude; Lewis Atterbury Stimson Prize in Mathematics; Departmental Honors in Mathematics and Psychology
	University of Wisconsin-Madison: Graduate Research Fellowship
2003-2006	National Science Foundation Graduate Research Fellowship
2006-2008	Interdisciplinary Training Program in Education Sciences Fellowship
2007	University of Wisconsin-Madison: Royalty Research Foundation Collaborative Research Award (also awarded 2005); Hertz Foundation Research Travel Award (also awarded 2005, 2006); Vilas Travel Grant Award
	Society for Personality and Social Psychology Graduate Student Poster Award

C. Selected Peer-Reviewed Publications

Most relevant to the current application:

1. Olson J, **Schrager SM**, Clark LF, Dunlap SL, Belzer M. Subcutaneous testosterone: An effective delivery mechanism for masculinizing young transgender men. *LGBT Health*. 2014;1(3):165-167.

2. Simon LK, **Schrager SM**, Clark LF, Belzer M, Olson J. Parental support and mental health among transgender adolescents. *J Adolesc Health*. 2013;53(6): 791-793.

3. **Schrager SM**, Olson J, Beharry M, Belzer M, Goldsich K, Desai M, Clark LF. Young men and the morning after: A missed opportunity for emergency contraception provision? *J Fam Plann Reprod Health Care*. 2014 Jan 24 [Epub ahead of print].

Additional recent publications of importance to the field:

4. Wu S, Baker C, Lang ME, **Schrager SM,** Liley FF, Papa C, Mira VM, Balkian A, Mason WH. A randomized controlled trial of nebulized hypertonic saline for bronchiolitis. *JAMA Pediatr*. 2014;168(7):657-663.

5. **Schrager SM**, Latkin C, Weiss G, Kubicek K, Kipke MD. High risk sexual activity in the House and Ball community: Influence of social networks. *Am J Public Health*. 2014;104(2):326-331.

6. Goldbach JT, **Schrager SM**, Dunlap SL, Holloway IW. The application of minority stress theory to marijuana use among sexual minority adolescents. *Subst Use Misuse*. In press.

7. Herrick A, Stall RD, Egan JH, **Schrager SM**, Kipke MD. Pathways towards risk: Syndemic conditions mediate the effect of adversity on HIV risk behaviors among young men who have sex with men (YMSM). *J Urban Health*. In press.

8. Holloway IW, **Schrager SM**, Wong CF, Smith L, Kipke MD. Network correlates of sexual health advice seeking and substance use among members of the Los Angeles House and Ball communities. *Health Educ Res*. 2014;29(2):306-318.

9. Wong CF, **Schrager SM**, Holloway IW, Meyer IH, Kipke MD. Minority stress experiences and psychological well-being: The impact of support from and connection to social networks within the Los Angeles House and Ball communities. *Prev Sci*. 2014;15(1):44-55.

10. Traube DE, **Schrager SM**, Holloway IW, Weiss G, Kipke MD. Environmental risk, social cognition, and drug use among young men who have sex with men: Longitudinal effects of minority status on health processes and outcomes. *Drug Alcohol Depen*. 2013;127(1):1-7.

11. Kecojevic A, Wong CF, **Schrager SM**, Silva K, Jackson Bloom J, Iverson E, Lankenau SE. Initiation into prescription drug misuse: Differences between lesbian, gay, bisexual, transgender (LGBT) and heterosexual high-risk young adults in Los Angeles and New York. *Addict Behav*. 2012;37(11):1289-1293.

12. **Schrager SM**, Do C, Holloway IW, Cheng EM, Chen AY. Profile of insurance coverage in a national inpatient sample. *American Journal of Public Health Research*. 2013;1(1):27-31.

13. Chen AY, **Schrager SM**, Mangione-Smith R. Quality indicators for primary care of complex pediatric patients. *Pediatrics*. 2012;129(3):433-445.

14. Traube DE, Holloway IW, **Schrager SM**, Kipke MD. Utilizing Social Action Theory as a framework to determine correlates of illicit drug use among young men who have sex with men. *Psychol Addict Behav*. 2012;26(1):78-88.

15. **Schrager SM**, Wong CF, Weiss G, Kipke MD. HIV testing and risk behaviors among young men who have sex with men in Los Angeles County. *Am J Health Promot*. 2011;25(4):244-247.

D. Research Support

Ongoing Research Support

R21 HD 082813-01A1 (Goldbach/Schrager), 09/25/14 – 08/31/16
National Institute of Child Health and Human Development (NICHD)
"Measuring Stress Among Diverse Adolescents"
Although sexual minorities consistently report health disparities compared to heterosexuals, the relationship between minority stressors and negative health outcomes remains unclear due to lack of available measures. We will develop an instrument to measure minority stress among racial and ethnically diverse LGBT adolescents. Results will support operationalization of minority stress constructs for adolescents, development of targeted health interventions, and opportunities to measure minority stress in longitudinal designs.
Role: Co-Principal Investigator

R01 DA 034067-01A1 (Lankenau), National Institute on Drug Abuse (NIDA) 07/01/13 – 06/30/18
"Medical Marijuana, Emerging Adults & Community: Connecting Health and Policy"
This five-year study will determine whether: (1) young medical marijuana (MM) patients experience an overall improvement in physical and psychological health; (2) young MM patients experience changes in patterns of misuse of alcohol, prescription, and illicit drugs; and (3) MM dispensaries exert positive or negative effects on emerging adults in their communities. Findings will guide members of the public health community towards devising MM policies that maximize health and minimize negative effects on youth and communities.
Role: Co-Investigator

R01 DA032600-01A1 (Traube), National Institute on Drug Abuse (NIDA) 09/30/12 – 08/31/15
"Isolating Targets with Existing Data to Prevent Teen Drug Use in Child Welfare"
We will conduct analyses of an extant national probability cohort of child welfare involved teens to determine the prevalence and impact of substance use, predictors of substance abuse over the course of adolescent development, and the role that current child welfare services play in ameliorating substance use and abuse.
Role: Co-Investigator

U18 HS020506-01 (Mangione-Smith), 03/01/11 – 02/28/15
Agency for Healthcare Research and Quality (AHRQ)
"Center of Excellence on Quality of Care Measures for Children with Complex Needs"
The quality of care measures to be developed under this award will provide new tools to rigorously and comprehensively evaluate health care for children with complex needs. These measures will be designed for dissemination and use among all Medicaid and Child Health Insurance Programs (CHIP) nationally.
Role: Site Principal Investigator (July 2014-present)

Completed Research Support

KL2 Mentored Research Career Development Program (Olson), 07/01/12 – 06/30/15
Southern California Clinical and Translational Science Institute
"The Physiologic and Psychosocial Development of Gender Non-Conforming Youth"
The purpose of this study was to collect preliminary data on puberty suppression with GnRH analogues, measuring bone mineral density, hormone levels and anthropometric measures including Tanner staging, linear growth, weight and BMI in transgender peri-pubertal youth. Additionally, this study examined the impact of GnRH analogues on depression, anxiety, quality of life, body esteem and suicidal ideation.
Role: Research mentor and biostatistician

R01 HL088503-01A2 (Mangione-Smith; Chen), 03/01/09 – 02/28/14
National Heart, Lung, and Blood Institute (NHLBI)
"Developing Quality Measures to Assess Pediatric Inpatient Respiratory Care"

We developed a rigorously designed quality of care assessment tool to examine the degree to which hospitals caring for children adhere to recommended standards of care for respiratory illness and to determine the feasibility and validity of using administrative data to make these assessments. We used the tool to assess inpatient management for children treated for asthma, bronchiolitis, croup, pneumonia, and cystic fibrosis.
Role: Project manager and biostatistician

K02 HS018087-01 (Chen), Agency for Healthcare Research and Quality (AHRQ) 07/01/09 – 06/30/12
"Measuring Quality of Primary Care in Complex Pediatric Patients"
Children with complex medical conditions (i.e., a developmental condition or two or more chronic conditions) are often managed by multiple providers, but the chronic and complex nature of these conditions, coupled with fragmented interaction and communication, can lead to inconsistent and poorly managed care. Our main objective was to develop a set of rigorously designed medical-record-based quality of care measures using the medical home concept to assess primary care of complex pediatric patients.
Role: Project manager

R01 DA-022968-01 (Kipke), National Institute on Drug Abuse (NIDA) 04/01/08 – 03/31/12
"African American Young Men's Study"
The purpose of this study was to understand and characterize the structural, social, and cultural characteristics of the Ball and House communities in Los Angeles; Ball and House members' use of illicit drugs, involvement in HIV risk and protective behaviors, and their social and sexual networks; and the role that rejection, discrimination and internalized homophobia play with respect to encouraging drug use and HIV risk.
Role: Biostatistician

R01-DA-021299-04 (Lankenau), National Institute on Drug Abuse (NIDA) 09/01/07 – 08/31/11
"Non-Medical Prescription Drug Use Among High-Risk Youth"
This was a comparative study of high-risk youth aged 16 to 25 in New York City and Los Angeles who were homeless, polydrug users, and/or injection drug users. We sought to describe why high-risk youth initiate non-medical prescription drug use, describe variability in the forms of prescription drugs available and behavioral practices employed in their administration, chart the social trajectory of the transition from prescription drug use into other types of controlled substances, and assess the consequences of chronic use of prescription drugs on increased risk for onset of behaviors associated with exposure to HIV and STIs.
Role: Biostatistician

R03-DA-024976-02 (Traube), National Institute on Drug Abuse (NIDA) 09/01/08 – 05/31/11
"Drugs, Sexual Impulsivity, HIV: Psychosocial and Cognitive Risk Factors of YMSM"
This study aimed to empirically validate the chain of relationships depicted in Social Action Theory (SAT) to determine if the theory addresses the interaction of individual, contextual, and social correlates of sexual and drug risk taking behaviors as they relate to YMSM. We further validated SAT by testing and incorporating competing relationships depicted in other behavioral models to develop a comprehensive theory of the social, psychosocial and cognitive risk factors for drug use, sexual impulsivity, and HIV among YMSM.
Role: Biostatistician

R21-DA-024588-01 (Kipke), National Institute on Drug Abuse (NIDA) 02/15/08 – 01/31/10
"HIV Prevention for High Risk African American Young Men"
This study adapted an existing, evidence-based HIV prevention intervention, *Project AIM* (Adult Identity Mentoring), for use with 18-24 year old African American young men who have sex with men (AAYMSM). This study adapted *Project AIM* to be developmentally appropriate and culturally relevant for use with AAYMSM in Los Angeles and pilot tested the feasibility and acceptability of the adapted intervention.
Role: Biostatistician

5-R01-DA-15638-03 (Kipke), National Institute on Drug Abuse (NIDA) 09/01/03 – 06/30/09
"Drug Use, Sexual Risk and Health Promoting Behaviors Among At-Risk Youth"
This study involved community-based, theory-driven longitudinal research with an ethnically diverse cohort of at-risk young men to examine individual, familial, social, and interpersonal risk and protective factors associated with drug use and HIV risk behaviors.
Role: Biostatistician

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Spack, Norman MD	Associate Clinical Professor in Endocrinology
eRACOMMONS USER NAME (credential, e.g., agency login) (b)(6)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Williams College, MA	BA	06/65	Biology
University of Rochester School of Medicine and Dentistry, NY	MD	06/69	Medicine
Boston City Hospital, MA	Intern and Resident	06/72	Pediatrics
Children's Hospital Boston, MA	Fellow	06/75	Adolescent Medicine
Children's Hospital Boston, MA	Fellow	06/77	Diabetes
Children's Hospital Boston, MA	Fellow	06/93	Pediatric Endocrinology

A. Personal Statement

Norman Spack, M.D., is a Senior Associate in the Endocrine Division at Children's Hospital, Boston, and Associate Clinical Professor of Pediatrics at Harvard Medical School. A 1965 graduate of Williams College, he received his MD from University of Rochester School of Medicine and Dentistry in 1969. He completed a Pediatric Residency at Boston City and Children's Hospitals and fellowships in Adolescent Medicine and Endocrinology at Children's, where he was on the team that first used the A1c test in a pediatric population. In 1978, Dr. Spack co-founded the first community-based private practice of Adolescent Medicine in New England. In 1998, he was appointed Clinical Director of the Endocrine Division. He served on the Admissions Committee of Harvard Medical School and is on the Peer Review Committee of Children's Hospital.

He was a member of the 2005 International Consensus Conference on Intersex and on the Endocrine Society's 7-person international task-force that published clinical guidelines for the management of transsexual adolescents and adults in 2009.

Dr. Spack has received awards for his teaching, clinical care, and community service and has mentored dozens of endocrinologists, some now chairing pediatric endocrine deptartments. In 2007, with David Diamond M.D., he co-founded Children's Hospital's GeMS, Gender Management Service, an interdisciplinary clinical program for patients with Disorders of Sex Development (Intersex) or Transgenderism. It is the first such program outside of Europe. He was lead author in a March 2012 Pediatrics article on transgender youth, the first article on that subject in that journal. His review article on transgenderism appeared in JAMA in 2012.

The goal of the proposed research is to investigate early medical treatment in transgender youth. Specifically, we will evaluate the impact of GnRH agonists administered for suppression of puberty on mental health and metabolic parameters and the safety and effect of cross-sex hormones. While these treatments are currently suggested by The Endocrine Society's Clinical Practice Guidelines, they have not been studied extensively in the U.S. population. Dr. Spack, as the co-founder and director of the GeMS program at Boston Children's Hospital, is well suited to lead the institution's participation in this important proposal.

B. Positions and Honors

Positions and Employment

1977-78 Instructor in Pediatrics- Harvard Medical School
1978-96 Clinical Instructor in Pediatrics- Harvard Medical School
1997-12 Assistant Professor of Pediatrics- Harvard Medical School

2013 Associate Clinical Professor of Pediatrics- Harvard Medical School

Appointments at Hospital/Affiliated Institutions

1974-98 Courtesy Staff -Saints Memorial Medical Center, Lowell, MA
1976-80 Assistant in Medicine-Children's Hospital Boston
1978-98 Active Staff-Newton-Wellesley Hospital, Newton, MA
1981- Associate in Medicine-Boston Children's Hospital
1983-95 Medical Staff-N.E. Deaconess Hospital, Boston, MA
1990-95 Medical Staff-Waltham-Weston Hospital, Waltham, MA
1999-01 Active Staff-Lowell General Hospital, Lowell, MA
1999-01 Consulting Staff-St. Elizabeth's Hospital, Boston, MA
1999-10 Consulting Staff-Caritas Norwood Hospital, Norwood, MA

Other Professional Positions

1974-84 Liaison to Children's Hospital- Bridge Over Troubled Waters, Boston, MA
1981-85 Medical Advisory Board- Bridge Over Troubled Waters, Boston, MA
1985-89 Medical Consultant- Multi-Service Center of Newton, MA
1987-92 Coordinator, Prospective Study of Vascular Complications in Adolescent Diabetics- Eye Research Institute Boston and Baylor University School of Medicine
1993-99 Director- Diabetes & Endocrine Youth Program, Saints Memorial Med Center, Lowell, MA
1999-01 Director- Pediatric Endocrine Clinic, Lowell General Hospital, Lowell, MA

Other Experience and Professional Memberships

1975-2002 American Academy of Pediatrics- Member
1975- Society for Adolescent Medicine- Writer, Endocrine Section, First Board Examination
1978- Massachusetts Medical Society- Member
1993- Project Hope Medical Alumni- Member
1996- Harry Benjamin International Gender Dysphoria Association (WPATH)- Member& Abstract Reviewer for Biennial International meeting
1996- Lawson Wilkins Pediatrics Endocrine Society- Member
1997- The Endocrine Society- Member
2005- Standing committee on Disorders of Sex Development, Pediatric Endocrine Society- Member
2005- Standing committee on Disorders of Sex Development, Pediatric Endocrine Society- Member
2008-09 Endocrine Society International Task Force on Clinical Management of Transsexual Persons and co-author of the resulting published Guidelines- Member

Honors

1964 Williams College: Lehman Scholar College; Undergraduate service to college.
1985 Anne Woolf Award: Juv. Diabetes Assoc of Greater Boston for Service to Children with Diabetes
1987 Mead Johnson Clinical Scholar: Dept of Medicine; Teaching
1994 Children's Hospital: Service; Employee Recognition Award
1996 Janeway Service Award: Department of Medicine; Service
2012 David Weiner Award to GeMS from Children's Board of Trustees for Leadership Innovation in Child Health
2012 Annual lecture in honor of John F. Crigler, Jr. MD, Dept of Medicine Grand Rounds ,Sponsored by Endocrine Division
2012 Bicentennial Medal from Williams College for Lifetime Achievement in Transgender Care/Advocacy

C. Selected Peer-reviewed Publications

1. Tishelman A, Kaufman R, Edwards-Leeper L, Madel, F, Shumer DE, **Spack, N**. Serving transgender youth: challenges, dilemmas, and clinical examples. Prof Psychol-Res Pr. 2014. In press.
2. **Spack NP.** Clinical Crossroads, Management of Transgenderism. *JAMA*. 2013;209(5):478-484.
3. **Spack NP,** Edwards-Leeper L, Feldman HA, Leibowitz S, Mandel F, Diamond DA, Vance SR. Characteristics of children and adolescents with gender identity disorder referred to a pediatric medical center. *Pediatrics*. 2012;129(3):418-425.

4. Perrin E, Smith N, Davis C, **Spack N,** Stein MT. Gender variant and gender dysphoria in two young children. *J Dev Behav Pediatr*. 2010;31(2):161-4.
5. Goddard DS, Liang MG, Chamlin SL, Svoren BM, **Spack NP**, Mulliken JB. Hypopituitarism in PHACES Association. *Pediatric Dermatology*,2006. Sept-Oct;23(5):476-80.
6. Poussaint TY, Barnes PD, Anthony DC, **Spack NP**, Scott RM, Tarbell NJ. Hemorrhagic pituitary adenomas of adolescence. *American Journal of Neuro-radiology*. 1996;17:1907-12.
7. Feke GT, Buzney SM, Ogasawara H, Fujio N, **Spack NP**, Gabbay KH. Retinal circulatory abnormalities in type 1 diabetes. *Investigative Ophthalmology & Visual Science*. 1994;35: 2968-75.
8. Gabbay KH, **Spack NP**, Loo S.Hirsch HF and Ackil A. Aldose Reductase Inhibition: Studies with Alrestratin. *Metabolism*. 1979;28(4):471–6.

D. Research Support

Dr. Spack is not supported by grants

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Daniel Shumer, MD	Fellow in Endocrinology
eRACOMMONS USER NAME (credential, e.g., agency login) (b)(6)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Northwestern University, Chicago, IL	BA	08/03	Psychology
Northwestern University, Feinberg School of Medicine, Chicago, IL	MD	05/08	Medicine
University of Vermont / Vermont Children's Hospital	Residency	06/11	Pediatrics
University of Vermont / Vermont Children's Hospital	Chief Resident	06/12	Pediatrics
Harvard University / Boston Children's Hospital, MA	Fellow	Current	Pediatric Endocrinology
Harvard School of Public Health, Boston, MA	MPH (expected)	Current	Clinical Effectiveness

A. Personal Statement

The goal of the proposed research is to investigate early medical treatment in transgender youth. Specifically, we will evaluate the impact of GnRH agonists administered for suppression of puberty on mental health and metabolic parameters and the safety and effect of cross-sex hormones. While these treatments are currently suggested by The Endocrine Society's Clinical Practice Guidelines, they have not been studied extensively in the U.S. population. As a fellow at Boston Children's Hospital (BCH), I have dedicated my clinical time and research to the transgender health care. I have participated in the transgender clinic at BCH since the beginning of fellowship and now care for my own patient cohort. My research focuses on measuring mental health parameters in the transgender patient population. I am also receiving a Masters of Public Health at Harvard School of Public Health as a fellow in the Harvard Pediatric Health Services Research Fellowship. This fellowship is training me for a research and clinical career in the transgender field. I plan to continue as faculty at BCH after fellowship in July 2015 with an administrative, clinical, and research role in the transgender program. The clinical and research skills I have been acquiring during my fellowship have prepared me to contribute to this important project as a co-investigator.

B. Positions and Honors

Positions and Employment

2008-2009 Pediatric Internship, Vermont Children's Hospital, Burlington, VT
2009-2011 Pediatric Residency, Vermont Children's Hospital, Burlington, VT
2011-2012 Pediatric Chief Resident, Vermont Children's Hospital, Burlington, VT
2012- Pediatric Endocrinology Fellow, Boston Children's Hospital, Boston, MA
2013- Investigational Review Board Member, The Fenway Institute, Boston, MA
2013- Research Fellow, Harvard Pediatric Health Services Research Fellowship, Boston, MA

Other Experience and Professional Memberships

2012- Pediatric Endocrine Society

C. Selected Peer-reviewed Publications

1. **Shumer DE**, Spack NP. Current management of Gender Identity Disorder in Childhood and Adolescence: Guidelines, Barriers and Areas of Controversy. *CurrOpinEndocrinol Diabetes Obes.* 2013;20(1):69-73
2. Reisner SL, Vetters R, Leclerc M, Zaslow S, Wolfrum S, **Shumer D**, Mimiaga, MJ. Mental health of transgender youth in care at an adolescent urban community health center: a matched retrospective cohort study. Journal of Adolescent Health. 2014. In press.
3. Tishelman A, Kaufman R, Edwards-Leeper L, Madel, F, **Shumer DE**, Spack, N. Serving transgender youth: challenges, dilemmas, and clinical examples. Prof Psychol-Res Pr. In press.
4. **Shumer DE**, Thaker V, Taylor GA, Wassner AJ. Severe hypercalcemia due to subcutaneous fat necrosis: presentation, management and complications. Arch Dis Child Fetal Neonatal Ed. 2014;99(5):F419-21.
5. **Shumer, DE**, Mehringer JE, Braverman LE, Dauber A. Acquired Hypothyroidism in an Infant Related to Excessive Maternal Iodine Intake: Food for Thought. Endocr Pract. 2013;19(4):729-31

D. Research Support

Ongoing Research Support

Dr. Shumer is currently supported by a training grant through June 2015: 1T32HD075727-01

Completed Research Support

No completed research projects for the past three years (Federal or non-Federally-supported).

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Amy C. Tishelman	Director of Clinical Research, Disorder of Sexual Development-Gender Management Service Director of Psychology, Department of Urology Boston Children's Hospital Director of Research, Child Protection Program Massachusetts General Hospital Assistant Professor, Harvard Medical School
eRA COMMONS USER NAME (credential, e.g., agency login) (b)(6)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Clark University, Worcester, MA	B.A.	1977	Psychology
West Virginia University, Morgantown, WV	M.A.	1985	Clinical Psychology
University of Oklahoma Health Sciences Center	Pre-Doctoral Internship	1987	Pediatric Psychology/ Neuropsychology
West Virginia University, Morgantown, WV	Ph.D.	1988	Clinical Psychology
Center for Advanced Study in the Behavioral Sciences, Stanford, CA	Summer Fellow	1990	Human Development and Psychopathology
Children's Hospital Boston/Harvard Medical School	Fellow	1992-94	Clinical Research Fellow on Family Violence
The Bunting Institute, Radcliffe College and Harvard Medical School/Boston Children's Hospital (Joint Fellowship)	Fellow	1993-95	Family Violence

A. Personal Statement

Amy C. Tishelman, Ph.D. is a clinical psychologist and an Assistant Professor at Harvard Medical School. She is currently Director of Clinical Research and a senior staff psychologist for the Disorders of Sexual Development-Gender Management Service (DSD-GeMS) at Boston Children's Hospital (BCH), where she has been asked to develop a clinical research program related to transgender and gender non-conforming youth, and youth with DSD. She also serves as BCH Director of Psychology in the Urology Department. In addition, Dr. Tishelman is Research Director and a senior staff psychologist for the Child Protection Program at Massachusetts General Hospital. Prior to her current appointments, she was the BCH Director of Research and Training for the Child Protection Program and, earlier, BCH Director of Child Protection Clinical Services (CPCS). She has an abiding interest in clinical work with vulnerable children and families, as well as in scholarship designed to enhance clinical care. Dr. Tishelman is on the editorial boards of several journals, including Child Abuse & Neglect, the Journal of Child Sexual Abuse (JCSA), and the Journal of Family Violence and is an Associate Editor of the Journal of Child and Adolescent Trauma (JCAT). She recently co-edited special double issues of both JCSA and JCAT. Additionally, Dr. Tishelman is a sought after expert in the forensic realm and speaks frequently on issues related to her areas of expertise. She is also a part-time faculty member in the Psychology Department of Boston College, where she has been employed since 1993, and is co-teaching a class annually on Child Maltreatment (with Robin Deutsch, Ph.D.) at the Massachusetts School of Professional Psychology in The Center of Excellence for Children, Families and the Law.

B. Positions and Honors

Positions and Employment

1986-1987 Clinical Psychology Intern, University of Oklahoma Health Sciences Center, Oklahoma City, OK
1987-1988 Lecturer, Department of Psychology, State University of New York, Binghamton, NY
1988-1992 Assistant Professor, Department of Psychology, State University of New York, Binghamton, NY

1993-	Part-time Faculty, Department of Psychology, Boston College, Chestnut Hill, MA
1994-2011	Instructor, Harvard Medical School, Boston, MA
1995-1997	Affiliated Clinician, Psychological Services, Inc. Brockton, MA
1995-2002	Senior Psychologist, Child Protection Program, Boston Children's Hospital, Boston, MA
1995-2003	Clinical Psychologist, Private practice, Cambridge, MA
1999-1999	Staff Psychologist, Child Protection Program, Boston Children's Hospital, Boston, MA
2002-2003	Supervising Psychologist, Optimal Weight for Life Clinic, Children's Hospital, Boston, MA
2002-2005	Director, Child Protection Program, Boston Children's Hospital, Boston, MA
2005-2012	Director, Training and Research, Child Protection Program, Children's Hospital Boston, MA
2011-	Assistant Professor, Harvard Medical School
2013-	Director of Clinical Research, Senior Staff Psychologist, Disorders of Sexual Development-Gender Management Service, Boston Children's Hospital, Boston, MA
2013-	Director of Psychology, Department of Urology, Boston
2013-	Director of Research and Senior Psychologist, Child Protection Program, Massachusetts General Hospital, Boston, MA
2113-	Part-time faculty, Massachusetts school of Professional Psychology

Selected Other Experience

2002-2012	Mental Health Consultant: Suffolk County Child Advocacy Center, Boston, MA
2003-2011	Disaster Response Network (DRN) Steering Committee, Massachusetts Psychological Association
2004-2006	Governors Commission on Sexual and Domestic Violence: Child and Adolescent Committee
2006-2011	Advisory Council, Department of Education Safe and Supportive Learning Environment Project
2007-2010	Ethics Advisory Committee, Children's Hospital Boston
2007-2010	Co-Chair, Child/Youth Services Committee, Governor's Council on Sexual and Domestic Violence, Patrick Administration
2008-2012	Co-Chair, Massachusetts, Guardians Ad Litem Task Force
2007-	Governor's Council on Sexual and Domestic Violence, Patrick Administration
2008-2011	Institutional Review Board (IRB), Children's Hospital Boston, Primary Representative, Psychiatry
2011-2014	Institutional Review Board (IRB), Children's Hospital Boston, Alternate Representative, Psychiatry

Editorial Leadership Roles

2007-2010	Editorial Board, Journal of Child and Adolescent Trauma
2010	Guest Co-Editor, Special Double Issue, Journal of Child Sexual Abuse: Tishelman & Geffner (Eds.), 2010. *Forensic, Cultural and Systems Issues in Child Sexual Abuse Cases,* Volume 19, 5 & 6.
2011	Guest Co-Editor, Special Double Issue, Journal of Child and Adolescent Trauma: Tishelman & Geffner (Eds.), 2011. *Child and Adolescent Trauma Across the Spectrum of Experience: Interpersonal and Ecological Factors. Journal of Child and Adolescent Trauma*
2010-	Editorial Board, Child Abuse and Neglect
2011-	Editorial Board, Journal of Child Sexual Abuse
2011-	Associate Editor, Journal of Child and Adolescent Trauma
2012-	Editorial Board, Journal of Family Violence

Selected Professional Memberships

American Psychological Association
World Professional Association on Transgender Health
Society of Pediatric Psychology

C. Selected Peer-reviewed Publications

Most relevant to the current application (in chronological order)

1. Bell-Dolan, D.J., Foster, S.L., **& Tishelman, A.C.** (1989). An alternative to negative nomination sociometric measures. *Journal of Clinical Child Psychology, 18*, 153-157.

2. Hansen, D.J., Smith, G.M., **Tishelman, A.C.,** Conway, L.P. & MacMillan, V.M. (1989). Parental problem-solving skills and child behavior problems: A comparison of physically abusive, neglectful, clinic and community families. *Journal of Family Violence, 4*, 353-368.
3. Hansen, D. J., **Tishelman, A. C.,** Hawkins, R. P., & Doepke, K. (1990). Habits with potential as Disorders: Prevalence, severity and other characteristics among college students. *Behavior Modification, 14*, 66-80.
4. Evans, I.M., Okifugi, A., Engler, L., Bromley, K & Tishelman, A.C. (1993). Home-school communication in the treatment of child behavior problems. *Child and Family Behavior Therapy, 15,* 37-60.
5. DeRoma, V.M., Hansen, D.J.,**Tishelman, A.C**. & D'Amico, P.(1997). Influence of information related to child physical abuse on professional ratings of adjustment and prognosis. Child Abuse and Neglect, 21, 293-308.
6. **Tishelman, A.C.,** Haney, P., Greenwald O'Brien, J & Blaustein, M. (2010). A framework for school-based psychological evaluations: Utilizing a 'trauma lens'. *Journal of Child and Adolescent Trauma*, 3 (4), 279-302.
7. **Tishelman, A.C.,** Meyer, S.K. Haney, P., McLeod, S.K. (2010). Clinical-Forensic dichotomy in sexual abuse evaluations: Moving toward an integrative model. *Journal of Child Sexual Abuse, 19 (*5), 590-608.
8. **Tishelman, A.C.** & Geffner, R. (2010). Forensic, cultural, and systems Issues in child sexual abuse cases: An introduction. *Journal of Child Sexual Abuse*, *19 (5)*, 485-490.
9. **Tishelman, A.C.** & Geffner, R. (2010). Forensic, cultural, and systems issues in child sexual abuse cases - Part 2: Research and practitioner issues. *Journal of Child Sexual Abuse, 19 (6)*, 609- 617.
10. **Tishelman, A.C**. & Geffner, R. (2011). Child and adolescent trauma across the spectrum of experience: Research and clinical interventions. *Journal of Child and Adolescent Trauma, 4,*1-7.
11. Geffner, R. & **Tishelman, A.C**. (2011). Child and adolescent trauma across the spectrum of experience: Underserved populations and psychological abuse. *Journal of Child and Adolescent Trauma, 4 (2)*, 87-89.
12. Williams, J. Nelson-Gardell, D., Faller, K., Cordisco-Steele & **Tishelman, A.C**. (2013). Is there a place for extended assessments for evaluating concerns about child sexual abuse? Perceptions of 1,294 child maltreatment professionals. *Journal of Forensic Social Work,* 88-105.
13. Hidalgo, M.A. , Ehrensaft, D., **Tishelman, A.C**., Clark, L., Garofalo, R., Rosenthal, S., Spack, N.P & Olson, J. (2013). The gender affirmative model: What we know and what we aim to learn. *Human Development,* 56, 285-290.
14. Williams, J. Nelson-Gardell, D., Faller, K.,**Tishelman, A.C.** & Cordisco-Steele, L.(2014). Is there a place for extended assessments in addressing child sexual abuse allegations? How sensitivity and specificity impact professional perspectives. *Journal of Child Sexual Abuse*, 23, 179-197
15. **Tishelman, A.C.,** Mandel, F. H., Kaufman, R., Edwards-Leeper, L. & Spack, N.P. (in press). Serving Transgender Youth: Clinical Practices, Challenges, and Dilemmas. *Professional Psychology: Research and Practice.*

D. Selected Ongoing and Completed Research Support

Funded

2009-2014: Domestic Violence and Child Interview Practices during Guardian Ad Litem Evaluations: A Preliminary Study
Surveys current approaches to the assessment of domestic violence in custody/access disputes by Custody Evaluators within and outside of Massachusetts.
Current Status: Data collection and analysis completed.
Role: PI

2014: Disclosure in Disorders of Sexual Development
This is a qualitative research study designed to better understand factors that impact how three populations of patients with DSD (Kleinfelter's Syndrome, Turner's Syndrome, and Complete Androgen Insensitivity Syndrome) experience disclosure of medical information, how they disclose to others, and factors impacting their quality of life and relationships.
Current Status: Research protocol successfully reviewed by Scientific Review Committee, and BCH IRB. This study is currently being reviewed by Compliance personnel at BCH. Internally funded by the Department of Urology at BCH.
Role: PI

2014: Cultural issues in Child Sexual Abuse Forensic Interviews: A Qualitative Approach
Qualitative project involving semi-structured interviews of staff involved in forensic interviews of children alleging child sexual abuse, in four geographic regions in the United States; examines important and frequent cultural issues perceived by these interviewers; internally funded by the Child Protection Program at MGH.
Current Status: Recently approved by IRB at MGH and at UMass Amherst. Active research will commence shortly.
Role: PI (with Lisa Fontes, Ph.D.)

Unfunded
2010: Psychosocial and Disclosure Information in Children Evaluated for Child Sexual Abuse: A Preliminary Study of Descriptive Information and Data Correspondence
In children referred for sexual abuse evaluations, behavioral and psychological status of the disclosing and non-disclosing child, from archival evaluation records.
Current Status: Data collection (A subset of this data is being used as part of the dissertation of a BCH staff member.)
Role: PI

2010-2014: Professional Perceptions of the Need for Extended Assessments
This is a collaborative study with colleagues at other institutions nationally (Faller, Nelson-Gardell, Cordisco-Steele & Tishelman) surveying professionals to gather information about 1) their perceptions and experience of the need for extended assessments of allegations of child maltreatemnet, 2) existing extended assessment resources in their communities, and 3) respondent expertise in conducting extended assessments.
Current Status: Data collection and analysis completed. Two publications have resulted from this study; we have a final research paper under review at present.
Role: PI

2013: Psychological Characteristics of Gender Dysphoric Adolescents Presenting for Evaluation and Possible Medical Treatment in a Pediatric Medical Center Gender Clinic
This study has created a database of patients seen for gender dysphoria in the Gender Management Service (GeMS) at Boston Children's Hospital. The database is being used to describe the psychological characteristics of adolescents requesting medical intervention in such a clinic.
Current Status: Data analysis
Role: PI (with Laura Edwards-Leeper, Ph.D. and Dan Shumer, M.D.)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Robert Garofalo MD, MPH	Division Head – Adolescent Medicine Professor of Pediatrics – Northwestern U.
eRA COMMONS USER NAME (credential, e.g., agency login) (b)(6)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Duke University; Durham, NC	BS	05/88	Biological Psychology
New York University School of Medicine; NY, NY	MD	06/92	Medicine
Harvard University School of Public Health; Boston, MA	MPH	06/99	Family and Community Health
Postdoctoral Training			
Children's Hospital of Philadelphia; Phila, PA	Intern	07/92-06/93	Pediatrics
Children's Hospital of Philadelphia; Phila, PA	Resident	07/93-06/95	Pediatrics
Children's Hospital; Boston, MA	Fellow	07/95-06/97	Pediatric Advocacy
Children's Hospital; Boston, MA	Fellow	07/00-06/01	Adolescent Medicine

A. Personal Statement

The primary aim of this proposal is to observational and longitudinal outcomes research related to medical interventions in gender non-conforming children and adolescents. As a pediatrician I believe this work to critically needed in the field to help inform evidence –based practices which is currently lacking as we advise and counsel parents and families. I feel my background in both clinical care and research as it relates to transgender health is well-suited to proposed research. My research career has focused on the collection of basic data on marginalized populations and the translation of this data into intervention development. I have extensive experience engaging transgender women and young MSM age 16-24, in longitudinal and STI/HIV prevention research. I have extensive experience running and being the site PI of clinical and translational research projects funded by the NIH. I have been PI or Co-PI on 6 NIH grants (3 specific to HIV risk among MSM), 2 CDC research grants, and Co-Investigator on 3 additional NIH grants. Across these projects I have developed the skills to lead interdisciplinary and multi-site clinical research teams. Specific to this application, I worked extensively over the past year with the other site PI's on this proposal. I am the Director of The Lurie Children's Hospital Center for Gender, Sexuality and HIV Prevention as well as the Co-Director of our Program in Gender and Sex Development. I also serve as the hospital's Division Head of Adolescent Medicine. I have over 10 years' experience doing clinical work with the proposed populations of youth and adolescents. I have led the formation of a multidisciplinary clinical and research team at our institution as they relate to gender non-conforming children and adolescents. I served on the Institute of Medicine Committee on "The Health of Lesbian, Gay, Bisexual and Transgender People" where my expertise in youth, transgender health and HIV were focal points of my involvement. It is the findings from this Committee that in large part motivate the proposed research. I will take primary responsibility for the implementation of the scientific aims of this project at Lurie Children's as well as the dissemination of our findings. I will appropriately mentor junior and Co-Investigators at my site including Dr.'s Hidalgo, Leibowitz, Finlayson and Simons as this is their primary academic and clinical interest but to-date have not had significant experience with NIH funded research. In addition, along with Dr. Belzer from Children's Hospital of Los Angeles, I will help co-mentor the contact PI Joanna Olsen as I have done throughout her young and promising career. While Dr. Olson may be relatively inexperienced with NIH-funded multisite clinical trials, it is my opinion that she is the emerging clinical leader in this field. The proposed network of 4 sites gave very careful consideration in deciding the contact PI for this proposal. I have fuill confidence that with the appropriate guidance and mentoring that Dr. Olson is ideally suited to lead this effort. She has my full support.

B. Positions and Professional Experience

1997-01	Instructor in Pediatrics, Harvard Medical School
1997	Health Policy Fellow: Office of Senator Edward M. Kennedy. Washington, DC.
1997-01	Assistant in Medicine/Attending Physician, Division of General Pediatrics Children's Hospital/Harvard Medical School, Boston, MA
1997-01	Director of Adolescent Medicine. JRI/Sidney Borum Community Health Center. Boston, MA.
2001-	Attending Physician, Division of General Academic Pediatrics/Infectious Diseases Lurie Children's Hospital (formerly Children's Memorial Hospital)/Northwestern University Medical School, Chicago, IL
2001-11	Program Director/Principal Investigator: PATH Youth Network. HRSA/Ryan White Title IV-funded collaboration for Adolescent HIV: Children's Memorial Hospital and Howard Brown Health Center, Chicago, IL.
2001-	Director of Adolescent HIV Services, Lurie Children's Hospital, Chicago, IL
2002-05	Director of Youth Services; Howard Brown Health Center, Chicago, IL
2006-2011	Duty Director/Director of Youth Services; Howard Brown Health Center, Chicago, IL
2008-	Associate Professor of Pediatrics and Preventive Medicine; Northwestern University Feinberg School of Medicine. Chicago, IL

Committee Service

1997-00	Co-coordinator of the HIV/AIDS Stewardship Committee. Harvard Medical School. Boston, MA
1998-00	Government Affairs Committee: National AIDS Policy Center for Children Youth and Families. Washington, DC
2002	Chair of Organizing Committee. International conference sponsored by the National Security Education program. *Pediatric and Adolescent HIV: An International Perspective*. Northwestern University Feinberg School of Medicine
2000-03	Co-Director of Lesbian, Gay, Bisexual and Transgendered Youth Special Interest Group. Society for Adolescent Medicine
2003-	Professional Education Curriculum Review Committee; Department of Preventive Medicine. Northwestern University School of Public Health
2003-	Board of Directors. Gay and Lesbian Medical Association. San Francisco, CA
2004-	Adolescent Research Advisory Committee. NIAID/Pediatric AIDS Clinical Trials Group (PACTG)
2005-	President. Gay and Lesbian Medical Association. San Francisco, CA
2006	NIH Scientific Review Committee. HIV Behavioral Research Group - AARR G(03). July 2006
2009-	National Community Advisory Board. Human Rights Campaign. Healthcare Equality Index
2010-11	National Academy of Sciences/Institute of Medicine Committee. LGBT Research Gaps/Opportunities
2010-15	NIH Scientific Review Committee. Behavioral and Social Consequences of HIV/AIDS
2011	Expert Advisory Panel. The Joint Commission. Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care for LGBT Communities: A Field Guide

Honors.

1988	Magna Cum Laude – Duke University. Durham, NC
1992	Alpha Omega Alpha (AOA) – New York University School of Medicine. NY, NY
1992	AOA Achievement Award – New York University School of Medicine. NY, NY
2000	Employee of the Year. Justice Resource Institute (JRI). Boston, MA
2001	Community Service Award Beth Israel Deaconess Medical Center. Boston, MA
2005	Friend for Life Award. Howard Brown Health Center. Chicago, IL
2007	GLMA Achievement Award. Gay and Lesbian Medical Association
2011	City of Chicago LGBT Hall of Fame Inductee

C. Publications – (selected academic articles and book chapters in chronological order – from 35)

Most relevant to the current application:

1. Wilson E, Garofalo R, Harris R, Herrick A, Martinez M, Martinez J, Belzer M. (2009). Transgender Female Youth and Sex Work: HIV Risk and a Comparison of Life Factors Related to Engagement in Sex Work. AIDS and Behavior, 13(5):902-913. PMCID: PMC2756328.

2. Wilson EC, Garofalo R, Harris RD, Martinez J, Belzer M. (2010). Sexual risk-taking among transgender male-to-female youths with different partner types. Am J Public Health, 100(8):1500-5. PMCID: PMC2901273.
3. Mustanski BS, **Garofalo R**, Emerson E. (2010). Mental Health Disorders, Psychological Distress, and Suicidality in a Sample of Lesbian, Gay, Bisexual, and Transgender Youths. *Am J Public Health*, 100(12): 2426-2432. PMCID: PMC2978194.
4. Dowshen N, Forke CM, Johnson AK, Kuhns LM, Rubin D, Garofalo R. (2011). Religiosity As a Protective Factor Against HIV Risk Among Young Transgender Women. J Adolesc Health; 48(4):410-414.
5. Brennan J, Kuhns LM, Johnson AK, Belzer M, Wilson EC, **Garofalo R**. (2012). Syndemic Theory and HIV-Related Risk Among Young Transgender Women: The Role of Multiple, Co-Occurring Health Problems and Social Marginalization. *American Journal of Public Health,* 102(9):1751-1757. PMCID: PMC3416048.
6. Garofalo R, Johnson A, Kuhns L, Cotten C, Joseph H, Margolis A. (2012). Life Skills: Evaluation of a Theory-Driven Behavioral HIV Prevention Intervention for Young Transgender Women. J Urban Health, 89(3):419-431. PMCID: PMC3368050.
7. Wilson EC, Iverson E, **Garofalo R**, Belzer M. (2012). Parental Support and Condom Use Among Transgender Female Youth. *Journal of the Association of Nurses in AIDS Care,* 23(4):306-317. PMCID: PMC3288276.
8. Bird JDP, Kuhns L, **Garofalo R**. (2012). The Impact of Role Models on Health Outcomes for Lesbian, Gay, Bisexual, and Transgender Youth. *Journal of Adolescent Health*, 50(4):353-357. PMCID: PMC3313463.
9. Hotton AL, **Garofalo R**, Kuhns LM, Johnson AK. (2013). Substance Use as a Mediator of the Relationship Between Life Stress and Sexual Risk among Youth Transgender Women, 25(1): 62-71.
10. **Garofalo R.** (2014). Tipping points in caring for the gender nonconforming child and adolescent, 46(6): 227-229.
11. Olson J, **Garofalo R**. (2014). The peripubertal gender-dysphoric child: Puberty suppression and treatment paradigms. Pediatr Annals, 42(6):e132-137.

Additional recent publications of importance to the field:

12. **Garofalo R,** Mustanski BS, McKirnan D, Herrick A, Donenberg GR. (2007). Methamphetamine and young men who have sex with men: Understanding patterns and correlates of use and the association with HIV-related sexual risk. *Archives Pediatr Adolesc Med*, 161:591-596.
13. **Garofalo R**, Herrick A, Mustanski BS, Donenberg GR. (2007). Tip of the iceberg: Young men who have sex with men, the Internet and HIV risk. *Am J Public Health*, 97(6): 1113-1117.
14. **Garofalo R,** Mustanski BS, Donenberg GR. (2008). HIV Prevention with Young Men Who Have Sex with Men: Parents Know and Parents Matter; Is it Time to Develop Family-Based Programs for This Vulnerable Population? *J Adolesc Health*, 43:201-204. PMCID: PMC2601675.
15. **Garofalo R**, Mustanski B, Johnson A, Emerson E. (2010). Exploring Factors That Underlie Racial/Ethnic Disparities in HIV Risk among Young Men Who Have Sex with Men. *J Urban Health*, 87(2):318-323. PMCID: PMC2845827.

D. Research Support

Ongoing Research Support

R01MH094323-01 Garofalo / Mimiaga (PIs) 06/13/2011 – 03/31/2016
NIMH

HIV Prevention Intervention for Young Transgender Women

The purpose of this study is to test the efficacy of a uniquely targeted HIV risk reduction intervention for young transgender women (YTW), ages 16 to 24, at risk for HIV acquisition or transmission.

R01DA025548 Garofalo / Mustanski (PIs) 04/01/2009 – 01/31/2014
NIDA

Syndemic Development and HIV Risk Among Vulnerable Young Men

This project will investigate a syndemic of psychosocial health issues linked to HIV among YMSM ages 16-20. This syndemic includes HIV risk, drug use, internalizing mental health problems, and violence exposure. The overarching goals of this study are twofold: 1) to provide much-needed epidemiological data on the prevalence of HIV and related health issues in order to inform public health priorities; and 2) to collect vital information on risk and protective factors to inform the development of an intervention targeting this vulnerable population.

R34DA031053 Garofalo (PI) 09/30/2010 – 05/31/2014
NIDA
Text Messaging Intervention to improve Adherence Among HIV-positive Youth and Young Adults
This study is a randomized controlled trial which will test the efficacy of a SMS text messaging intervention on antiretroviral adherence rates among non-adherent youth and young adults living with HIV, ages 16-29.

R34MH097622 Schneider 03/01/2012 - 02/28/2015
NIH/NIMH
Network supported care for young black men newly diagnosed with HIV
Description: This goal of this project is to refine and pilot test a flexible Network Supported Engagement in Care (NSEC) intervention that recruits and motivates one or more organic social support network members of recently HIV diagnosed young black men who have sex with men (YBMSM) to improve engagement in HIV primary care.
Role: Co-Investigator

Completed Research Support:
U01 HD052172 Garofalo (PI) 10/01/2006 – 02/28/2013
NICHD
The PATH Youth Program: HIV/AIDS Interventions in Adolescents
This award is for our site to be a member of the Adolescent Medicine Trials Network (ATN). The ATN conducts clinical and behavioral research projects with HIV+ adolescents and youth at risk of acquiring HIV.

UR6 PS000396 Garofalo (PI) 09/01/2006 – 08/31/2008
CDC
Life Skills Intervention: Safety & Coping Among Transgender Youth and Young Adults
This study, funded by the HIV prevention research branch of the CDC, is to develop and pilot test and HIV prevention intervention for at-risk transgender youth age 14-24. The developed multi-dimensional intervention will be based upon Bronfenbrenner's Social-Ecological Model.

R34 MH079714 Mustanski (PI) 06/01/2007 – 05/31/2010
NIMH
Internet-based HIV/STI prevention for young MSM receiving HIV testing
This three year study involves using the Transtheoretical Model of Behavior Change for the phased development and testing of an online HIV prevention program targeting the unique mechanisms of risk of young adult men who have sex with men (MSM) age 18-24 who recently tested negative from HIV.
Role: Co-Investigator

R34 MH079707 Garofalo (PI) 09/01/2007 – 11/31/2010
NIMH
Intervention Development: Reducing HIV Risk in Vulnerable Youth
This three year study supports the development of a group-based intervention for an ethnically-diverse sample of young men who have sex with other men age 14-20. The intervention, based upon the Social-Personal Model of HIV Risk, will target the unique mechanisms of this high-risk adolescent population

R01HD051438 Eyre (PI) 07/01/2007 – 06/30/2012
NICHD
Cultural Predictors of HIV Risk in African-American Adolescents
This award is for a qualitative and ethnographic study seeking to understand the cultural underpinnings of HIV in African-American male and female adolescents. This is a 3 site study: San Francisco, CA; Chicago, IL; and Birmingham, AL.
Role: Co-Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Simons, Lisa K.	Attending Physician *Ann and Robert H. Lurie Children's Hospital of Chicago* Instructor of Pediatrics *Northwestern University Feinberg School of Medicine*
eRA COMMONS USER NAME (credential, e.g., agency login) (b)(6)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of Pennsylvania	BA	05/01	Biological Basis of Behavior
Sackler School of Medicine, Tel Aviv, Israel	MD	06/07	Medicine
Johns Hopkins Children's Center, Baltimore, MD		06/10	Residency, Pediatrics
Children's Hospital Los Angeles, CA		06/13	Fellowship, Adolescent Medicine

A. Personal Statement

The primary aim of this proposal is to gather observational and longitudinal outcomes related to the impact of medical treatment for transgender children and adolescents in the United States. As an adolescent medicine fellow with career interests in health care for marginalized youth, I spent three years working at Children's Hospital Los Angeles (CHLA) Center for Transyouth Health and Development learning more about the needs of the transgender population and training in specialized health care for transgender adolescent and young adults. Additionally, during fellowship I worked at a homeless shelter (Covenant House), a drop-in center (Jeff Griffith Youth Center), and a community clinic (Saban Free Clinic) providing health care to homeless and underinsured adolescents. Each of these sites served a disproportionately high number of transgender-identified youth, many of whom shared their experiences of rejection by peers and family; physical, verbal and sexual harassment or assault; and chronic homelessness. A number of these youth suffered from depression and suicidal ideation, and many described prior suicide attempts. While some transgender adolescents I encountered reported poor access to health care, other shared negative experiences trying to obtain even routine medical care. In 2013, I came to Ann & Robert H. Lurie Children's Hospital of Chicago specifically to expand my experience and knowledge base in gender care for youth and young adults, and here I am gaining valuable experience under the mentorship of Dr. Robert Garofalo, MD, MPH. My working relationship with Dr. Olson at CHLA, one of my primary mentors during fellowship at CHLA, remains strong.

B. Positions and Honors

Positions and Employment

2010-2013 Clinical Research Fellow, Division of Adolescent Medicine, Children's Hospital Los Angeles, CA
2013- Attending Physician, Lurie Children's Gender Development Clinic, Division of Adolescent Medicine, Ann and Robert H. Lurie Children's Hospital of Chicago, IL
2013- Instructor of Pediatrics, Northwestern University Feinberg School of Medicine, Chicago, IL
2014- Physician (part-time), Heartland Health Community Center, community-based health center offering comprehensive health care to homeless people of all ages, Chicago, IL

Honors and Awards

2012 Young Scholars Award, North American Society of Pediatric and Adolescent Gynecology

C. Selected Peer-reviewed Publications

Journal Articles

1. **Simons L**, Schrager SM, Clark LF, Belzer M, Olson J. Parental support and mental health among transgender adolescents. *Journal of Adolescent Health*. 2013;53(6):791-793.
2. **Simons LK**, Leibowitz SF, Hidalgo MA. Understanding gender variance in children and adolescents. Understanding gender variance in children and adolescents. *Pediatr Ann*. 2014;43(6):e126-31.

Published Abstracts

1. **Simons L**, Olson J, Belzer M, Clark L, Schrager S. The Relationship between Parental Support and Depression and Suicidality in Transgender Adolescents. Journal of Adolescent Health. 2012;50(2):S29.
2. Olson J, Clark L, Schrager S, **Simons L**, Belzer M. Baseline Characteristics of Transgender Youth Naïve to Cross-Sex Hormone Therapy. Journal of Adolescent Health. 2013;52(2):S35-36.

D. Research Support

While I have not yet received research support, as a fellow I was a co-investigator on Dr. Johanna Olson's) longitudinal observational study (funded by an intramural faculty research grant at Children's Hospital Los Angeles) assessing the impact of a multidisciplinary treatment model for transgender youth that includes provision of cross-sex hormone therapy, psychological counseling and case management.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Marco A. Hidalgo, PhD	**Psychologist** – Division of Adol. Medicine **Assistant Professor** of Psychiatry and Behavioral Sciences, Northwestern Univ., Feinberg School of Medicine
eRA COMMONS USER NAME (credential, e.g., agency login) (b)(6)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
San Francisco State Univ; San Francisco, CA	BA	05/04	Psychology
DePaul University; Chicago, IL	MA	06/07	Clinical/Community Psychology
DePaul University; Chicago, IL	PhD	06/11	Clinical Psychology
Postdoctoral Training			
Harvard Medical School, Boston, MA	Fellowship	08/11-08/12	Clinical Psychology

A. Personal Statement

This project proposes to conduct an observational study examining the safety of hormonal interventions and the physiological and psychological outcomes associated with these treatments in a sample of peri- and post-pubertal gender-variant youth gathered from 4 subspecialty clinics serving this population across the US. I have devoted my early career to conducting clinical practice and research among lesbian, gay, bisexual, and transgender/gender-variant youth (LGBT) and my work thus far has prepared me well to contribute to the proposed project as a Co-Investigator. At Lurie Children's, where I provide direct clinical care within a multidisciplinary, subspecialty service offering medical and behavioral health care to gender-variant youth, I rely on evidence-based practice to evaluate and treat gender dysphoria as well as mood, anxiety, traumatic stress, and emotional adjustment disorders in gender-nonconforming and transgender youth. In my research, I have applied mixed-methods approaches to develop, implement, and evaluate HIV prevention interventions among sexual minority males at-risk for HIV-exposure. The majority of my publications to date relate to clinical care and HIV prevention in populations including gender-variant youth, young men who have sex with men (MSM) and other gay/bisexual males. My early career research will continue to expand upon these areas, focusing on the examination of psychosocial resilience in gender-variant youth, and HIV prevention as it relates psychosocial health in adolescent and adult transgender women. I am currently a Co-Investigator on an NIH-funded RCT comparing the effects of individual versus couples-level HIV test counseling on antiretroviral initiation and adherence in MSM, and I plan on applying this methodology to examine couple-level factors affecting HIV transmission in partnerships where one partner is a transgender woman. I have directed a NIH-funded research protocol awarded to Dr. Garofalo (R34 MH079707) and my experience in this role has prepared me well for my administrative and supervisory responsibilities on the proposed study. As a Co-Investigator on this project, I will assist Investigators in directly supervising and managing frontline research activities involving project direction and data management. Specifically, I will supervise the Lurie Children's Project Coordinator in their management of day-to-day tasks by coordinating IRB submissions, developing and overseeing effective recruitment strategies and providing ongoing advice regarding confidential data collection/management procedures. I will also participate directly in data collection efforts, conducting the behavioral health portions of study visits. I will also assist the Data Manager in refining assessment instruments, managing study databases, and creating data manuals. Last, I will contribute to the dissemination of our findings in collaboration with the investigative team.

B. Positions and Professional Experience

2004-2006 Project Director, (PIs: GW Harper and MI Fernandez) Adolescent Community Health Research Group, DePaul University, Chicago, IL
2007-2008 Instructor in Psychology, DePaul University
2008-2010 Research Director in Behavioral Research, (PI: Garofalo) Howard Brown Health Center/Lurie Children's, Chicago, IL

2010-2011 Predoctoral Intern in Clinical Psychology, Center for Addiction Medicine, Alexian Bros Behavioral Health Hospital, Hoffman Estates, IL
2011-2012 Clinical Fellow of Psychology in Psychiatry, Harvard Medical School, Boston, MA
2012-2013 Behavioral Research Scientist, Academic General Pediatrics, Lurie Children's Hospital, Chicago, IL
2013-Present Medical Psychologist, Division of Adolescent Medicine, Lurie Children's Hospital, Chicago, IL

Committee Service

2006-2008 National Student Representative, Executive Committee, Division 27 (Society for Community Research and Action), American Psychological Association.
2014-2016 Founding Chair, Gender Variance Special Interest Group, Division 53 (Society of Clinical Child and Adolescent Psychology), American Psychological Association

Honors.

2004 Magna Cum Laude – San Francisco State University. San Francisco, CA
2010 Recipient, Scrivner Memorial Research Grant ($5,000) – American Psychological Foundation
2013 Finalist, Robert H. DuRant Award for Statistical Rigor and Innovation in Adolescent Health Research – Society for Adolescent Health and Medicine 2014, Austin, TX

C. Selected Peer-reviewed Publications

Most relevant to the current application

1. Simons L, Leibowitz S, **Hidalgo MA**. Understanding gender variance in children and adolescents. *Pediatric Annals*. 2014;43(6):e126-e131. PMID: 24972420
2. **Hidalgo MA**, Ehrensaft D, Tishelman AC, Clark, LF, Garofalo, R, Rosenthal, S., Spack, NP, & Olson, J. The gender affirmative model: What we know and what we aim to learn. *Human Development*. 2013;56(5):285-290.

Additional recent publications of importance to the field:

1. **Hidalgo MA**, Kuhns LM, Hotton AL, Johnson AK, Mustanski B, Garofalo R. The MyPEEPS Randomized Controlled Trial: A Pilot of Preliminary Efficacy, Feasibility, and Acceptability of a Group-Level, HIV Risk Reduction Intervention for Young Men Who Have Sex with Men. *Archives of Sexual Behavior*. 2014:1-11 [epub ahead of print] PMID: 25135064.
2. Garofalo R, Kuhns LM, **Hidalgo M**, et al. Impact of Religiosity on the Sexual Risk Behaviors of Young Men Who Have Sex With Men. *J Sex Res*. Jul 29 2014:1-9. PMID: 25072796
3. **Hidalgo MA**, Cotten C, Johnson AK, Kuhns L, Garofalo R. "Yes, I am More Than Just That": Gay/Bisexual Young Men Residing in the US Discuss the Influence of Minority Stress on Their Sexual Risk Behavior Prior to HIV-infection. *Int J Sex Health*.2013; 25(4):291-304.
4. Wilson BM, Harper G, **Hidalgo MA**, Jamil O, Torres R, Isabel Fernandez M. Negotiating Dominant Masculinity Ideology: Strategies Used by Gay, Bisexual and Questioning Male Adolescents. *Amer J Community Psychology*. 2010;45(1-2):169-185. PMID: 20082238
5. Warren J, Fernández MI, Harper GW, **Hidalgo MA**, Jamil OB, Torres RS. Predictors of Unprotected Sex among Young Sexually Active African American, Hispanic, and White MSM: The Importance of Ethnicity and Culture. *AIDS and Behavior*. 2008;12(3):459-468. PMID:17721725
6. Oden, K., Hernández, B., & **Hidalgo, M. A.** (2010). Payoffs of participatory action research: Racial and ethnic minorities with disabilities reflect on their research experiences. *Community Development: Journal of the Community Development Society*, *41*(1), 21-31. PMID: 20668640
7. Hernández, B., Balcazar, F., Keys, C., **Hidalgo, M. A.**, & Rosen, J. (2006). Taking it to the streets: Ethnic minorities seek inclusion. *Community Development: Journal of the Community Development Society*, *37*, 13-25.

D. Research Support

Completed Research Support:

R34 MH079707 R. Garofalo (PI) 9/1/07 – 11/31/10
NIMH
Intervention Development: Reducing HIV Risk in Vulnerable Youth

This three year study supported the development of a group-based intervention for an ethnically-diverse sample of young men who have sex with other men age 14-20. The intervention, based upon the Social-Personal Model of HIV Risk, targeted the unique mechanisms of this high-risk adolescent population
Role: Project Director

Ongoing Research Support:
R01 HD075655-01A1 R. Garofalo/ R. Stephenson/ M. Mimiaga (PIs) 04/10/13 – 03/31/18
NICHD
CVCTPlus: A Couples-Based Approach to Linkage to Care and ARV Adherence
Multisite RCT evaluating, over 24 mos, couples-based HIV testing versus standard of care on antiretroviral initiation and adherence in gay/bisexual male couples.
Role: Co-Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Leibowitz, Scott	Attending Physician, *Ann and Robert H. Lurie Children's Hospital of Chicago* Assistant Professor, *Northwestern University Feinberg School of Medicine*
eRA COMMONS USER NAME (credential, e.g., agency login)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Cornell University, Ithaca, NY	BS	05/00	Human Development
Sackler School of Medicine, Tel Aviv, Israel	MD	05/04	Medicine
Long Island Jewish Medical Center/Zucker Hillside Hospital, Glen Oaks, NY		06/08	Residency, Psychiatry
Boston Children's Hospital, MA		06/10	Fellowship, Child and Adolescent Psychiatry

A. Personal Statement

This research proposal aims to assess the long-term medical effects of pubertal suppression with GnRH agonists on transgender adolescents across the four main centers in the United States who are offering such intervention. As a psychiatrist who has developed a psychosocial consultative clinic to meet the needs of gender nonconforming and transgender youth across the developmental spectrum, this research is of particular interest to me and is highly needed to determine the safety of this intervention. Puberty, if unsuppressed, leads to irreversible changes that are often devastating to individuals whose affirmed gender is discordant with their anatomy. The acute and long-term psychiatric implications related to untreated internal distress (gender dysphoria) are significant, with much higher rates of depression, suicidal ideation and behavior, anxiety, potential substance use disorders, high risk-taking behaviors, etc. in this population, even among those youth whose parents are considered accepting. Initial research has shown the marked psychiatric benefits of using pubertal suppression as a method to extend the period of exploration during a time that allows an adolescent to not experience the unwanted irreversible effects of puberty. I will participate on the research team at Lurie Children's Hospital of Chicago by participating in project development calls, assessing patients, and providing the psychiatrist's perspective throughout the various time points of the study.

B. Positions and Honors

Positions and Employment

2010-2013 Instructor of Psychiatry, Harvard Medical School, Boston, MA

2010-2013 Attending Child and Adolescent Psychiatrist, Boston Children's Hospital, MA
I worked both within the Department of Psychiatry and the Division of Adolescent and Young Adult Medicine during this period. In the Department of Psychiatry, I established a consultative psychosocial gender identity clinic that provided assessement, consultation, and ongoing behavioral health services to gender nonconforming and dysphoric youth across the developmental spectrum. In the Division of Adolescent and Young Adult Medicine, I served as the primary psychopharmacologist working on a multidisciplinary team in a primary care setting.

2013- Assistant Professor of Psychiatry and Behavioral Sciences, Northwestern University Feinberg School of Medicine, Chicago, IL

2013- Attending Child and Adolescent Psychiatrist, Head Child and Adolescent Psychiatrist for the Gender and Sex Development Program, Ann and Robert H. Lurie Children's Hospital of Chicago, Department of Psychiatry, Chicago, IL

I currently work on the multidisciplinary team to help assess, consult, and treat the behavioral health aspects of gender nonconforming and dysphoric youth across the developmental spectrum. Our team is involved in clinical, research, and advocacy efforts on behalf of this population for youth in the Chicago metropolitan area and beyond. We are the first major academic pediatric medical center in the Midwest to provide the full range of services to these youth, and are the only clinic in the country to be represented by the full range of disciplines. I also work on the Consultation Liaison service and general outpatient service in the Department of Psychiatry.

Other Experience and Professional Memberships

2009-	Sexual Orientation and Gender Identity Issues Committee, American Academy of Child and Adolescent Psychiatry
2013-	Committee Co-Chair, Sexual Orientation and Gender Identity Issues Committee, American Academy of Child and Adolescent Psychiatry
2012-	Trevor Project Advisory Council
2012-	American Association of Medical Colleges, Lesbian, Gay, Bisexual, Transgender, and Disorders of Sex Development Affected Individuals Patient Care Project Advisory Committee

Honors

2011	Campaign for American's Kids Junior Scholar Award, American Academy of Child and Adolescent Psychiatry
2012	Prism Award, GLBT and Friends Committee, Boston Children's Hospital

C. Selected Peer-reviewed Publications

1. **Leibowitz S**, Spack N. "The Development of a Gender Identity Psychosocial Clinic: Treatment Issues, Logistical Considerations, Interdisciplinary Cooperation, and Future Initiatives." *Child and Adolescent Psychiatric Clinics of North America.* 2011; 20(4):701-724.
2. Stoddard J, **Leibowitz S**, Ton H, Snowdon S. "Improving Medical Education About Gender-Variant Youth and Transgender Adolescents." *Child and Adolescent Psychiatric Clinics of North America.* 2011;20(4):779-791.
3. **Leibowitz S,** Telingator C. "Assessing Gender Identity Concerns in Children and Adolescents: Evaluation, Treatments, and Outcomes." *Current Psychiatry Reports.* 2012;14(2):111-120.
4. Adelson, S. et al. "Practice Parameter on Gay, Lesbian, or Bisexual Sexual Orientation, Gender Nonconformity, and Gender Discordance in Children and Adolescence." *Journal of American Academy of Child and Adolescent Psychiatry.* 2012;51(9):957-974. (member of the AACAP committee, Sexual Orientation and Gender Identity Issues Committee, cited in the Attribution section)

D. Research Support

No ongoing or completed research projects for the past three years (Federal or non-Federally-supported).

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Courtney Anne Finlayson	Assistant Professor of Pediatrics
eRA COMMONS USER NAME (b)(6)	

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of Michigan	BS with honors	1995-1999	Biology
Northwestern University, Evanston, IL	MD	1999-2003	
Rush University, Chicago, IL	Residency	2003-2006	Pediatrics
Northwestern University, Children's Memorial Hospital, Chicago, IL	Fellowship	2006-2009	Pediatric Endocrinology

A. Personal Statement

The goal of the proposed research is to study and improve care for youth who are transgender and gender dysphoric. This is an understudied and generally poorly understood population. In the past, few pediatric endocrinologists have had the knowledge and willingness to care for these children. I am the endocrinologist for the Gender & Sex Development Program at the Ann & Robert H. Lurie Children's Hospital of Chicago. I have had a specific interest in these patients which has guided my research and clinical training. My research as an endocrinology fellow was in the laboratory of Dr. J. Larry Jameson studying sex development. As a junior faculty member, I worked with Dr. Norman Spack in the Gender Management Services program at the Children's Hospital Boston. Following my move to Chicago, I have been the primary endocrinologist to assist in developing our program. As a result of this training and my interest in this population, I am prepared to participate in the proposed project.

B. Positions and Honors

Positions and Employment

2003-2006 Pediatric Resident, Rush University
2003 Staff Physician, American Diabetes Association Triangle D Camp, Illinois
2006 Staff Physician, American Diabetes Association Triangle D Camp, Illinois
2007 Staff Physician, American Diabetes Association Triangle D Camp, Illinois
2006-2009 Pediatric Endocrinology Fellow, Children's Memorial Hospital, Northwestern University
2009-2010 Instructor, Department of Pediatrics, Division of Pediatric Endocrinology, Children's Hospital Boston, Harvard Medical School
2010-2014 Instructor, Department of Pediatrics, Division of Pediatric Endocrinology, Ann & Robert H. Lurie Children's Hospital of Chicago, Northwestern University
2014- Assistant Professor, Department of Pediatrics, Division of Pediatric Endocrinology, Ann & Robert H. Lurie Children's Hospital of Chicago, Northwestern University

Other Experience and Professional Memberships

2003-2010 Member, American Academy of Pediatrics
2006- Member, Endocrine Society
2007- Member, Lawson Wilkins Pediatric Endocrine Society

Honors

1999	Phi Beta Kappa, University of Michigan
2008	Lawson Wilkins Pediatric Endocrine Society Fellows Travel Grant
2008	Endocrine Society Endocrine Trainee Day Travel Grant

C. Selected Peer-reviewed Publications

1. Harris RM, Finlayson C, Weiss J, Fisher L, Hurley L, Barret T, Emge D, Bathgate RA, Agoulnik AI, Jameson JL. A missense mutation in LRR8 of RXFP2 is associated with cryptorchidism. Mamm Genome. 2010. 21(442-9).
2. Weiss J, Hurley LA, Harris RM, Finlayson C, Tong M, Fisher LA, Moran JL, Beier DR, Mason C, Jameson JL. ENU mutagenesis in mice identifies candidate genes for hypogonadism. Mamm Genome. 2012. 23(5-6):346-55.

D. Research Support

No ongoing or completed research projects for the past three years (Federal or non-Federally-supported).

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Joel E. Frader, M.D., M.A.	A Todd Davis Professor of Academic General Pediatrics, Prof. Medical Humanities and Bioethics
eRA COMMONS USER NAME (credential, e.g., agency login) (b)(6)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Columbia University, NYC	BA	1970	Sociology
Tufts University School of Medicine, Boston, MA	MD	1974	
University of Pennsylvania, Philadelphia, PA	MA	1980	Sociology

A. Personal Statement

I pursue scholarly work in pediatric palliative care and medical ethics, especially ethics in pediatrics, human subjects research, transplantation, children with disorders of sex development (DSD), gender nonconformity, clinical innovation, and conscientious objection by health care professionals. I do qualitative social science studies collaboratively with Kelly Michelson, MD, a pediatric critical care physician, on families and staff in the pediatric intensive care unit facing decisions to provide or forgo life-sustaining treatment. My main clinical interests are in pediatric palliative and hospice care, multidisciplinary care of children with DSD and gender nonconformity, and parent support for difficult decisions under conditions of uncertainty.

B. Positions and Honors

Positions and Employment

1974-76	Intern and 2nd Year Resident (Pediatrics): Tufts-New England Medical Center
1976-79	3rd Year Resident (Pediatrics) and Robert Wood Johnson Clinical School, Children's Hospital of Philadelphia and University of Pennsylvania
1979-81	Assistant Professor of Pediatrics, University of Pennsylvania School of Medicine
1981-90	Assistant Professor of Pediatrics, Children's Hosp. of Pittsburgh and University of Pittsburgh School
1986-97	Associate Director, Center for Medical Ethics, University of Pittsburgh
1990-97	Associate Professor of Pediatrics, University of Pittsburgh School of Medicine
1997-2000	Associate Professor of Pediatrics, Assoc. Prof. of Medical Ethics and Humanities, Children's Memorial Hospital and Northwestern University
2000-03	Professor of Pediatrics and Professor of Medical Humanities and Bioethics, Northwestern University
2001-03	Interim Chief, Division of General Academic Pediatrics, Children's Memorial Hospital
2003-	Chief, Academic General Pediatrics, Children's Memorial Hospital (now Lurie Children's Hospital)
2013-	Director, Bridges Pediatric Palliative Care Program, Lurie Children's Hospital

Ethics-Related Experience and Professional Memberships

1983-86	Member, Council (Board of Directors), Society for Health and Human Values (Now American Society for Bioethics and Humanities)
1989-96	Member, Board of Directors, Society for Bioethics Consultation
1990-98	Member, Committee on Bioethics, American Academy of Pediatrics
1991-94	President-elect, President, Immediate Past-president, Society for Health and Human Values
1994-98	Chair, Committee on Bioethics, American Academy of Pediatrics
1994-98	Member, Committee on Ethics, American College of Obstetricians and Gynecologists
1997	Member, NIH Special Study Section: Informed Consent in Research Involving Human Participants

1998	Member, NIH Study Section: Ethical, Legal, and Social Implications of the Human Genome Project
1998-2000	Associate Member, Ethics Committee, American Board of Pediatrics
1998-2007	Ethics Reviewer, NIH Study Section: Hyperaccelerated Award—Mechanisms in Immune Disease Trials
1997	Member, Ad hoc NIH Study Section: Research on Ethical Issues in Human Studies
2000-01	Ethics Member, NHLBI Data Safety Monitoring Board: Fetal Tracheal Occlusion for Severe Diaphragmatic Hernia Clinical Trial
2000	Member, NIH Consensus Development Panel: Antenatal Corticosteroids Revisited: Repeat Courses
2000-03	Member, NHLBI Data Safety Monitoring Board: Recombinant CC10 for Prevention of Neonatal BPD
1999-03	Member, Hastings Center Project on Families and Traumatic Brain Injury
2001-03	Member, Hastings Center Project: Surgically Shaping Children
2002-03	Member, Work Group on Ethical Issues in Human Germline Genetic Modification Research (Convened by R. Dresser, Washington University School of Law)
2003-04	Member, University of Virginia Task Force: Regulating Innovative Surgery: Development of Recommendations for National Policy
2004-09	Member, NHLBI DSMB for Randomized Trial of Pulmonary Valve Replacement in Tetralogy of Fallot and Thymic Tolerance Trial in Pediatric Heart Transplant
2007-	Member, NIDCD DSMB for Phase II randomized clinical trial for Recurrent Respiratory Papillomatosis
2007-10	Member, NIAID Study Section: Ancillary Studies in Immunomodulation Clinical Trials

Honors

1976-79	Robert Wood Johnson Clinical Scholar, University of Pennsylvania
1993	Elected Fellow, The Hastings Center
1995	Elected Member, American Pediatrics Society
2009	Named A Todd Davis Professor of Academic General Pediatrics, Feinberg School of Medicine
2112	Named William G. Bartholome Awardee for Ethical Excellence, American Academy of Pediatrics

C. Selected Peer-reviewed Publications

1. Frader J: Difficulties in providing intensive care. Pediatrics 1979;64(1):10-16.
2. Lantos JD, Frader J: Extracorporeal membrane oxygenation and the ethics of clinical research in pediatrics. N Engl J Med 1990;323:409-413.
3. Truog RD, Brett AS, Frader J: The problem with futility. N Engl J Med 1992;326:1560-64.
4. Frader J, Caniano DA: Research and innovation in surgery. In McCullough LB, Jones JW, Brody BA, eds, Surgical Ethics. Oxford University Press, 1998.
5. Flanagan-Klygis E, Friedman Ross L, Lantos J, Frader J, Yogev R: Disclosing the diagnosis of HIV in pediatrics. J Clin Ethics 2000;12(2)150-157.
6. Daaboul J, Frader J: Management of the patient with intersex: a middle way. J Ped Endocrin Metab, 2001;14(9):1575-
7. Dreger A, Chase C, Sousa A, Gruppuso PA, Frader J: Changing the nomenclature/taxonomy for intersex: a scientific and clinical rationale. J Pediatr Endo Metab 2005;18(8): 729-733.
8. Bosk CL, Frader J. It's not easy wearing green: the art of surgical innovation and the science of clinical trials. In Reitsma AM, Moreno JD eds., Ethical Guidelines for Innovative Surgery. University Publishing Group, 2006.
9. Darugar MA, Harris RM, Frader JE. Consent and cultural conflicts: ethical issues in pediatric anesthesiologists' participation in female genital cutting. In, Von Norman, G, Palmer S, Jackson S, Rosenbaum S, and Cahana A, eds., Clinical Ethics in Anesthesiology: A Case-Based Textbook. New York, Cambridge University Press, 2011.
10. RM Harris, Frader J. Ethical issues in the treatment of pediatric patients with disorders of sex development. In, Diekema DS, Mercurio MR, Adam MB, eds, Clinical Ethics in Pediatrics: A Case-Based Textbook, New York, Cambridge University Press, 2011.

11. Frader J, Kodish E, Lantos JD. Symbolic resuscitation, medical futility, and parental rights. Pediatrics 2010; 126(4):769-772.
12. Michelson KN, Emanuel L, Carter A, Brinkman P, Clayman ML, Frader J. Pediatric intensive care unit family conferences: one mode of communication for discussing end-of-life care decisions. Pediatr Crit Care Med 2011;12(6):e336-43).
13. Michelson KN, Blehart K, Hochberg T, James K, Frader J. Bereavement photography for children: program development and healthcare professionals' response. Death Studies E-pub 11 Jan 2013.
14. Michelson KN, Patel R, Haber-Barker N, Emanuel L, Frader J. End-of-life care decisions in the pediatric intensive care unit: roles professionals play. Pediatr Crit Care Med, 2013;14(1):e34-44.
15. Michelson KN, Clayman ML, Haber-Barker N, Ryan C, Rychlik K, Emanuel L, Frader J. The use of family conferences in the pediatric intensive care unit. J Pall Med. 2013;16(12):1595-601.

D. Research Support

Dr. Frader does not have any ongoing or completed research projects for the past three years (Federal or non-Federally-supported).

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Rosenthal, Stephen M. M.D.	Professor of Pediatrics
eRA COMMONS USER NAME (credential, e.g., agency login) (b)(6)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Yale University, CT	B.A.	1968-72	Psychology
Columbia Univ., College of Physicians & Surgeons, NY	M.D.	1972-76	Medicine
Presbyterian Hospital, Columbia University, NY		1976-79	Intern/Resident, Pediatrics
University of California, San Francisco		1979-82	Fellow, Pediatric Endocrinology

A. Personal Statement

In addition to my role as Program Director for our NIH-funded T32 Pediatric Endocrinology Fellowship at UCSF, I also serve as Director of the Pediatric Endocrine Clinics, Co-Director of the Disorders of Sex Development (DSD) Clinic, and founder and Medical Director of the UCSF Child and Adolescent Gender Center (CAGC). The UCSF CAGC serves as the Pediatric/Adolescent clinical arm of the widely recognized UCSF Center of Excellence for Transgender Health. The CAGC provides multi-disciplinary care to gender non-conforming/transgender youth and adolescents, and is the only such multi-disciplinary gender program in northern California, attracting patients not only from California, but from as far away as Alaska, Florida, and Egypt. A steady increase in referrals (8-10/month) has led to a quadrupling of services in the last two years. In recognition of my experience providing care and developing protocols for transgender youth, I have been appointed as the official representative of the Pediatric Endocrine Society (PES) to the Endocrine Society's (ES) Clinical Practice Guidelines Revision Task Force for the Care of Transgender Individuals, and was appointed to the World Professional Association for Transgender Health (WPATH) Consensus committee for revisions of the International Classification of Disease (ICD)-11 pertaining to transgender youth and adults. I have authored 7 manuscripts on transgender youth, including a recent "State-of-the-art" invited review in *Pediatrics* and an invited review in the "Approach to the Patient" series for the *Journal of Clinical Endocrinology and Metabolism*. I have been an invited speaker on transgender youth at annual meetings of PES and ES, as well as at the most recent international meeting of WPATH, and have lectured on this subject at academic centers throughout the U.S. As a reflection of the national and international impact of the UCSF CAGC, our program for transgender youth is being featured in an upcoming documentary produced by the British Broadcasting Corporation (BBC). I am also the recipient of the UCSF Chancellor Award for LGBT leadership in recognition of my work with transgender youth and am the recipient of the UCSF Family Advisory Council Caring Tree Award and the UCSF Haile T. Debas Academy of Medical Educators Excellence in Teaching Award. I have had significant experience conducting multi-center trials, and I am currently serving as site PI for NIH/NICHD Disorders of Sex Development: Platform for Basic and Translational Research (1R01HD068138-01A1).

B. Positions and Honors

Positions and Employment

1982-83 Clinical Instructor in Pediatrics, University of California San Francisco, CA
1983-92 Assistant Professor of Pediatrics, University of California San Francisco, CA
1992-98 Associate Professor of Pediatrics, University of California San Francisco, CA
1998- Professor of Pediatrics, University of California San Francisco, CA
2006- Director, Pediatric Endocrine Clinics, University of California San Francisco, CA

2008-11	Associate Program Director, Pediatric Endocrinology, University of California San Francisco, CA
2011-	Program Director, Pediatric Endocrinology, University of California San Francisco, CA
2011-	Medical Director, Child and Adolescent Gender Center, University of California San Francisco, CA

Other Experience and Professional Memberships

1991-	Elected to Society for Pediatric Research
2000-05	Appointed to Drug and Therapeutics Committee, Lawson Wilkins Pediatric Endocrine Society
2000-05	Appointed to Special Programs Committee, The Endocrine Society
2002-04	Chair, Drug and Therapeutics Committee, Lawson Wilkins Pediatric Endocrine Society
2005-08	Appointed to Meetings and Educational Programs Committee of The Endocrine Society
2007-13	Appointed to Ethics Committee, Pediatric Endocrine Society
2008-11	Appointed to Annual Meeting Steering Committee, The Endocrine Society
2010-13	Elected to Board of Directors, Pediatric Endocrine Society
2012-	Appointed to the Clinical Endocrine Education Committee, The Endocrine Society
2013	Appointed to the World Professional Association for Transgender Health Consensus Committee for ICD-11 revisions pertaining to transgender youth and adults
2014	Appointed as the Pediatric Endocrine Society's official representative to the Endocrine Society's Clinical Practice Guidelines Revision Task Force for the Care of Transgender Individuals

Honors

2012	UCSF Family Advisory Council Caring Tree Award
2013	Chancellor Award for Gay, Lesbian, Bisexual, and Transgender Leadership
2014	UCSF Haile T. Debas Academy of Medical Educators Excellence in Teaching Award

C. Selected Peer-reviewed Publications (Selected from 65 peer-reviewed publications)

Most relevant to current application (in reverse chronological order)

1. **Rosenthal SM**. Approach to the Patient: Transgender Youth: Endocrine Considerations. J Clin Endocrinol Metab, 2014 Aug 20:jc20141919. Epub ahead of print.
2. Vance S, Ehrensaft D, **Rosenthal SM**. Psychological and medical care of gender nonconforming youth. Pediatrics, in press 2014.
3. Bonifacio J, **Rosenthal SM**. Gender variance and dysphoria in children and adolescents. Pediatr Clin North Am, in press 2014.
4. Lee PA, Wisniewski A, Baskin L, Vogiatzi MG, Vilain E, **Rosenthal SM**, Houk C. Advances in diagnosis and care of persons with DSD over the last decade. Int J Pediatr Endocrinol, in press 2014.
5. Vance S, Halpern-Felsher B, **Rosenthal SM**. Health care providers' comfort with and barriers to care of transgender youth. J Adolesc Health, in press 2014.
6. Sherer I, Baum J, Ehrensaft D, **Rosenthal SM**. Gender Nonconforming/Gender Expansive and Transgender Children and Teens. Contemporary Pediatrics, under review (invited manuscript), 2014.
7. Hidalgo MA, Ehrensaft D, Tishelman AC, Clark LF, Garofalo R, **Rosenthal SM**, Spack NP, Olson J. The gender affirmative model: What we know and what we aim to learn. Human Development 56:285-290, 2013.
8. Sherer I, **Rosenthal SM**, Ehrensaft D, Baum J: Child and Adolescent Gender Center: A multidisciplinary collaboration to improve the lives of gender nonconforming children and teens. Pediatr Rev 33:273-275, 2012.

Additional recent publications (in reverse chronological order)

9. Herold KC, Gitelman SE, Willi SM, Gottlieb PA, Waldron-Lynch F, Devine L, Sherr J, **Rosenthal SM**, Adi S, Jalaludin MY, Michels AW, Dziura J, Bluestone JA: Teplizumab treatment may improve C-peptide responses in participants with type 1 diabetes after the new onset period: a randomized controlled trial. Diabetologia 56:391-400, 2013.
10. Cheung CC, Cadnapaphornchai MA, Ranadive SA, Gitelman SE, **Rosenthal SM**: Persistent elevation of urine Aquaporin-2 during water loading in a child with Nephrogenic Syndrome of Inappropriate Antidiuresis (NSIAD) caused by a R137L mutation in the V2 Vasopressin receptor. Int J Pediatr Endocrinol 3:1-6, 2012.

11. Aslan IR, Baca EA, Charlton W, **Rosenthal SM**: Respiratory syncytial virus (RSV) infection as a precipitant of thyroid storm in a previously undiagnosed case of Graves disease in a prepubertal girl. Int J Pediatr Endocrinol 2011:138903. Epub 2011 Mar 22.
12. Rochdi MD, Vargas GA, Carpentier E, Oligny-Longpre G, Chen S, Kavoor, A, Gitelman SE, **Rosenthal SM**, von Zastrow M, Bouvier M: Functional characterization of vasopressin type 2 receptor substitutions (R137H/C/L) leading to nephrogenic diabetes insipidus and nephrogenic syndrome of inappropriate antidiuresis: Implications for treatments. Mol Pharmacol 77:836-845, 2010.
13. Meyer GE, Chesler L, Liu D, Youngren J, Goldfine ID, Weiss WA, Matthay KK, **Rosenthal SM**: Nordihydroguaiaretic acid inhibits insulin-like growth factor signaling, growth and survival in human neuroblastoma cells. J Cell Biochem 102:1529-1541, 2007.
14. Feldman BJ*, **Rosenthal SM***, Vargas GA, Fenwick RG, Huang EA, Matsuda-Abedini M, Lustig RH, Mathias RS, Portale AA, Miller WL, Gitelman SE. Nephrogenic syndrome of inappropriate antidiureses. Identification of novel activating mutations in the vasopressin type 2 receptor causing a newly described genetic disease. N Engl J Med. 352:1884-90 2005. ***denotes co-first author**
15. Tiffin N, Adi S, Stokoe D, Wu NY, **Rosenthal SM**: Akt phosphorylation is not sufficient for insulin-like growth factor-stimulated myogenin expression but must be accompanied by down-regulation of mitogen-activated protein kinase/extracellular signal-regulated kinase phosphorylation. Endocrinology 145:4991-4996, 2004.

D. Research Support

Ongoing Research Support

1R01HD068138-01A1 Vilain (PI) 09/26/2011 - 06/30/2016
NIH/ NICHD
Disorders of Sex Development: Platform for Basic and Translational Research
Role: Site PI

Completed Research Support

U01 DK61010 2009-2012
NIDDK/NIH
UCSF Trial Net: UCSF Trial Net: A Phase II Trial of Imantinib in New Onset Type I Diabetes
Role: Co-PI

R01 2006-2011
NIH/NIDDK/Juvenile Diabetes research Foundation
Phase II Trial of hOKT3 γ1 (Ala-Ala) administered from 4 months to 12 months after diagnosis of Type 1 diabetes mellitus
Role: Co-PI

N01-AI 15416 2005-2012
NIH/NIAID/ITN/NIDDK
Phase II trial of hOKT3 γ1 (Ala-Ala) for treatment of new onset Type 1 Diabetes Mellitus
Role: Co-PI

Immune Tolerance Network 2005-2012
NIH/NIAID
Thymoglobulin for treatment of new onset type 1 diabetes mellitus
Role: Co-PI

Basic Research Award Rosenthal (PI) 2009-2011
ImClone Systems, Inc.
The Therapeutic Potential of A12 Anti-IGF-IR Antibody and Radiation in Neuroblastoma
Role: PI

Thrasher Research Fund 2005-2008
Targeted agents that synergize with radiation in high risk neuroblastoma; The goal of this study was to assess inhibitors of insulin-like growth factors (IGF)-1 signaling and other agents that synergize with radiation in high risk neuroblastoma.
Role: Co-PI

Basic Research Award Rosenthal (PI) 2005-2008
John A. Kerner, M.D. Foundation
Small Molecule Inhibitors of the IGF-I Receptor as a Potential Treatment for Neuroblastoma
Role: PI

N01-AI 15416 2005-2010
NIH/NIAID/ITN/NIDDK
Phase II trial of hOKT3 γ1 (Ala-Ala) for treatment of new onset Type1 diabetes mellitus
The goal of this study was to attempt to prolong endogenous insulin secretion in those with new onset type 1 diabetes mellitus utilizing an anti-CD3 monoclonal antibody at 6 month intervals for a total of 3 doses. This study was part of a multi-center trial.
Role: Co-PI

Translational Basic Research Award Rosenthal (PI) 2004-2005
Pfizer, Inc.
IGFs and Skeletal Muscle: Implications for Myotherapy.
This study explored the mechanisms which influence the decision of skeletal myoblasts to proliferate of differentiate in response to IGFs.
Role: PI

R01 2001-2010
NIH/NIDDK/Juvenile Diabetes Research Foundation
Phase II trial of hOKT3 γ1 (Ala-Ala) administered from 4 months to 12 months after diagnosis of Type1 diabetes mellitus
The goal of this study was to attempt to prolong endogenous insulin secretion in those with new onset type 1 diabetes mellitus utilizing a humanized, anti-CD3 monoclonal antibody. This study was part of a multi-center trial.
Role: Co-PI

R01 DK44181-10 Rosenthal (PI) 1998-2003
NIDDK
IGFs and Skeletal Muscle Cell Differentiation.
The major goals of this project were to investigate the molecular mechanisms by which the insulin-like growth factors (IGFs) regulate myogenesis.
Role: PI

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Ehrensaft, Diane Ph.D.	Clinical Psychologist Adjunct Associate Professor of Pediatrics
eRA COMMONS USER NAME (credential, e.g., agency login) (b)(6)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of Michigan	B.A.	1968	Psychology
University of Michigan	Ph.D.	1974	Psychology

A. Personal Statement

In my roles as Director of Mental Health of the Child and Adolescent Gender Center and attending psychologist at the gender clinic in the Department of Pediatrics at Benioff Children's Hospital UCSF, I oversee the psychological assessment and treatment of all gender non-conforming children and youth who come through our program. This work is complemented by the extensive ongoing clinical work I do with gender nonconforming children and their families in my private practice. Since completing my doctoral dissertation at the University of Michigan on the topic of gender socialization in pre-school children, gender has consistently been the focus of my academic and clinical work. My research and writing has involved in-depth clinical studies of gender-nonconforming children and their families. As new medical interventions have been introduced to facilitate the care and treatment of these children and youth, specifically puberty blockers and cross-sex hormones, it has come to my attention that longitudinal research is now needed to demonstrate whether these medical and accompanying psychological interventions are having good effect in providing supports and positive mental health outcomes for gender-nonconforming and transgender children and youth, and look forward to seeing such a study launched with interdisciplinary and multi-site participation.

B. Positions and Honors

Positions and Employment

2011-	Clinical Faculty, Pediatrics, Psychologist, University of California, San Francisco (UCSF) Gender Clinic
2009-	Director of Mental Health, Child and Adolescent Gender Center
1981-	Clinical Psychologist, Private Practice, Oakland, California
1999-	Faculty, Psychoanalytic Institute of Northern California
1992-	Senior Clinician, A Home Within (non-profit organization addressing emotional needs of children/youth in foster care)
1982-	Licensed Clinical Psychologist (California License # PSY 7342)
1995-1999	Clinical Faculty, Mt. Zion Psychiatric Department, University of California, San Francisco
1992-1998	Clinical Faculty, Ann Martin Children's Center, Piedmont, California
1986-1992	Clinical Faculty, Department of Psychiatry, Children's Hospital San Francisco
1986-1990	Clinical Consultant, Children's Hospital Medical Center of Northern California, Oakland
1985-1986	Consulting Psychologist, Health America Rockridge, Oakland, California
1982-1988	Independent Contractor to Child Development Center, Children's Hospital Medical Center of Northern California
1981-2004	Professor, The Wright Institute, Berkeley
1980-1983	Mental Health Consultant, Alameda Headstart, Alameda, CA
1979-1981	Faculty, University of San Francisco
1977-1979	Faculty, Field Studies Program, University of California, Berkeley
1974-1978	Faculty, Interdisciplinary Program on Day Care and Child Development, University of California, Berkeley
1974-1978	Faculty, School of Social Welfare, University of California, Berkeley

1972-1973 Faculty, Sociology Department, Sir George Williams University, Montreal, Quebec

Other Experience and Professional Memberships

1968, 1969, 1970 NIMH Fellowship, University of Michigan
1971 Rackham Pre-doctoral Fellowship, University of Michigan
1972 University of Michigan Dissertation Grant
1982 Election to Board of the Section on Childhood and Adolescence, Division of Psychoanalysis, American Psychological Association
1992 Election to Board of the Section on Women, Gender, and Psychoanalysis, Division of Psychoanalysis, American Psychological Association
2002 Appointment to Board of Directors, Division of Psychoanalysis, American Psychological Association
2004 Election to Board of the Section on Psychoanalysis and Social Justice, Division of Psychoanalysis, American Psychological Association
2011 Appointment as co-chair of the 2015 Division of Psychoanalysis meeting, San Francisco

Honors

2012 Annual Scholarship Award Advancement of Gender Issues in Psychoanalysis APA, Division of Psychoanalysis
2013 Recognition Award for Outstanding Service, Childhood and Adolescence, APA, Division of Psychoanalysis

C. Selected Peer-Reviewed Publications (Selected from 32 peer-reviewed publications)

Most relevant to the current application (in reverse chronological order)

1. Vance S, **Ehrensaft D**, Rosenthal SM. Psychological and medical care of gender nonconforming youth. Pediatrics, 2014, in press.
2. Sherer I, Baum J, **Ehrensaft D**, Rosenthal SM. Gender Nonconforming/Gender Expansive and Transgender Children and Teens. Under review (invited manuscript) at Contemporary Pediatrics, 2014.
3. **Ehrensaft D**. Found in transition: Our littlest transgender people. Contemporary Psychoanalysis, 2014, in press.
4. **Ehrensaft, D.** Learning from Gender-nonconforming Children. The Psychoanalytic Study of the Child, 2014 (in press).
5. **Ehrensaft D**. "Look, Mom, I'm a Boy—Don't Tell Anyone I Was a Girl." Journal of LGBT Youth, 10:1–20, 2013.
6. Hidalgo MA, **Ehrensaft D**, Tishelman AC, Clark LF, Garofalo R, Rosenthal SM, Spack NP, Olson J. The gender affirmative model: What we know and what we aim to learn. Human Development 56:285-290, 2013.
7. Sherer I, Rosenthal SM, **Ehrensaft D**, Baum J: Child and Adolescent Gender Center: A multidisciplinary collaboration to improve the lives of gender nonconforming children and teens. Pediatr Rev 33:273-275, 2012.
8. **Ehrensaft, D**. From gender identity disorder to gender identity creativity: True gender self therapy. Journal of Homosexuality, 59, 337–356, 2012.
9. **Ehrensaft D.** Boys will be girls, girls will be boys: Children affect parents as parents affect children in gender nonconformity. Psychoanalytic Psychologist 28: 528-548, 2011.
10. **Ehrensaft D.** One pill makes you boy, one pill makes you girl. International Journal of Applied Psychoanalytic Studies, 6: 12–24, 2009.
11. **Ehrensaft D.** Raising Girlyboys: A Parent's Perspective. Studies in Gender and Sexuality 8(3): 269-302, 2007.
12. **Ehrensaft D.** The Stork Didn't Bring Me, I Came From a Dish: Psychological Experiences of Children Conceived through Assisted Reproductive Technology. Journal of Infant, Child, and Adolescent Psychotherapy 6(2): 124-140, 2007.

Additional recent publications of importance to the field (in reverse chronological order)

13. **Ehrensaft D.** What's your gender? In C. Bonovitz & A. Harlem (eds.), Developmental Approaches to Therapeutic Action in Child Psychotherapy, New York: Routledge, 2014, in press.

14. **Ehrensaft D.** A terrible thing happened on the way to becoming a girl. In P. Cohen, K. M. Sossin, & R. Ruth (eds.), Healing After Parent Loss in Childhood and Adolescence, New York: Rowman & Littlefield, 2014.
15. **Ehrensaft, D.** Gender born, gender made: Raising healthy gender-nonconforming children. New York: The Experiment, 2011.

D. Research Support

No ongoing and completed research projects for the past three years (Federal or non-Federally-supported).

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Glidden, David V.	Professor of Biostatistics
eRA COMMONS USER NAME (credential, e.g., agency login) (b)(6)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of California, Berkeley, CA	B.A.	1988	Statistics
University of Washington, Seattle, WA	Ph.D.	1993	Biostatistics
Harvard University, Boston, MA	Fellowship	1995	Biostatistics

A. Personal Statement

I will work as a resource for Dr. Schrager and will provide advice and support on analytic approaches. I will contribute expertise on the statistical design of the study, the framing of hypotheses and development of analysis strategies to test those hypotheses with focus on the analysis of the metabolic data. I will be responsible for the design, analysis plan development, and execution of these analyses.

B. Positions and Honors

Positions and Employment

1988-1993 Research Assistant, University of Washington
1993-1995 Research Fellow, Harvard University, Boston MA
1995-1997 Research Associate, Harvard University, Boston, MA
1997-2003 Assistant Adjunct Professor, University of California, San Francisco
2003-2007 Associate Professor in Residence, University of California, San Francisco
2007- Professor in Residence University of California, San Francisco

Honors and Awards

1988 W.W. Stout Fellowship, Graduate School, University of Washington
1988-1990 Graduate Fellowship Award, Graduate School, University of Washington
1990-1993 National Research Service Award, National Heart, Lung and Blood Institute
1993 School of Public Health Outstanding Student Citation for Biostatistics, Univ. of Washington
2007 TICR Award for Excellence in Teaching

C. Selected Peer-reviewed Publications

Most relevant to the current application

1. Anderson PL, Glidden DV, Liu A, Buchbinder S, Lama JR, Guanira JV, McMahan V, Bushman LR, Casapi M, Montoya-Herrera O, Veloso VG, Mayer KH, Chariyalertsak S, Schechter M, Bekker LG, Kallas EG, Grant RM for the iPrEx Study Team. Emtricitabine-Tenofovir concentrations and pre-exposure prophylaxis efficacy in men who have sex with men. *Science Translational Medicine*, 2012.
2. Grant RM, Lama JR, Anderson PL, McMahan V, Liu AY, Vargas L, Goicochea P, Casapía M, Guanira-Carranza JV, Ramirez-Cardich ME, Montoya-Herrera O, Fernandez T, Veloso VG, Buchbinder SP, Chariyalertsak S, Schechter M, Bekker LG, Mayer KH, Kallas EG, Amico KR, Mulligan K, Bushman LR, Hance RJ, Ganoza C, Defechereux P, Postle B, Wang F, McConnell JJ, Zhang JH, Lee J, Rooney JF, Jaffe HS, Martinez AI, Burns DH, Glidden DV for the iPrEx Study Team. Pre-exposure chemoprophylaxis for HIV prevention in men who have sex with men. *New England Journal of Medicine*, 363: 2587-99, 2010.

3. Glidden DV. Design by Trail. *Nature* 490 :350-1. doi: 10.1038/490350a, 2012 (invited commentary on Rolland, et al, doi:10.1038/nature11519).

Additional recent publications of importance to the field (in chronological order)

4. Fleming TR, Prentice RL, Pepe MS, Glidden D. Surrogate and auxiliary endpoints in clinical trials with potential applications in cancer and AIDS research. Statistics in Medicine 13:955-968, 1994.
5. Glidden DV, Self SG. Semiparametric likelihood estimation in the Clayton-Oakes model. Scandinavian Journal of Statistics 26:363-372, 1999.
6. Glidden DV, Wei LJ. Rank estimation of treatment differences based on repeated measurements subject to dependent censoring. Journal of the American Statistical Association 94:888-895, 1999.
7. Glidden, DV. A two-stage estimator of the dependence parameter in the Clayton-Oakes model. Lifetime Data Analysis 6:141-156, 2000.
8. Para MF, Glidden DV, Coombs RW, Collier AC, Condra JH, Craig C, Bassett R, Leavitt R, Snyder S, McAuliffe V, Boucher C and AIDS Clinical Trials Group Protocol 333 Team. Baseline human immunodeficiency virus type 1 phenotype, genotype, and RNA response after switching from long-term hard-capsule saquinavir to indinavir or soft-gel capsule saquinavir in AIDS Clinical Trials Group Protocol 333. Journal of Infectious Diseases 182:733-743, 2000.
9. Glidden DV. Robust inference for event probabilities with non-Markov data. Biometrics 58:361-368, 2002.
10. Glidden DV. Rejoinder to the discussion of P.R. Burton and M.P. Epstein. Gen Epidemiol 23:219-20, 2002.
11. Glidden DV, Liang K-Y, Chiu Y-F, Pulver AE. Multipoint affected sibpair linkage methods for localizing susceptibility genes for complex diseases. Genetic Epidemiology 24:107-177, 2003.
12. Glidden DV, Vittinghoff E. Modelling clustered survival data from multicentre clinical trials. Stat Med 23:369-88, 2004.
13. Vittinghoff E, Glidden DV, Shiboski SC, McCulloch CE. Regression Methods in Biostatistics: Linear, Logistic, Survival and Repeated Measures Models. Springer, New York, 2005.
14. Glidden DV. Pairwise dependence diagnostics for clustered failure time data. Biometrika 94:371-85, 2007.
15. Geng EH, Glidden DV, Bangsberg DR, Bwana MB, Musinguzi N, Nash D, Metcalfe JZ, Yiannoutsos CT, Martin JN, Petersen ML. A causal framework for understanding the effect of losses to follow-up on epidemiologic analyses in clinic-based cohorts: The case of HIV-infected patients on antiretroviral therapy in Africa. American Journal of Epidemiology, doi: 10.1093/aje/kwr444

D. Research Support

Ongoing Research Support

U01AI064002-07 (Grant; UCSF PI Glidden) 1/31/13-11/30/14
NIH
Chemoprophylaxis for HIV Prevention in Men Expansion
Statistics Core for a randomized trial of chemoprophylaxis for HIV, which evaluates the safety and efficacy of daily oral tenofovir. Supplement to NIH-NIAID U01 AI064002 (Grant).
Role: Co-Investigator

U01 AI069911 (Yiannoutsos; Martin PI UCSF subcontract) 8/5/06-7/31/16
NIH/University of Indiana
East Africa IEDEA Regional Consortium
To contribute and analyze data for the International Epidemiologic Databases to Evaluate AIDS (IEDEA) from the Mbarara, Uganda-based ISS and UARTO cohorts.
Role: Co-Investigator

Completed Research Support

R01NS063876 McQuillen 9/1/09-8/30/12
NIH-NINDS
White Matter Injury in Critically Ill Newborns with Congenital Heart Disease

The goal of this study is to use perioperative advanced MR imaging in fetuses and neonates with congenital heart disease to determine if fetal and postnatal delayed brain development is a risk factor for perioperative white matter injury.
Role: Co-Investigator

P01 NS41997 Carlson; Project 3 Prusiner 7/1/07-6/30/12
NIH-NINDS/McLaughlin Research Inst.
Functional Genetics of Susceptibility to Prions
To develop cell culture models based on neurospheres, to understand the cell biology of various prions strains, and to enable rapid assay of of prions from a range of species.
Role: Co-Investigator

UL1 RR024131 Johnston (PI) 9/30/06-6/30/11
NIH-NCRR
Clinical and Translational Science Institute
To enhance training and infrastructure to foster the translation of discoveries in basic science into practices that promote the health of our patients and our community.
Role: Co-Investigator

U01 AI064002 Grant / Shafer (PI) 8/15/05-1/31/09
NIH/NIAID/Gladstone Inst. Effort ended 1/31/08
Chemoprophylaxis for HIV Prevention in Peruvian Men
To evaluate the safety and efficacy of chemoprophylaxis for HIV prevention in a randomized and blinded trial of daily oral tenofovir versus placebo among men in Peru.
Role: Co-investigator

R01 NS046432 Barkovich (PI) 9/15/04-5/31/08
NIH/NINDS Effort ended 5/31/07
MRSI and DTI of Brain Injury in Preterm Neonates
To determine if MR techniques detect metabolic or microstructural abnormalities associated with subsequent cognitive, visual, motor, and auditory deficits more accurately than current clinical parameters.
Role: Co-investigator

R01 HL65411 Glidden (PI) 4/1/01-3/31/06
NIH/NHLBI
Failure Time Methods for Family Disease Studies
The long-term objective of this research is the development of sound methodologies that will facilitate studying the role of both genetic and environmental factors in cardiovascular disease. The short-term goal of the proposal is to develop statistical methods for age at onset data from population-based family studies of disease incidence.
Role: Principal Investigator

U62/CCU922423 Rutherford (PI) 9/30/02-3/31/06
CDC
Univ. Technical Assistance Projects in Support of the Global AIDS Program: Uganda
Project will provide technical assistant in support of the Global AIDS Program to Uganda. Assistance will be provided in the areas of training, research methodology, and evaluation and monitoring.
Role: Co-investigator

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 1

ORGANIZATIONAL DUNS*: 0522779360000

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2015 **End Date*:** 06-30-2016 **Budget Period:** 1

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Johanna		Olson	M.D.	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Marvin		Belzer	MD	Co-Investigator							
3 .				(b)(6)									
4 .	Dr.	Sheree		Schrager	PhD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
0	Post Doctoral Associates	(b)(4)	0.00	0.00	(b)(4)	(b)(4)	(b)(4)
0	Graduate Students		0.00	0.00			
0	Undergraduate Students		0.00	0.00			
1	Secretarial/Clerical						
1	Study Coordinator						
1	Data Manager						
1	Clinical Research Manager						
1	Psychologist						
5	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 1

ORGANIZATIONAL DUNS*: 0522779360000
Budget Type*: ● Project ○ Subaward/Consortium
Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2015 **End Date*:** 06-30-2016 **Budget Period:** 1

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	0.00
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 1

ORGANIZATIONAL DUNS*: 0522779360000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2015 **End Date*:** 06-30-2016 **Budget Period:** 1

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	(b)(4)
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Outpatient Care Costs - Labs	
9 . Participant Incentives	
10 . Participant Transportation	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Robert Lee, 415-437-7820
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*
	0.00

K. Budget Justification*	File Name: 1234-CHLA Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 2

ORGANIZATIONAL DUNS*: 0522779360000

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2016 **End Date*:** 06-30-2017 **Budget Period:** 2

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Johanna		Olson	M.D.	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Marvin		Belzer	MD	Co-Investigator							
3 .	Dr.	Leslie		Clark	PhD	Co-Investigator							
4 .	Dr.	Sheree		Schrager	PhD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
1	Secretarial/Clerical	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Study Coordinator						
1	Data Manager						
1	Clinical Research Manager						
1	Psychologist						
5	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 2

ORGANIZATIONAL DUNS*: 0522779360000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2016 **End Date*:** 06-30-2017 **Budget Period:** 2

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees — Total Participant Trainee Support Costs	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 2

ORGANIZATIONAL DUNS*: 0522779360000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2016 **End Date*:** 06-30-2017 **Budget Period:** 2

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	(b)(4)
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Outpatient Care Costs - Labs	
9 . Participant Incentives	
10 . Participant Transportation	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Robert Lee, 415-437-7820
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Budget Justification* File Name: 1234-CHLA Budget Justification.pdf
(Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 3

ORGANIZATIONAL DUNS*: 0522779360000

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2017 **End Date*:** 06-30-2018 **Budget Period:** 3

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Johanna		Olson	M.D.	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Marvin		Belzer	MD	Co-Investigator							
3 .	Dr.	Leslie		Clark	PhD	Co-Investigator							
4 .	Dr.	Sheree		Schrager	PhD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
1	Secretarial/Clerical	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Study Coordinator						
1	Data Manager						
1	Clinical Research Manager						
1	Psychologist						
5	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 3

ORGANIZATIONAL DUNS*: 0522779360000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2017 **End Date*:** 06-30-2018 **Budget Period:** 3

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees — Total Participant Trainee Support Costs	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 3

ORGANIZATIONAL DUNS*: 0522779360000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2017 **End Date*:** 06-30-2018 **Budget Period:** 3

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	(b)(4)
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Outpatient Care Costs - Labs	
9 . Participant Incentives	
10 . Participant Transportation	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Robert Lee 415-437-7820
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Budget Justification*	File Name: 1234-CHLA Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 4

ORGANIZATIONAL DUNS*: 0522779360000

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2018 **End Date*:** 06-30-2019 **Budget Period:** 4

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Johanna		Olson	M.D.	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Marvin		Belzer	MD	Co-Investigator							
3 .	Dr.	Leslie		Clark	PhD	Co-Investigator							
4 .	Dr.	Sheree		Schrager	PhD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
1	Secretarial/Clerical	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Study Coordinator						
1	Data Manager						
1	Data Coordinating Site Statistician						
1	Clinical Research Manager						
1	Psychologist						
6	**Total Number Other Personnel**						

Total Other Personnel (b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 4

ORGANIZATIONAL DUNS*: 0522779360000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2018 **End Date*:** 06-30-2019 **Budget Period:** 4

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 4

ORGANIZATIONAL DUNS*: 0522779360000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2018 **End Date*:** 06-30-2019 **Budget Period:** 4

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	(b)(4)
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Outpatient Care Costs - Labs	
9 . Participant Incentives	
10 . Participant Transportation	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Robert Lee, 415-437-7820
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Budget Justification* File Name: 1234-CHLA Budget Justification.pdf
(Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 5

ORGANIZATIONAL DUNS*: 0522779360000

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period:** 5

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Johanna		Olson	M.D.	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Marvin		Belzer	MD	Co-Investigator							
3 .	Dr.	Leslie		Clark	PhD	Co-Investigator							
4 .	Dr.	Sheree		Schrager	PhD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
1	Post Doctoral Associates	(b)(4)			(b)(4)	(b)(4)	(b)(4)
	Graduate Students						
	Undergraduate Students						
1	Secretarial/Clerical						
1	Study Coordinator						
1	Data Manager						
1	Data Coordinating Site Statistician						
1	Clinical Research Manager						
6	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 5

ORGANIZATIONAL DUNS*: 0522779360000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period:** 5

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees — Total Participant Trainee Support Costs	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 5

ORGANIZATIONAL DUNS*: 0522779360000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period:** 5

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	(b)(4)
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Outpatient Care Costs - Labs	
9 . Participant Incentives	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Robert Lee, 415-437-7820
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Budget Justification*	File Name: 1234-CHLA Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

BUDGET JUSTIFICATION – CHILDREN'S HOSPITAL LOS ANGELES

On 2/4/14, NICHD approved our request for a waiver of policy and would accept our large grant application for review (please see Attachment). The total direct costs excluding the consortium F&A costs approved were $ (b)(4) . The total direct costs excluding the consortium F&A costs for this resubmission are $ (b)(4) .

A. Senior/Key Personnel

Johanna Olson, M.D., Lead/ Principal Investigator ((b)(4) Calendar Months (CM) Y1; (b)(4) CM Y2-Y4; (b)(4) CM Y5)

Qualifications: Dr. Olson's research has primarily focused on transgender youth. She has a strong experience in research on issues of transgender youth including a two-year CHLA new investigator award and is one and a half years into her KL2 translational science award examining the impact of treatment of transgender youth. Dr. Olson is one semester from finishing a Master's Degree in Clinical and Biomedical Investigations at USC, and has two first author papers about transgender youth currently under review. Finally, she has extensive clinical experience treating transgender youth over the past five years. She expanded the Center for Transyouth Health and Development to include care and consultative services for children of all ages, and over the past two years worked to quadruple the number of patients served by the Center.

Role on Project: As principal investigator, Dr. Olson is responsible for overseeing all aspects of the proposed work at the CHLA site and coordinating with the Principal Investigators and Co-Investigators at the other three sites. Dr. Olson will oversee the activities of the Data Coordinating Site and serve as the liaison to the larger group of PI and Co-investigators. Dr. Olson will oversee development and implementation of the protocols for data collection, including physiologic and psychosocial data, at CHLA. As principal investigator she will be primarily responsible for overseeing coordination of care services for participants enrolled in the study at CHLA, assist in the development of the implementation protocol and contribute to presentations and manuscripts based on study data. **Total Salary Requested Y1-Y5: $** (b)(4)

Marvin Belzer, M.D., Co-Investigator ((b)(4) CM Y1; (b)(4) CM Y2-Y4; (b)(4) CM Y5)

Qualifications: Dr. Belzer is the Director of the Division of Adolescent Medicine and has been PI for Los Angeles Adolescent Trials Network site for the past 13 years. He has been primary mentor for Dr. Olson over the past three and a half years. As a longstanding member of the NICHD funded Adolescent Trials Network, he has been involved in research with HIV+ adolescents and transgender adolescents for several years. Dr. Belzer has provided clinical care for transyouth for over 20 years.

Role on Project: As a Co-Investigator, Dr. Belzer will provide mentorship, expertise, and guidance to Dr. Olson in implementing this complex multi-site research endeavor. **Total Salary Requested Y1-Y5: $** (b)(4)

Leslie F. Clark, Ph.D., M.P.H., Co-Investigator ((b)(4) CM Y1 and Y5; (b)(4) CM Y2-Y4)

Qualifications: Dr. Clark is a social health psychologist with training in public health and the Director of Research for the Division of Adolescent Medicine, Department of Pediatrics, at the USC Keck School of Medicine. She has worked on issues of gay and transgender youth for 18 years. Her CDC- and NIH-funded work include development, implementation, and evaluation of behavioral interventions for minority adolescents, young gay men, transgender youth, homeless youth and HIV+ youth. She was a founding member of the Behavioral Leadership Group of the NIH-funded Adolescent Trials Network and has extensive research experience with standardized measures, instrument development, implementation fidelity, and analysis of longitudinal data sets.

Role on Project: Dr. Clark will have a principal role in design of the study, methodological decision making, setting up study protocols, and survey instrument design. Dr. Clark will be responsible for coordinating the psychosocial aspects of the proposed work, including finalization of psychosocial measures with the behavioral health Co-Is, as well as establishing and maintaining a central repository of measures and relevant literature. She will also assist with survey development, data collection protocols, and intervention implementation plans. She will collaborate in cross-site data analysis, preparation of manuscripts, and strategic dissemination of discovery. **Total Salary Requested Y1-Y5: $** (b)(4)

(b)(4)

Sheree M. Schrager, Ph.D., M.S., Co-Investigator (CM Y1-Y5)
Qualifications: Dr. Schrager is a social psychologist with extensive knowledge of advanced statistical methods relevant to social and physical sciences and experience collecting and analyzing cross-sectional and longitudinal psychological and health datasets. She is currently the Co-Investigator of a NIDA-funded R01 grant studying substance use among adolescents in the child welfare system and has numerous publications on LGBT adolescents and young adults. As a senior manager at CHLA, she manages federally funded research projects, including design of study protocols and instruments; ensuring compliance with IRB and funding source requirements; documenting research processes, including intervention, process, and evaluation data; generating data analysis plans and supervising researchers responsible for data collection, management, and analysis; leading project-related training and meetings; and developing manuscripts for publication.
Role on Project: Dr. Schrager will advise the study core responsible for establishing standard procedures, merging collected data, and managing, analyzing, and reporting on data from all four study sites and collaborate with the project PIs and Co-Is to provide scientific leadership and direction, particularly related to psychological variable measurement and operationalization. She will provide direction to the CHLA site study coordinator, data collection staff, data manager, and biostatistician responsible for data management, cleaning, and analysis. She will also assist with survey development and constructing the protocols that will standardize the data collection and merging procedures; oversee the programming of final data collection instruments and pilot testing of ACASI programming logic; and provide advanced statistical consultation to the project, including diagnosing data problems, developing and executing analytical plans, and advising the analytic team on appropriate longitudinal data analysis methods and procedures. **Total Salary Requested Y1-Y5: $** (b)(4)

B. Other Personnel

(b)(4)

To Be Named, Post-Doc Fellow (CM Y5)
A Post-Doctoral Fellow will be hired in year 5 to assist in the longitudinal modeling and other data analyses associated with the project and develop manuscripts for publication. **Total Salary Requested Y5: $** (b)(4)

(b)(4)

(b)(6) **, Secretarial/Clerical (Research Assistant) (CM Y1-Y5)**
(b)(6) will be responsible for ordering supplies, scheduling conference calls, arranging travel for annual meetings, and conference participation of PIs and Co-investigators. (b)(6) will provide general administrative support to core staff and will report to Drs. Schrager and Olson. **Total Salary Requested Y1-Y5: $** (b)(4)

(b)(4) (b)(4) (b)(4)

To Be Named, Study Coordinator (CM Y1; CM Y2-4; CM Y5)
She/he will conduct CHLA Institutional Review Board (IRB) activities, create and implement procedures for study visits per the protocol, collect study data, interact with study participants, and provide feedback to the CHLA research team. **Total Salary Requested Y1-5: $** (b)(4)

(b)(4) (b)(4) (b)(4)

To Be Named, Data Manager (CM Y1; CM Y2-Y3; CM Y4-5)
This person will have extensive experience in quantitative research, including the development of data collection protocols, the design of data collection instruments, quality control, and the management of large complex data sets. This person will assist in the generation of cross-site protocols for data collection; templates for the Human Subjects IRB Boards at each site; and forms for respondent recruitment, enrollment and tracking, as well as for off-protocol and adverse events documentation. This person will train site-specific data collection staff; generate tracking tools; and enact quality control procedures for monitoring fidelity of protocol implementation, adverse event reporting, and all study forms. The data manager will be responsible for ensuring that site data are safely transferred via secure protocols to CHLA for cleaning and merging. The data manager will generate tracking reports regarding the accrual of respondents at each site as well as specific characteristics of the emerging cross-site data file. In addition, this person manages the overall data set, merging different elements, cleaning, creating composite variables and scales and running descriptive statistics such as characteristics of subjects for the entire sample (male v. female, other demographics, etc.) for the larger study group. She/he will be responsible for the establishing and maintaining a manual of all documents as implemented, IRB protocols, amendments, approvals, adverse event reporting, and correspondence. **Total Salary Requested Y1-Y5: $** (b)(4)

(b)(4)

To Be Named, Data Coordinating Site Statistician (CM Y4; CM Y5)

(b)(4)

A Data Coordinating Site Statistician is budgeted for small amounts in the last year to support both central analyses to be used by all sites as well as any analyses to support future collaborative funding efforts. **Total Salary Requested Y4-Y5: $**(b)(4)

(b)(4)

(b)(6), **Clinical Research Manager (** **CM Y1-Y5)** (b)(6)

(b)(6) has strong skills in managing clinical research trials. experience includes budget management, supervision of research protocol implementation, conducting quality assurance activities, and IRB and regulatory documentation. (b)(6) will supervise the CHLA Study Coordinator, provide support and assistance for study-related activities, and conduct quality assurance activities. **Total Salary Requested Y1-Y5: $**(b)(4)

(b)(4) (b)(4)

(b)(6), **Psychologist (** **CM Y1,** **CM Y2-Y4)**

(b)(6) has extensive experience in providing individual, family, and group therapy to transgender youth. (b)(6) will provide psychological evaluation of CHLA study participants, therapeutic services, and urgent assessments related to research participation. **Total Salary Requested Y1-Y4: $**(b)(4)

Fringe Benefits

The fringe benefit rate for USC Faculty (Dr. Olson, Dr. Belzer and Dr. Clark) is 31.1% of Salaries. The fringe benefit rate for Children's Hospital Los Angeles staff (the rest of the personnel) is 25.5%. Total Fringe Benefits are: Year 1 $(b)(4); Year 2 $(b)(4); Year 3 $(b)(4); Year 4 $(b)(4); Year 5 $(b)(4). **Total Fringe Benefits Requested Y1-Y5: $**(b)(4)

C. Equipment

No Equipment in excess of $(b)(4) per item will be purchased.

D. Travel

The Data Coordinating Site requests travel funds to support an annual trip for non-CHLA PI and Co-Investigators to meet in Los Angeles to discuss research agendas, progress, and products. Domestic travel is budgeted at $1,000 per person (including airfare, hotel, and per diem) for two investigators from San Francisco and $1,500 per person (including airfare, hotel, and per diem) for four investigators from the sites outside of California. In addition, the PI or a Co-I at each site will make one domestic trip to a relevant professional conference, grantee meeting, or to consult with other researchers ($1,750 for hotel, airfare, and per diem). A total of $15,000 is requested for travel in Year 1. In Year 2, $10,000 is requested for the annual PI/Co-I meeting and $4,000 for domestic travel for relevant professional conference, grantee meeting, or to consult with other researchers for at total of $14,000. In Year 3, $7,449 is budgeted for the PI/Co-I meeting. In Year 4, $8,000 is requested for the annual PI/Co-I meeting and $2,278 for domestic travel for relevant professional conference, grantee meeting, or to consult with other researchers for at total of $10,278. In Year 5, $8,000 is requested for the annual PI/Co-I meeting and $7,492 for domestic travel for relevant professional conference, grantee meeting, or to consult with other researchers for at total of $15,492. **Total Travel Requested Y1-Y5: $62,219**

E. Participant/Trainee Support Costs

No Participant/Trainee Supports Costs are being requested.

F. Other Direct Costs

Other Direct Costs are as follows:

F1. Materials and Supplies: Computers are budgeted at $(b)(4) each per site and one for the data manager in Year 1. Software for data collection, management, and storage will be purchased for the four site specific laptops and the data manager computer and is requested at $(b)(4) in Year 1. Project specific supplies for use in study activities are proposed at $(b)(4) for Year 1, $(b)(4) for Year 2, $0 for Years 3 through 5 for a Total of $(b)(4). **Total Materials and Supplies Requested Y1-Y5: $(b)(4)**

F2. Publication Costs: No Publication Costs are being requested.

F3. Consultant Services: No Consultant Services are being requested.

F4. ADP/Computer Services: No ADP/Computer Services are being requested.

F5. Subawards/Consortium/Contractual Costs: Consortium costs are as follows:

Boston Children's Hospital:

	Direct	Indirect ((b)(4)%)	TOTAL Per Year
Year 1	$	$	$
Year 2	$	$	$
Year 3	$	$	$
Year 4	$ (b)(4)	$ (b)(4)	$ (b)(4)
Year 5	$	$	$
TOTAL	**$**	**$**	**$**

Lurie Children's Hospital of Chicago: (b)(4)

	Direct	Indirect ((b)(4)%)	TOTAL Per Year
Year 1	$	$	$
Year 2	$	$	$
Year 3	$	$	$
Year 4	$ (b)(4)	$ (b)(4)	$ (b)(4)
Year 5	$	$	$
TOTAL	**$**	**$**	**$**

University of California San Francisco: (b)(4)

	Direct	Indirect ((b)(4)%)	TOTAL Per Year
Year 1	$	$	$
Year 2	$	$	$
Year 3	$	$	$
Year 4	$ (b)(4)	$ (b)(4)	$ (b)(4)
Year 5	$	$	$
TOTAL	**$**	**$**	**$**

Cost sharing: Expertise across the specialties will be available for all of the sites. In this manner, we are able to avoid duplication and increased cost of specialists at each site. Subawards/Consortium/Contractual cost for Year 1 are $(b)(4), Year 2 $(b)(4), Year 3 $(b)(4), Year 4 $(b)(4), Year 5 $(b)(4). **Total Subawards/Consortium/Contractual Costs Requested Y1-Y5: $(b)(4).**

F6. Equipment or Facility Rental /User Fees: No Equipment or Facility Rental/User Fees are being requested.

F7. Alterations and Renovations: No Alterations and Renovations are being requested.

F8. Outpatient Care Costs: While it is our expectation that insurance will cover the labs associated with this proposal for the most part, we acknowledge that there may be instances where obstacles arise and insurance is unable to cover labs required for research windows as proposed. Therefore, we are requesting $(b)(4) to cover an estimated 10-20% of laboratory costs in Year 1, $(b)(4) in Year 2, $(b)(4) in Year 3, $(b)(4) in Year 4, and $(b)(4) in Year 5. The funding request fluctuates over the years to correlate with the flow of patient visits based on the visit timeline. Children's Hospital Los Angeles has a DHHS-negotiated research patient care rate agreement for in-house clinical research labs at 38% of cost; however, many of these labs are sent to off-site laboratories such as Quest, and those charges are at cost. Examples of expected labs and their associated costs are:

-Gonadotropin Assay (Follicle Stimulating Hormone) $(b)(4)
-Free Testosterone Assay $(b)(4)
-Total Testosterone Assay $(b)(4)
-Estradiol Ultra Sensitive Assay $(b)(4)
Total Outpatient Care Costs Requested Y1-Y5: $(b)(4)

(b)(4) (b)(4)

F9. Participant Incentives: Compensation of $40 will be provided at each visit to the participants. For the early pubertal cohort, the parent-child dyad will receive only $40 even though they are both considered research subjects. We anticipate the following numbers of visits by year: Year 1: ; Year (b)(4); Year 3: ; Year 4: , Year 5: . Therefore we request $(b)(4) for Year 1, $(b)(4) for Year 2, $(b)(4) in Year 3, $(b)(4) for Year 4, and $ for Year 5.
Total Participant Incentives Requested Y1-Y5: $(b)(4)

(b)(4) (b)(4)

F9. Participant Transportation: For the site-specific activities, participant transportation is requested at $70 per site visit for those participants who do not have reliable transportation. We request $(b)(4) (18 visits) for Year 1, $(b)(4) (72.5 visits) for Year 2, $(b)(4) (50 visits) for Year 3, $(b)(4) (25 visits) for Year 4, and $0 for Year 5. **Total Participant Transportation Requested Y1-Y4: $(b)(4)**

G. Total Direct Costs

Total Direct Costs are as follows:

	Direct
Year 1	$
Year 2	$
Year 3	$
Year 4	$
Year 5	$
TOTAL	**$**

(b)(4)

H. Indirect Costs

Indirect costs (Facilities & Administrative Costs) are based on Modified Total Direct Costs and are (b)(4)% as approved by the Department of Health and Human Services on 2/5/14.

(b)(4)

	Indirect (%)
Year 1	$
Year 2	$
Year 3	$
Year 4	$
Year 5	$
TOTAL	**$**

(b)(4)

I. Total Direct and Indirect Costs

	Direct	Indirect (b)(4) (b)(4)%	TOTAL Per Year
Year 1	$	$	$
Year 2	$	$	$
Year 3	$	$	$
Year 4	$ (b)(4)	$ (b)(4)	$ (b)(4)
Year 5	$	$	$
TOTAL	$	$	$

J. Fee

No Fee is being requested.

Timeline of Project Activities: Funds will be used to implement the research project according to the following Timeline of Project Activities:

Activities	YEAR 1 (SEP '14-AUG '15)				YEAR 2 (SEP '15-AUG '16)				YEAR 3 (SEP '16-AUG '17)				YEAR 4 (SEP '17-AUG '18)				YEAR 5 (SEP '18-AUG '19)			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Start Up and Project Implementation Activities																				
Ongoing cross-site decisional calls	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Protocol development/IRB approval	X	X																		
Hire project data manager	X																			
Pilot test measures and procedures		X																		
Program and test ACASI		X																		
Hire/train project coordinators and staff			X																	
Convene yearly cross site meetings	X				X				X				X				X			
Data Collection: Early Pubertal Cohort																				
Recruit and consent subjects			X	X	X	X	X	X	X	X										
Baseline ACASI/physiologic data			X	X	X	X	X	X	X	X										
6,12, 24-month assessments					X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Data Collection: Late Pubertal Cohort																				
Recruit and consent subjects			X	X	X	X	X	X												
Baseline ACASI/physiologic data			X	X	X	X	X	X	X											
6,12, 24-month assessments					X	X	X	X	X	X	X	X	X	X	X	X	X			
Data Management, Analysis, and Write Up																				
Data management			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Data analysis							X	X	X	X	X	X	X	X	X	X	X	X	X	X
Dissemination and publications								X	X	X	X	X	X	X	X	X	X	X	X	X

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		
Section B, Other Personnel		
Total Number Other Personnel		
Total Salary, Wages and Fringe Benefits (A+B)		
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs	(b)(4)	(b)(4)
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1		
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		
Section H, Indirect Costs		
Section I, Total Direct and Indirect Costs (G + H)		
Section J, Fee		

Tracking Number: GRANT11778555

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 1

ORGANIZATIONAL DUNS*: 0765937220000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Boston Children's Hospital

Start Date*: 07-01-2015 **End Date*:** 06-30-2016 **Budget Period:** 1

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Norman		Spack	MD	PD/PI	(b)(4)				(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Amy		Tishelman	PhD	Co-Investigator							
3 .	Dr.	Daniel		Shumer	MD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Research Nurse	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Project Coordinator						
2	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 1

ORGANIZATIONAL DUNS*: 0765937220000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Boston Children's Hospital

Start Date*: 07-01-2015 **End Date*:** 06-30-2016 **Budget Period:** 1

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees	Total Participant Trainee Support Costs

RESEARCH & RELATED Budget (C-E) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 1

ORGANIZATIONAL DUNS*: 0765937220000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Boston Children's Hospital

Start Date*: 07-01-2015 **End Date*:** 06-30-2016 **Budget Period:** 1

F. Other Direct Costs	Funds Requested ($)*
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Joseph Guarnieri, 212-264-2069
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Budget Justification*	File Name: 1241-Boston Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 2

ORGANIZATIONAL DUNS*: 0765937220000
Budget Type*: ○ Project ● Subaward/Consortium
Enter name of Organization: Boston Children's Hospital

Start Date*: 07-01-2016 **End Date*:** 06-30-2017 **Budget Period:** 2

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Dr.	Norman		Spacks	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2.		(b)(6)											
3.	Dr.	Daniel		Shumer	MD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Research Nurse						
1	Project Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Research Assistant						
3	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)
						Total Salary, Wages and Fringe Benefits (A+B)	(b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 2

ORGANIZATIONAL DUNS*: 0765937220000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Boston Children's Hospital

Start Date*: 07-01-2016 **End Date*:** 06-30-2017 **Budget Period:** 2

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 2

ORGANIZATIONAL DUNS*: 0765937220000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Boston Children's Hospital

Start Date*: 07-01-2016 **End Date*:** 06-30-2017 **Budget Period:** 2

F. Other Direct Costs	Funds Requested ($)*
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Joseph Guarnieri, 212-264-2069
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Budget Justification*	File Name: 1241-Boston Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 3

ORGANIZATIONAL DUNS*: 0765937220000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Boston Children's Hospital

Start Date*: 07-01-2017 **End Date*:** 06-30-2018 **Budget Period:** 3

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Norman		Spack	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .				(b)(6)									
3 .	Dr.	Daniel		Shumer	MD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person 60,546.00

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Research Nurse						
1	Project Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Research Assistant						
3	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)
						Total Salary, Wages and Fringe Benefits (A+B)	(b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 3

ORGANIZATIONAL DUNS*: 0765937220000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Boston Children's Hospital

Start Date*: 07-01-2017 **End Date*:** 06-30-2018 **Budget Period:** 3

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 3

ORGANIZATIONAL DUNS*: 0765937220000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Boston Children's Hospital

Start Date*: 07-01-2017 **End Date*:** 06-30-2018 **Budget Period:** 3

F. Other Direct Costs	Funds Requested ($)*
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Joseph Guarnieri, 212-264-2069
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Budget Justification*	File Name: 1241-Boston Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 4

ORGANIZATIONAL DUNS*: 0765937220000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Boston Children's Hospital

Start Date*: 07-01-2018 **End Date*:** 06-30-2019 **Budget Period:** 4

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Dr.	Norman		Spack	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2.		(b)(6)											
3.	Dr.	Daniel		Shuman	MD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Research Nurse						
1	Project Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Research Assistant						
3	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 4

ORGANIZATIONAL DUNS*: 0765937220000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Boston Children's Hospital

Start Date*: 07-01-2018 **End Date*:** 06-30-2019 **Budget Period:** 4

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 4

ORGANIZATIONAL DUNS*: 0765937220000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Boston Children's Hospital

Start Date*: 07-01-2018 **End Date*:** 06-30-2019 **Budget Period:** 4

F. Other Direct Costs	Funds Requested ($)*
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Joseph Guarnieri, 212-264-2069
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Budget Justification*	File Name: 1241-Boston Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 5

ORGANIZATIONAL DUNS*: 0765937220000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Boston Children's Hospital

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period:** 5

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Dr.	Norman		Spack	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2.				(b)(6)									
3.	Dr.	Daniel		Shumer		Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Research Nurse						
1	Project Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Research Assistant						
3	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 5

ORGANIZATIONAL DUNS*: 0765937220000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Boston Children's Hospital

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period:** 5

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 5

ORGANIZATIONAL DUNS*: 0765937220000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Boston Children's Hospital

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period:** 5

F. Other Direct Costs	Funds Requested ($)*
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Joseph Guarnieri, 212-264-2069
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Budget Justification*	File Name: 1241-Boston Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

BUDGET JUSTIFICATION – BOSTON CHILDREN'S HOSPITAL

A. Senior/Key Personnel

(b)(4)

Norman Spack, M.D., Principal Investigator (Calendar Months (CM) Y1-Y5)
Qualifications: Dr. Spack is a Pediatric Endocrinologist and a principal in Boston Children's Hospital's Gender Management Service (GeMS) which opened in 2007. GeMS was the first pediatric academic program in the western hemisphere to treat early adolescents with gender dysphoria.
Role on Project: He will collaborate with the project Principal Investigators and relevant Co-Investigators to create and finalize a cross-site study implementation protocol, so that each site carries out the project in the same manner. He will take primary responsibility for the implementation of the scientific aims of this project at Boston Children's Hospital as well as collaborate to disseminate findings. **Total Salary Requested Y1-5: $** (b)(4)

(b)(4)

Amy Tishelman, Ph.D., Co-Investigator (CM Y1-5)
Qualifications: Dr. Tishelman is a Clinical Psychologist with significant expertise in scholarship and clinical realms. Before joining the GeMS team, she was the Director of Child Protection Clinical Services at Boston Children's Hospital and subsequently Director of Training and Research for that program.
Role on Project: She will share responsibility for the scientific and fiscal integrity of this project, provide support to research participants when needed, and will oversee all research activities at Boston Children's Hospital. She will assist in directly supervising and managing frontline research activities involving project direction and data management. Specifically, Dr. Tishelman, along with Dr, Shumer, will supervise the Project Coordinator in her/his management of day-to-day tasks by coordinating IRB submissions, developing and overseeing effective recruitment strategies, and providing ongoing advice regarding confidential data collection/ management procedures. She will share responsibility for data interpretation and dissemination of findings with Drs. Spack and Shumer. **Total Salary Requested Y1-5: $** (b)(4)

(b)(4)

Daniel Shumer, M.D., Co-Investigator (CM Y1-Y5)
Qualifications: Dr. Shumer is a Pediatric Endocrinologist at Boston Children's Hospital.
Role on Project: As a clinical co-investigator Dr. Shumer will support the PIs around all issues of research at the Boston site. These include hiring, study design, setting up study protocols, and survey instrument design. Along with Dr. Tishelman, he will train and supervise the Project Coordinator and Research Assistant, train the Registered Nurse, and help to oversee all aspects of the research activities at Boston Children's Hospital. He will also assist in data collection protocols and intervention implementation plans. He will collaborate in data analysis, preparation of manuscripts, and dissemination activities. He will conduct patient assessments, review laboratory results, prescribe medication, and consult with the study team on all endocrinological issues such as bone development and growth. Dr. Shumer will assist in protocol development and attend project meetings, phone calls, and other study related interactions as needed **Total Salary Requested Y1-5: $** (b)(4)

B. Other Personnel

(b)(4)

To Be Named, Research Nurse, R.N. (CM Y1-Y5)
The Research Nurse will be an individual with a Registered Nurse degree or higher and will have substantial research experience with LGBT, YMSM, and/or YGBM populations. He/she will conduct study-related research visits in collaboration with study faculty and engage in activities such as assessments, collection of study related specimens, and regulatory documentation. **Total Salary Requested Y1-5: $** (b)(4)

(b)(4) (b)(4)

To Be Named – Project Coordinator (CM Y1; CM Y2-Y4; CM Y5) (b)(4)
The Project Coordinator will be an individual with a clinical master's degree and substantial research experience with LGBT populations. He/she will meet regularly with project investigators and will coordinate project development, participant recruitment, and overall project implementation. He/she will work with the Co-Is to communicate with the site IRB, coordinate recruitment and retention, manage day-to-day operations of the project, and oversee confidential data collection procedures. He/she will also assist in refining assessment instruments, preparation of procedural manuals, and assist in maintaining IRB approval. He/she will coordinate

and attend staff meetings and other study related collaborations as needed. **Total Salary Requested Y1-5: $** (b)(4)

To Be Named – Research Assistant ((b)(4) **CM Y2-5)**
The Research Assistant will provide data collection support. He/she will also participate in all study-related meetings, calls, and collaborations and assist the Project Coordinator as needed. **Total Salary Requested Y2-5: $** (b)(4)

Fringe Benefits

The fringe benefit rate is (b)(4) % of Salaries. Total Fringe Benefits are: Year 1 $ (b)(4); Year 2 $ (b)(4); Year 3 $ (b)(4); Year 4 $ (b)(4); Year 5 $ (b)(4). **Total Fringe Benefits Requested Y1-Y5: $** (b)(4)

C. Equipment

No Equipment in excess of $5,000 per item will be purchased.

D. Travel

No Travel is requested.

E. Participant/Trainee Support Costs

No Participant/Trainee Supports Costs are being requested.

F. Other Direct Costs

No Direct Costs are being requested.

G. Total Direct Costs

Total Direct Costs are as follows:

	Direct
Year 1	$ (b)(4)
Year 2	$
Year 3	$
Year 4	$
Year 5	$
TOTAL	$

H. Indirect Costs

Indirect costs (Facilities & Administrative Costs) are based on Modified Total Direct Costs and are (b)(4) % in Year 1 and (b)(4) % in Years 2 - 5 as approved by the Department of Health and Human Services on 10/1/2013.

	Indirect (b)(4) %	Indirect (b)(4) %
Year 1	$ (b)(4)	
Year 2		$ (b)(4)
Year 3		$

Year 4	$ (b)(4)
Year 5	$
TOTAL	**$**

I. Total Direct and Indirect Costs

	TOTAL Per Year
Year 1	$ (b)(4)
Year 2	$
Year 3	$
Year 4	$
Year 5	$
TOTAL	**$**

J. Fee

No Fee is being requested.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		(b)(4)
Section B, Other Personnel		
Total Number Other Personnel	14	
Total Salary, Wages and Fringe Benefits (A+B)		
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1		
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		
Section H, Indirect Costs		
Section I, Total Direct and Indirect Costs (G + H)		
Section J, Fee		

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 1

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2015 **End Date*:** 06-30-2016 **Budget Period:** 1

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Robert		Garofalo	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Lisa		Simons	MD	Co-Investigator - Pediatrician							
3 .	Dr.	Marco		Hidalgo	PhD	Co-Investigator - Psychologist							
4 .	Dr.	Scott		Leibowitz	MD	Co-Investigator - Psychiatrist							
5 .	Dr.	Courtney		Finlayson	MD	Co-Investigator - Endocrinologist							
6 .	Dr.	Joel		Frader	MD	Ethicist							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Nurse						
2	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 1

ORGANIZATIONAL DUNS*: 0744387550000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2015 **End Date*:** 06-30-2016 **Budget Period:** 1

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 1

ORGANIZATIONAL DUNS*: 0744387550000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2015 **End Date*:** 06-30-2016 **Budget Period:** 1

F. Other Direct Costs	Funds Requested ($)*
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Mmodified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Denise Shirlee, 214-767-3261
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Budget Justification*	File Name: 1242-Lurie Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 2

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2016 **End Date*:** 06-30-2017 **Budget Period:** 2

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Robert		Garofalo	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Lisa		Simons	MD	Co-Investigator - Pediatrician							
3 .	Dr.	Marco		Hidalgo	PhD	Co-Investigator - Psychologist							
4 .	Dr.	Scott		Leibowitz	MD	Co-Investigator - Psychiatrist							
5 .	Dr.	Courtney		Finlayson	MD	Co-Investigator - Endocrinologist							
6 .	Dr.	Joel		Frader	MD	Ethicist							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Data Manager						
1	Nurse						
3	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 2

ORGANIZATIONAL DUNS*: 0744387550000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2016 **End Date*:** 06-30-2017 **Budget Period:** 2

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 2

ORGANIZATIONAL DUNS*: 0744387550000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2016 **End Date*:** 06-30-2017 **Budget Period:** 2

F. Other Direct Costs	Funds Requested ($)*
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Denise Shirlee, 214-767-3261
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Budget Justification*	File Name: 1242-Lurie Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 3

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2017 **End Date*:** 06-30-2018 **Budget Period:** 3

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Robert		Garofalo	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Lisa		Simons	MD	Co-Investigator - Pediatrician							
3 .	Dr.	Marco		Hidalgo	PhD	Co-Investigator - Psychologist							
4 .	Dr.	Scott		Leibowitz	MD	Co-Investigator - Psychiatrist							
5 .	Dr.	Courtney		Finlayson	PhD	Co-Investigator - Endocrinologist							
6 .	Dr.	Joel		Frader	MD	Ethicist							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Data Manager						
1	Nurse						
3	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 3

ORGANIZATIONAL DUNS*: 0744387550000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2017 **End Date*:** 06-30-2018 **Budget Period:** 3

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 3

ORGANIZATIONAL DUNS*: 0744387550000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2017 **End Date*:** 06-30-2018 **Budget Period:** 3

F. Other Direct Costs	Funds Requested ($)*
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Denise Shirlee, 214-767-3261
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Budget Justification*	File Name: 1242-Lurie Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 4

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2018 **End Date*:** 06-30-2019 **Budget Period:** 4

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Robert		Garofalo	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Lisa		Simons	MD	Co-Investigator - Pediatrician							
3 .	Dr.	Marco		Hidalgo	PhD	Co-Investigator - Psychologist							
4 .	Dr.	Scott		Leibowitz	MD	Co-Investigator - Psychiatrist							
5 .	Dr.	Courtney		Finlayson	MD	Co-Investigator - Endocrinologist							
6 .	Dr.	Joel		Frader	MD	Ethicist							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Data Manager						
1	Nurse						
3	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 4

ORGANIZATIONAL DUNS*: 0744387550000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2018 **End Date*:** 06-30-2019 **Budget Period:** 4

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 4

ORGANIZATIONAL DUNS*: 0744387550000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2018 **End Date*:** 06-30-2019 **Budget Period:** 4

F. Other Direct Costs	Funds Requested ($)*
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Denise Shirlee, 214-767-3261
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Budget Justification*	File Name: 1242-Lurie Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 5

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period:** 5

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Robert		Garofalo	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Lisa		Simons	MD	Co-Investigator Pediatrician							
3 .	Dr.	Marco		Hidalgo	PhD	Co-Investigator Psychologist							
4 .	Dr.	Scott		leibowitz	MD	Co-Investigator Psychiatrist							
5 .	Dr.	Courtney		Finlayson	MD	Co-Investigator Endocrinologist							
6 .	Dr.	Joel		Frader	MD	Ethicist							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Data Manager						
1	Nurse						
3	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 5

ORGANIZATIONAL DUNS*: 0744387550000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period:** 5

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 5

ORGANIZATIONAL DUNS*: 0744387550000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period:** 5

F. Other Direct Costs	Funds Requested ($)*
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Denise Shirlee, 214-767-3261
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Budget Justification*	File Name: 1242-Lurie Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

BUDGET JUSTIFICATION – ANN AND ROBERT H. LURIE CHILDREN'S HOSPITAL OF CHICAGO

A. Senior/Key Personnel

(b)(4)

Rob Garofalo, M.D., MPH, Principal Investigator (Calendar Months (CM) Y1-Y5)
Qualifications: Dr. Garofalo is Director of Adolescent HIV Services and Director of the Center for Gender, Sexuality and HIV Prevention at Lurie Children's. He is also Associate Professor in the Departments of Pediatrics and Preventive Medicine, Northwest University's Feinberg School of Medicine. Dr. Garofalo has extensive experience in the clinical care of gender non-conforming children and young adults. His research career has focused on the collection of data, both behavioral and clinical biomarkers, in marginalized populations and the translation of this data into intervention development. As a PI on numerous federally funded studies, he has developed the skills to collaborate with and/or lead interdisciplinary and multi-site research teams.
Role on Project: He will take primary responsibility for the implementation of the scientific aims of this project at Lurie Children's as well as collaborate to disseminate findings. **Total Salary Requested Y1-5: $** (b)(4)

(b)(4)

Lisa Simons, M.D., Co-Investigator – Pediatrician (CM Y1-5)
Qualifications: Dr. Simons is Instructor of Pediatrics at Northwestern University, Feinberg School of Medicine and Attending Physician, Division of Adolescent Medicine at Ann & Robert H. Lurie Children's Hospital of Chicago.
Role on Project: She will share responsibility for the scientific and fiscal integrity of this project and will oversee all research activities at Lurie Children's. She will share responsibility for data interpretation and dissemination of findings with Dr. Garofalo. **Total Salary Requested Y1-5: $** (b)(4)

(b)(4)

Marco A. Hidalgo, Ph.D., Co-Investigator – Psychologist (CM Y1-Y5)
Qualifications: Dr. Hidalgo is a Medical Psychologist in the Division of Adolescent Medicine at Lurie Children's Hospital.
Role on Project: He will assist Investigators in directly supervising and managing frontline research activities involving project direction and data management. Specifically, Dr. Hidalgo will supervise the Project Coordinator in her/his management of day-to-day tasks by coordinating IRB submissions, developing and overseeing effective recruitment strategies, and providing ongoing advice regarding confidential data collection/ management procedures. He will also assist the Data Manager in refining assessment instruments, managing study databases, and creating data manuals. Dr. Hidalgo will attend staff meetings. **Total Salary Requested Y1-5: $** (b)(4)

(b)(4)

Scott Leibowitz, M.D., Co-Investigator – Psychiatrist (CM Y1-5)
Qualifications: Dr. Leibowitz is the only Psychiatrist appointed across all study sites. Dr. Leibowitz has extensive experience working with gender nonconforming children and adolescents.
Role on Project: He will assist in protocol development as well as conduct patient assessments at the Lurie site. Dr. Leibowitz will attend project meetings, phone calls, and other study related interactions as needed. **Total Salary Requested Y1-5: $** (b)(4)

(b)(4)

Courtney Finlayson, M.D., Co-Investigator – Endocrinologist (CM Y1-Y5)
Qualifications: Dr. Finlayson's work has focused on pediatric endocrinology and diabetes patients with a specific interest in disorders of sex development and puberty.
Role on Project: She will be the lead Endocrinologist at the Lurie site and will conduct patient assessments, review laboratory results, and consult with the study teams on all endocrinological issues such as bone development and growth. Dr. Finlayson will assist in protocol development and attend project meetings, phone calls, and other study related interactions as needed. **Total Salary Requested Y1-5: $** (b)(4)

(b)(4)

Joel Frader, M.D., Ethicist (CM Y1-Y5)
Qualifications: Dr. Frader is the Division Head of Academic General Pediatrics at the Lurie site.
Role on Project: He will examine ethical aspects of the implementation of clinical guidelines, including: identifying the age and developmental/maturational characteristics of decision-making capacity of children and adolescents for treatment; describing the ways in which clinicians and parents manage different points of view regarding treatment, particularly when parent perspectives are based on particular religious and philosophical

convictions; and ethical and legal issues surrounding school or voluntary organization exclusion or other discrimination based on gender nonconformity. Dr. Frader will also assist in protocol development and attend project meetings, phone calls, and other study related interactions as needed. **Total Salary Requested Y1-5: $**(b)(4)

B. Other Personnel

(b)(4) (b)(4)

To Be Named, Project Coordinator (CM Y1; CM Y2-Y5)
The Project Coordinator will be an individual with a clinical master's degree and substantial research experience with LGBT populations. He/she will meet regularly with project investigators and will coordinate project development, participant recruitment, and overall project implementation. He/she will work with the Co-Is to coordinate all IRB-related communication, coordinate recruitment and retention, and manage day-to-day operations of the project, including overseeing confidential data collection procedures. He/she will also assist in refining assessment instruments, preparing procedural manuals, and maintaining IRB approval. He/she will coordinate and attend staff meetings and other study related collaborations as needed. **Total Salary Requested Y1-5: $**(b)(4)

(b)(4)

(b)(6)**, Data Manager (CM Y2-5)**
The data manager will program the computerized data collection instrument and provide data management support (including maintenance of research records, preparation of progress reports, and IRB submission). will also participate in all study-related meetings, calls, and collaborations and assist in the preparation of manuscripts and the presentation of study findings at national conferences. **Total Salary Requested Y2-5: $**(b)(4)

(b)(6) (b)(4) (b)(4)

To Be Named, Research Nurse, R.N. (CM Y1; CM Y2-Y5)
The Research Nurse will be an individual with a Registered Nurse degree or higher and will have substantial research experience with LGBT, YMSM, and/or YGBM populations. He/she will conduct study-related research visits in collaboration with study faculty and engage in activities such as assessments, collection of study related specimens, and regulatory documentation. **Total Salary Requested Y1-5: $**(b)(4)

Fringe Benefits

Fringe Calculations are based on the Anne and Robert H. Lurie Children's Hospital of Chicago FY14-15 rate of % and total **$**(b)(4)**for Y1-5.**

(b)(4)

C. Equipment

No Equipment in excess of $5,000 per item will be purchased.

D. Travel

No Travel is requested.

E. Participant/Trainee Support Costs

No Participant/Trainee Supports Costs are being requested.

F. Other Direct Costs

No Direct Costs are being requested.

G. Total Direct Costs

Total Direct Costs are as follows:

	Direct
Year 1	$ (b)(4)
Year 2	$
Year 3	$
Year 4	$
Year 5	$
TOTAL	**$**

H. Indirect Costs

Indirect costs (Facilities & Administrative Costs) are based on Modified Total Direct Costs and are 50% in Years 1 - 5 as approved by the Department of Health and Human Services.

Year 1	$ (b)(4)
Year 2	$
Year 3	$
Year 4	$
Year 5	$
TOTAL	**$**

I. Total Direct and Indirect Costs

	TOTAL Per Year
Year 1	$ (b)(4)
Year 2	$
Year 3	$
Year 4	$
Year 5	$
TOTAL	**$**

J. Fee

No Fee is being requested.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		(b)(4)
Section B, Other Personnel		
Total Number Other Personnel	14	
Total Salary, Wages and Fringe Benefits (A+B)		
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1		
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		
Section H, Indirect Costs		
Section I, Total Direct and Indirect Costs (G + H)		
Section J, Fee		

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 1

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2015 **End Date*:** 06-30-2016 **Budget Period:** 1

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Stephen		Rosenthal	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Diane		Ehrensaft	PhD	Co-Investigator							
3 .	Dr.	David		Glidden	PhD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Study Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Clinical Research Nurse						
2	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 1

ORGANIZATIONAL DUNS*: 0948783370000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2015 **End Date*:** 06-30-2016 **Budget Period:** 1

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 1

ORGANIZATIONAL DUNS*: 0948783370000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2015 **End Date*:** 06-30-2016 **Budget Period:** 1

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Data Network Recharge	(b)(4)
9 . CCDSS	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Jeanette Lu, 415-437-7820
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Budget Justification*	File Name: 1243-UCSF Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 2

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2016 **End Date*:** 06-30-2017 **Budget Period:** 2

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Stephen		Rosenthal	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Diane		Ehrensaft	PhD	Co-Investigator							
3 .	Dr.	David		Glidden	PhD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Study Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Data Manager						
1	Clinical Research Nurse						
3	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 2

ORGANIZATIONAL DUNS*: 0948783370000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2016 **End Date*:** 06-30-2017 **Budget Period:** 2

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 2

ORGANIZATIONAL DUNS*: 0948783370000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2016 **End Date*:** 06-30-2017 **Budget Period:** 2

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Data Network Recharge	(b)(4)
9 . CCDSS	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Jeanette Lu, 415-437-7820
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Budget Justification*	File Name: 1243-UCSF Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 3

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2017 **End Date*:** 06-30-2018 **Budget Period:** 3

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Stephen		Rosenthal	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Diane		Ehrensaft	PhD	Co-Investigator							
3 .	Dr.	David		Glidden	PhD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Study Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Data Manager						
1	Clinical Research Nurse						
3	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 3

ORGANIZATIONAL DUNS*: 0948783370000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2017 **End Date*:** 06-30-2018 **Budget Period:** 3

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 3

ORGANIZATIONAL DUNS*: 0948783370000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2017 **End Date*:** 06-30-2018 **Budget Period:** 3

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Data Network Recharge	(b)(4)
9 . CCDSS	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Jeanette Lu, 415-437-7820
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Budget Justification*	File Name: 1243-UCSF Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 4

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2018 **End Date*:** 06-30-2019 **Budget Period:** 4

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Stephen		Rosenthal	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Diane		Ehrensaft	PhD	Co-Investigator							
3 .	Dr.	David		Glidden	PhD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Study Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Data Manager						
1	Clinical Research Nurse						
3	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 4

ORGANIZATIONAL DUNS*: 0948783370000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2018 **End Date*:** 06-30-2019 **Budget Period:** 4

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 4

ORGANIZATIONAL DUNS*: 0948783370000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2018 **End Date*:** 06-30-2019 **Budget Period:** 4

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Data Network Recharge	(b)(4)
9 . CCDSS	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Jeanette Lu, 415-437-7820
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Budget Justification*	File Name: 1243-UCSF Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 5

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ○ Project ● Subaward/Consortium

Enter name of Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period:** 5

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Stephen		Rosenthal	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Diane		Ehrensaft	PhD	Co-Investigator							
3 .	Dr.	David		Glidden	PhD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Study Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Data Manager						
1	Clinical Research Nurse						
3	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 5

ORGANIZATIONAL DUNS*: 0948783370000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period:** 5

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget (C-E) (Funds Requested)

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 5

ORGANIZATIONAL DUNS*: 0948783370000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period:** 5

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Data Network Recharge	(b)(4)
9 . CCDSS	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency DHHS, Jeanette Lu, 415-437-7820
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Budget Justification*	File Name: 1243-UCSF Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)

BUDGET JUSTIFICATION: UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

Salaries: Pursuant to University of California (UC) policy, salaries in the initial budget period are based on current published UC salary scales and include University mandated range adjustments and merit increases scheduled to occur before the proposed project start date. Pay rate increases in FY02 through FY05 are based on merit review schedules established by UCSF Academic Affairs.

A. Senior/Key Personnel

Stephen M. Rosenthal, M.D., Site Principal Investigator ((b)(4) **Calendar Months (CM) Y1-Y5)**
Qualifications: Dr. Rosenthal is Professor of Pediatrics at UCSF, Program Director for Pediatric Endocrinology, Co-Director of the Disorders of Sex Development Clinic, and founder and Medical Director of the UCSF Child and Adolescent Gender Center (CAGC). The UCSF CAGC serves as the Pediatric/Adolescent clinical arm of the widely recognized UCSF Center of Excellence for Transgender Health. The CAGC provides multi-disciplinary care to gender non-conforming/transgender youth and adolescents and is the only such multi-disciplinary gender program in Northern California, attracting patients not only from California, but from as far away as Alaska, Florida, and Egypt. Dr. Rosenthal has been appointed as the official representative of the Pediatric Endocrine Society (PES) to the Endocrine Society's (ES) Clinical Practice Guidelines Revision Task Force for the Care of Transgender Individuals and was appointed to the World Professional Association for Transgender Health (WPATH) Consensus committee for revisions of the International Classification of Disease (ICD)-11 pertaining to transgender youth and adults. Dr. Rosenthal has authored seven manuscripts on transgender youth, including a recent "State-of-the-art" invited review in *Pediatrics* and an invited review in the "Approach to the Patient" series for the *Journal of Clinical Endocrinology and Metabolism*. Dr. Rosenthal has been an invited speaker on transgender youth at annual meetings of PES and ES, as well as at the most recent international meeting of WPATH, and has lectured on this subject at academic centers throughout the U.S. Dr. Rosenthal is also the recipient of the UCSF Chancellor Award for LGBT leadership in recognition of his work with transgender youth and is the recipient of the UCSF Family Advisory Council Caring Tree Award and the UCSF Haile T. Debas Academy of Medical Educators Excellence in Teaching Award. Dr. Rosenthal is an established clinical investigator with greater than 30 years' experience in child and adolescent endocrinology and has significant experience conducting multi-center trials. He is currently serving as site PI for NIH/NICHD Disorders of Sex Development: Platform for Basic and Translational Research (1R01HD068138-01A1).
Role on Project: Dr. Rosenthal will have primary responsibility for the implementation of the scientific aims of this project at UCSF. He will collaborate in protocol development (in particular, the endocrine/metabolic parameters), data analysis, and dissemination of findings. **Total Salary Requested Y1-5: $** (b)(4)

Diane Ehrensaft, Ph.D., Co-Investigator and Psychologist ((b)(4) **CM Y1- Y5)**
Qualifications: Dr. Ehrensaft is Associate Professor of Pediatrics at UCSF and Mental Health Director of the UCSF Child and Adolescent Gender Center. She is a developmental and clinical psychologist and an internationally recognized child and adolescent gender specialist.
Role on Project: Dr. Ehrensaft will have a primary role in the design and implementation of mental health measures and will collaborate in data analysis and dissemination of findings. **Total Salary Requested Y1-5: $** (b)(4)

David V. Glidden, Ph.D., Biostatistician ((b)(4) **CM Y1-Y5)**
Qualifications: Dr. Glidden is Professor of Biostatistics at UCSF. He received his Ph.D. from the University of Washington in 1993 and spent four years at the Department of Biostatistics at the Harvard School of Public Health before joining the UCSF faculty in 1997. He has experience in developing methods for data analysis, has been an author of an intermediate textbook (Regression Methods in Biostatistics, Spring, 2nd edition, 2011), and has long experience collaborating with investigators in diverse medical specialties. He also has extensive experience in clinical trials, having been the lead statistician for a pivotal study (Grant et al, 2010; for which he was senior author) for chemoprophylaxis for the prevention of HIV acquisition. He is experienced in the analysis of longitudinal data.
Role on Project: Dr. Glidden will work as a resource for Dr. Schrager, Biostatistician at the Core Site, and will provide advice and support on analytic approaches. He will focus the bulk of his activities on the analysis of the

metabolic data. He will be responsible for the design, analysis plan development, and execution of these analyses. **Total Salary Requested Y1-5: $** (b)(4)

B. Other Personnel

(b)(4) (b)(4)

To Be Named, Study Coordinator (CM Y1; CM Y2-Y5)
Role on Project: The Study Coordinator will meet regularly with project investigators and will coordinate project development, participant recruitment, and overall project implementation. He/she will also work with the site PI to coordinate all Institutional Review Board (IRB)-related communications and will manage day-to-day operations of the project. **Total Salary Requested Y1-5: $** (b)(4)

(b)(4)

To Be Named, Data Manager (CM Y2-Y5)
Role on Project: The Data Manager will program computerized data collection and provide data management support, including maintenance of research records, preparation of progress reports, and assistance with IRB submissions. The Data Manager will also assist in the preparation of manuscripts and conference presentations. **Total Salary Requested Y1-5: $** (b)(4)

(b)(4) (b)(4)

To Be Named, Clinical Research Nurse (CM Y1; CM Y2-Y5)
Role on Project: The Clinical Research Nurse (Registered Nurse degree or more advanced) will conduct study-related research visits in collaboration with study investigators and will assist with collection of study-related specimens and regulatory documentation. **Total Salary Requested Y1-5: $** (b)(4)

Fringe Benefits

Fringe Benefits include health and life insurance, social security, Medicare, dental plan, vision, unemployment insurance, non-industrial disability insurance, worker's compensation insurance, and retirement. Our request is based on actual fringe rates for current employees, which varies according to each person's benefit enrollments. Fringe benefits for TBN employees are 47.8% of salaries for staff personnel, as of July 1, 2015. Fringe benefits for current and TBN employees escalate by 2% each year, based on campus budget projections and consistent with guidance from the University of California, San Francisco (UCSF) Office of Sponsored Research. Total Fringe Benefits are: Year 1 $ (b)(4); Year 2 $ (b)(4); Year 3 $ (b)(4); Year 4 $ (b)(4); Year 5 $ (b)(4). **Total Fringe Benefits Requested Y1-Y5: $** (b)(4)

C. Equipment

No Equipment in excess of $5,000 per item will be purchased.

D. Travel

No Travel is requested.

E. Participant/Trainee Support Costs

No Participant/Trainee Supports Costs are being requested.

(b)(4)

F. Other Direct Costs

UCSF Data Network Recharge: Effective November 1, 2009 the Chancellor's Executive Committee approved a UCSF data network services recharge. The recharge provides funding for critical equipment in support of the campus network. The funding model for data network service includes a UCSF-wide per capita recharge of $ /month/FTE. The rate increases in future years, as follows: 7/1/16-6/30/17: $ /month/FTE and $ /month/FTE from 7/1/17 until amended. As permissible by OMB A-21 and per review and agreement

(b)(4) (b)(4)

by our cognizant federal agency, UCSF data network costs are an allowable direct expense. **Total UCSF Data Network Recharge Requested: $** (b)(4)

Computing and Communication Device Support Services (CCDSS): CCDSS provides integral support to campus voice and data technology functions. CCDSS includes software installation/updates, internet security, hardware setup/configuration, and centrally managed patching, storage and backup. The university charges these expenses to all funding sources based on a monthly recharge rate per FTE, consistent with the university's current methodology used for data network services. The recharge rates are provided for under our approved DS-2, will be computed in accordance with applicable OMB requirements, including 2 CFR Part 220 (formerly Circular A-21), and will be reviewed and adjusted annually. **Total Computing and Communication Device Support Services Requested: $** (b)(4)

G. Total Direct Costs

Total Direct Costs are as follows:

	Direct
Year 1	$ (b)(4)
Year 2	$
Year 3	$
Year 4	$
Year 5	$
TOTAL	**$**

H. Indirect Costs

(b)(4)

Indirect costs (Facilities & Administrative Costs) are based on Modified Total Direct Costs and are % in Years 1 - 5 as approved by the Department of Health and Human Services.

Year 1	$ (b)(4)
Year 2	$
Year 3	$
Year 4	$
Year 5	$
TOTAL	**$**

I. Total Direct and Indirect Costs

	TOTAL Per Year
Year 1	$ (b)(4)
Year 2	$
Year 3	$
Year 4	$
Year 5	$
TOTAL	**$**

J. Fee

No Fee is being requested.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		(b)(4)
Section B, Other Personnel		
Total Number Other Personnel	14	
Total Salary, Wages and Fringe Benefits (A+B)		
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1	(b)(4)	
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		
Section H, Indirect Costs		
Section I, Total Direct and Indirect Costs (G + H)		
Section J, Fee		

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OMB Number: 0925-0001

1. Project Director / Principal Investigator (PD/PI)

Prefix: Dr.
First Name*: Johanna
Middle Name:
Last Name*: Olson
Suffix: M.D.

2. Human Subjects

Clinical Trial? ● No ○ Yes
Agency-Defined Phase III Clinical Trial?* ○ No ○ Yes

3. Permission Statement*

If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?

● Yes ○ No

4. Program Income*

Is program income anticipated during the periods for which the grant support is requested? ○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

Budget Period*	Anticipated Amount ($)*	Source(s)*

Tracking Number: GRANT11778555
Funding Opportunity Number: PA-12-111, Received Date: 2014-11-05T18:44:21.000-05:00

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5. Human Embryonic Stem Cells

Does the proposed project involve human embryonic stem cells?* ● No ○ Yes

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Cell Line(s): Specific stem cell line cannot be referenced at this time. One from the registry will be used.

6. Inventions and Patents (For renewal applications only)

Inventions and Patents*: ○ Yes ○ No

If the answer is "Yes" then please answer the following:

Previously Reported*: ○ Yes ○ No

7. Change of Investigator / Change of Institution Questions

☐ Change of principal investigator / program director

Name of former principal investigator / program director:

Prefix:

First Name*:

Middle Name:

Last Name*:

Suffix:

☐ Change of Grantee Institution

Name of former institution*:

PHS 398 Research Plan

Please attach applicable sections of the research plan, below.

OMB Number: 0925-0001

1. Introduction to Application (for RESUBMISSION or REVISION only)	1244-Introduction to Application.pdf
2. Specific Aims	1245-Specific Aims.pdf
3. Research Strategy*	1246-Research Strategy.pdf
4. Progress Report Publication List	
Human Subjects Sections	
5. Protection of Human Subjects	1267-Protection of Human Subjects.pdf
6. Inclusion of Women and Minorities	1268-Inclusion of Women and Minorities.pdf
7. Inclusion of Children	1269-Inclusion of Children.pdf
Other Research Plan Sections	
8. Vertebrate Animals	
9. Select Agent Research	
10. Multiple PD/PI Leadership Plan	1270-Multiple PI Leadership Plan.pdf
11. Consortium/Contractual Arrangements	1271-Consortium Contractual Arrangements.pdf
12. Letters of Support	1272-Letters of Support.pdf
13. Resource Sharing Plan(s)	1273-Resource Sharing Plan Data Sharing.pdf
Appendix (if applicable)	
14. Appendix	1247-Appx A WPATH and Endocrine Society Letters.pdf 1248-Appx B Consent Permission Assent Forms.pdf 1249-Appx C Early Pubertal Cohort TG Specific Measures.pdf 1250-Appx D Late Pubertal Cohort TG Specific Measures.pdf

INTRODUCTION TO RESUBMISSION APPLICATION

We would like to thank the committee for a thorough and detailed review of our proposal. We were pleased with a priority score of 26/12th percentile and that the reviewers clearly recognized the significance, importance, and critical need for this research examining health outcomes among transgender children and adolescents. Reviewers noted a great many strengths to the proposal including the overall team across institutions surrounding and supporting Dr. Olson as a new investigator, as well as the innovation of developing a national network of four primary institutions involved in the care of transgender youth. The committee also commented on the considerable impact with regard to public health that this study would have, providing the first U.S. longitudinal data evaluating medical intervention for transgender youth. The few weaknesses noted by the reviewers and individual reviews are addressed below, with corresponding changes italicized in brackets throughout the Research Strategy section.

Lack of a control group for the younger cohort receiving gonadotropin releasing hormone (GnRH) agonists for suppression of endogenous puberty by our estimation was the most significant issue raised by the initial review. We very much appreciate the reviewers' thoughtful comments and have carefully considered options trying to balance the scientific integrity and strength of the data collection with the ethics involved in being responsive to the needs of the target population. The PI's recognize that comparison of a treated vs. an untreated control group could be considered the gold standard for understanding impact of existing recommendations for care of transgender youth. However, the current standards of care from the Endocrine Society and the World Professional Association of Transgender Health (WPATH) were developed from a panel of scientific experts and a consensus-building process based largely upon clinical experience and existing minimal research, and each supports the positive impact of intervention and the negative impact of no intervention. In the context of these guidelines, we strongly believe that a non-intervention control group, or certainly any control group as part of a traditional randomized trial, would be both impractical and unethical (see the Endocrine Society and WPATH letters of support regarding our cohort design in Appendix A). In considering the reviewers' concerns, we are committed to collecting longitudinal outcome data from a group that might be considered a "natural control" – those youth appropriate for GnRH agonist treatment, but who refuse treatment as part of the informed consent process. In a small, but not rare, number of cases at our institutions, parents and/or the children may elect under certain circumstances (e.g., cost, fears given a lack of scientific evidence, etc.) to not initiate pubertal suppression. This outcome data will be collected along the same visit schedule as our treated cohort for comparison. In addition, as part of our original study design we will collect data on age and Tanner staging to be able to examine if early vs. delayed treatment in these young people affects health outcomes. Further discussion of a control group is included in section C3: Study Design.

Reviewers noted that demographic data collection was missing from the proposal. Age, place of birth, current residence, religion, ethnicity, and race will be collected at baseline. These are outlined in section C4b for the younger cohort and highlighted in section C5b for the older cohort of youth. Additionally, we plan to collect transgender experience data including assigned gender at birth, age of discovery of gender incongruence, age of disclosure to parents, and sexual orientation.

In order to address the reviewers concerns about **inclusion of multi-cultural participants**, we will translate ACASI instruments and informed consents into Spanish, so that monolingual Spanish speakers can participate. This has been added to the inclusion criteria for both cohorts. Additionally, the audio version of the ACASI will be available for younger children who may not be proficient in reading.

We appreciate the recommendation and will add a DSMB to oversee all aspects of our network's work. As one reviewer put quite nicely, "While this is technically an observational design, these vulnerable youth will be undergoing longitudinal medical treatment that could potentially have negative side effects."

As recommended by Reviewer 1, scheduled in-person meetings of core personnel at the 4 sites will occur at least bi-annually in person and quarterly via teleconference to improve the cohesiveness of the proposed study, discuss scientific oversight, and identify problems that arise so that they may be addressed in a timely and efficient manner. Monthly calls between the Project Coordinators will be scheduled to discuss and troubleshoot logistical issues that might arise that are site specific or worthy of discussion between the PI's.

One reviewer raised concerns about the inclusion of the UCSF site based upon what was submitted via the "Resources" page of the original grant submission. We apologize for not having adequately detailed that site's strengths but feel very strongly that UCSF is a key and vital component to our network and proposed research. We have included additional information about Dr. Rosenthal and the UCSF team in the Facilities and Resources section and this document now details the strengths this site brings to the proposed study as the pediatric/adolescent clinical arm of the nationally recognized UCSF Center of Excellence for Transgender Health.

SPECIFIC AIMS

Transgender children and adolescents, those who experience incongruence between assigned birth sex and internal gender identity, are a poorly understood and a distinctly understudied population in the United States. The limited available data suggest that transgender youth who are gender dysphoric (persistently distressed about gender incongruence) are at increased risk for **anxiety, depression, suicide, and substance use** compared to their peers. The development of undesired secondary sex characteristics during puberty intensifies the distress associated with gender incongruence and increases the risk for these conditions.

Current clinical practice guidelines aim to decrease gender dysphoria and ameliorate potential negative health outcomes. Treatment recommendations vary depending on the age and developmental stage of youth with gender dysphoria. For those youth in the earliest stages of pubertal development (Tanner 2-3), treatment with gonadotropin-releasing hormone (GnRH) agonists is recommended in order to suppress endogenous puberty and avoid the development of undesired secondary sex characteristics. In older adolescents in the later stages of pubertal development (Tanner 4-5), treatment with cross-sex hormones is recommended to induce desired masculine or feminine features. While these guidelines have been used at academic and community centers across the U.S., they are based on very limited data. Furthermore, there are **no available data examining the physiologic and metabolic consequences of cross-sex hormone treatment in youth.** This represents a critical gap in knowledge that has significant implications for clinical practice across the U.S. In 2011, a report of the Institute of Medicine called for the development of rigorous research aimed at understanding the health implications of hormone use and other transgender-specific issues.

The objective of the proposed research is to **provide evidence-based data to inform clinical care for transgender youth.** The study will leverage the partnership between four, university-affiliated, gender clinics across the U.S. to recruit two developmental cohorts and conduct **a multi-site, observational study** examining the safety of hormonal interventions and the physiological and psychosocial outcomes associated with these treatments. The Specific Aims are:

Aim 1: To evaluate the impact of **GnRH agonists** administered for puberty suppression, on **mental health, psychological well-being, physiologic parameters, and bone health** as well as document the safety of GnRH agonists in an **early-pubertal** cohort (Tanner stages 2-3; n=80) of transgender children and adolescents, comparing baseline and follow-up assessments at 6 months, 1 year, and 2 years after initiating treatment.

Hypothesis 1a: Patients treated with GnRH agonists will exhibit decreased symptoms of depression, anxiety, trauma symptoms, self-injury, and suicidality and increased body esteem and quality of life over time.
Hypothesis 1b: GnRH agonists will be tolerable and safe for early-pubertal transgender youth, i.e., fasting lipids and glucose, liver enzymes, electrolytes, insulin, and HbA1c will not increase above clinically safe ranges.
Hypothesis 1c: Raw bone density scores will remain stable for early-pubertal transgender youth receiving GnRH agonists; however, age-matched z-scores may decrease.

Aim 2: To evaluate the impact of **cross-sex hormones** administered for gender transition on **mental health, psychological well-being, and metabolic/physiologic parameters** as well as document the safety of cross-sex hormones in a **late-pubertal** cohort (Tanner stages 4-5; n=200) of transgender adolescents, comparing baseline and follow up assessments at 6 months, 1 year, and 2 years after initiating treatment.

Hypothesis 2a: Patients treated with cross-sex hormones will exhibit decreased symptoms of gender dysphoria, depression, anxiety, trauma symptoms, self-injury, and suicidality and increased body esteem and quality of life over time.
Hypothesis 2b: Cross-sex hormones will be tolerable and safe to use for late-pubertal transgender youth initiating phenotypic transition, i.e., will not increase fasting lipids and glucose, liver enzymes, electrolytes, and hemoglobin above clinically safe ranges.

Aim 3 (Exploratory): Based on evidence of high rates of substance use and HIV infection in some transgender adolescents (specifically, young transgender women), we will **determine substance use and sexual risk behavior over time**. *A priori* hypotheses regarding the impact of hormone treatment on sexual and substance use behaviors cannot be specified given that these behaviors increase through adolescence.

This multi-center study will be the **first in the U.S.** to evaluate longitudinal outcomes of medical treatment for transgender youth, and it will provide highly needed evidence-based data on the physiological and psychosocial effects and safety of treatments currently used for transgender youth.

A. SIGNIFICANCE

A1. Transgender Youth are an Underserved, Understudied Population

Transgender adolescents and children, those who experience incongruence between assigned birth sex and internal gender identity, are a poorly understood and understudied population in the United States. As detailed in the May 2011 Institute of Medicine (IOM)[1] report, "The Health of Lesbian, Gay, Bisexual, and Transgender People," the existing body of scientific evidence documenting health and well-being of transgender individuals is sparse. The report explicitly calls for NIH-supported research on transgender health needs, including the development of evidence-based data for providing transgender-specific health care to address gender dysphoria and rigorous research aimed at understanding the health implications of hormone use and other transgender-specific issues. In addition, the IOM report calls for longitudinal and cohort studies that incorporate a life course perspective to examine the specific experiences of transgender individuals across different chronological ages.

Research on transgender youth has historically focused on the disproportionate morbidity and mortality among transgender individuals in comparison to the population at large. One study of 55 transgender youth in New York City reported that 45% had seriously thought about suicide, and 26% had attempted suicide at least once, indicating that transgender youth specifically are at increased risk for **anxiety, depression, social isolation, and suicide** compared to non-transgender peers.[2-4] Our recent pilot study with a cohort of 70 multi-ethnic transgender youth at Children's Hospital Los Angeles (CHLA), the lead agency for the proposed study, supports these numbers, with 52% participants reporting thoughts of suicide and 30% reporting having attempted suicide at least once. Without appropriate care, as they age, transgender youth are likely to face economic and societal marginalization, incarceration, and physical abuse leaving them at significantly higher risk for drug abuse, violence, HIV acquisition, other sexual transmitted infections, and homelessness.[2,4-6]

A2. The "Dutch Model"

Over the past 30 years, a team of specialists in the Netherlands at the Amsterdam Center of Expertise on Gender Dysphoria observed that transgender individuals who underwent hormonal gender transition at earlier ages assimilated easier into their "new gender" roles because of improved physical outcomes.[7] Additionally, transgender youth suffering through an undesired endogenous puberty experience distress, and this "wrong puberty" has a strong negative impact on their emotional, academic, and family functioning.[7,8] Based on these clinical observations, Dutch clinician investigators initiated early treatment of transgender youth aimed at suppressing undesired puberty with gonadotropin-releasing hormone agonists (GnRHa's). GnRHa's have previously been used as the primary strategy for the suppression of puberty in children experiencing precocious puberty.[9] Early results from the first 70 gender dysphoric youth undergoing puberty suppression with GnRHa's in the Netherlands showed a decrease in behavioral and emotional problems, as well as a decrease in depressive symptoms. Improved general functioning for these youth was also reported.[10] By blocking the progression of puberty, the distress associated with full development of adult sexual characteristics incongruent with an internal gender identity is prevented.[11] A single study examining the physiologic impact of puberty suppression with GnRHa's reported that the first 21 patients undergoing this treatment had adequate suppression of their pituitary gonadal axis and no progression of their endogenous puberty. While on GnRHa's, height standard deviation scores decreased, and bone density remained in the same range for patients experiencing suppression. Compared to age-matched peers, bone density z-scores went down while patients were being suppressed.[11] In 2006, the "Dutch Model" was introduced, outlining this new approach to the care of transgender youth. Gender dysphoric adolescents 12 years and older are given GnRHa's to prevent (or minimize in those already undergoing puberty) the development of undesired secondary sexual characteristics. For youth on GnRHa's who continue to experience gender dysphoria through adolescence, appropriate cross-sex hormones (estrogen for the development of female characteristics and testosterone for the development of male characteristics) are added to the regimen to feminize or masculinize accordingly. The Dutch model recommends the addition of cross-sex hormones to allow the body to be brought into closer alignment with the identified internal gender when youth reach age 16. *[A recent follow up study from the Dutch team examining the impact of puberty suppression followed by cross sex hormones and gender reassignment surgery in 55 transgender young adults showed alleviation of gender dysphoria and steady improvement of psychological functioning.]*[12]

One important limitation of the Dutch model is the chronological age criterion that requires gender dysphoric children be at least age 12 before initiating suppression of puberty; however, by that age, it is well documented that many children in the United States are already well into their puberty.[13,14] In 2010, Biro et al. reported that across three metropolitan areas of the U.S., 42.1% of girls had Tanner 2 breast development by the age of

eight years.[15] Relying on this chronological age criterion rather than sexual developmental stage decreases early intervention potential and may increase risk for negative mental health outcomes. Additionally, only a few studies describe the physiological[11] and psychosocial impact of this treatment protocol for puberty suppression.[10] Finally, the recommendations from the Dutch model are based on data collected from a homogenous population of white, European youth living in relatively supportive environments and are not necessarily generalizable to multi-ethnic transgender youth in the U.S.

A3. The Endocrine Society Clinical Practice Guidelines

In 2009, using the best available evidence, the Endocrine Society incorporated the Dutch model into the clinical guidelines "Endocrine Treatment of Transsexual Persons," which includes recommendations for treatment of transgender youth.[16] In contrast to the Dutch model, the Endocrine Society recommends starting treatment with GnRHa's for puberty suppression based on sexual development (Tanner staging) rather than chronological age. These guidelines recommend puberty blocking medications for youth with gender dysphoria at the beginning stages of puberty (Tanner stage 2 or 3), followed by appropriate cross-sex hormone therapy at around age 16. Since the introduction of these guidelines, **no data have been collected in the U.S. on the physiologic and mental health impact, safety, or tolerability of pubertal-blocking medical interventions with GnRHa's for transgender youth, particularly in children younger than age 12**, leaving a gap in the evidence for this practice. Furthermore, the impact of GnRHa's on the bone health of transgender children, specifically in those younger than 12 years, remains unknown. **This study will investigate the physiologic and mental health impact of GnRHa administration as well as document the safety of GnRHa's in a large cohort of transgender children and adolescents in the early stages of puberty.**

The Endocrine Society Clinical Practice Guidelines include recommendations to initiate cross-sex hormones for gender dysphoric, late pubertal adolescents at around the age of 16. For those youth who are on GnRHa's, cross-sex hormones are added to the regimen. For those new to clinical care, cross-sex hormones are prescribed without GnRHa's, a protocol commonly used in both adolescents and adults. Studies in adult transgender populations have reported on the physiologic impact of cross-sex hormones,[17-19] but no studies to date have detailed the physiological impact of cross-sex hormone administration in transgender adolescents. **This study will investigate both the physiologic and the mental health impact of cross-sex hormone administration as well as document the safety of cross-sex hormones in transgender adolescents in the later stages of puberty.**

A4. Contribution of the Proposed Work

The lack of data supporting medical interventions for transgender youth combined with a shortage of providers knowledgeable in the complex psychosocial risk factors facing these young people contributes to a health disparity and public health crisis of considerable magnitude. The proposed investigation is highly significant in scope as it is the first longitudinal study collecting data - assessing both physiologic and mental health outcomes - to evaluate commonly used clinical guidelines for transgender youth in the U.S. In addition, we propose to do this work in four geographically distinct sites, in part because of the relative rarity of these conditions and also to increase the generalizability of the work. Results from this study have the potential to significantly impact the medical and mental health services provided to transgender youth in the U.S. by making available rigorous scientific evidence outlining the impact and safety of early treatment based on sexual development stage.

B. INNOVATION: The proposed study is innovative in the following ways:

B1. Creation of a National Network of Gender Centers to Study Treatment Outcomes of the Endocrine Society Clinical Practice Guidelines for Transgender Children and Adolescents

There are providers scattered around the U.S. (and the world) utilizing the Endocrine Society Clinical Practice Guidelines, but there are no formal empirical studies of related clinical outcomes in transgender children and adolescents. This application proposes to create a network of four academic hospitals (i.e., Children's Hospital Los Angeles/University of Southern California, Boston Children's Hospital, Lurie Children's Hospital of Chicago/Northwestern University, and the Benioff Children's Hospital/University of California San Francisco) strategically situated across the country with strong histories of clinical service in this area to investigate the impact of the treatment on multi-ethnic transgender youth. All four sites have dedicated transgender youth clinics, employ a similar model of care that includes medical and mental health professionals, and are considered the national leaders in the care of transgender children and adolescents. The involvement of these four sites provides the experience, expertise, and clinic populations for a research endeavor of this magnitude and importance. In addition to the significant combined clinical experience of these four sites, all of the sites have strong and deep-rooted ties to academic research.

B2. The Clinical Sites Provide Services to Diverse, Multiethnic, Transgender Children and Adolescents Across the Developmental Stages Targeted for this Study

Available data about the impact of the recommended treatment protocols come from a primarily white, European cohort in the Netherlands. This study proposes examining the impact of treatment on diverse, multiethnic, transgender youth more representative of the U.S. population.

B3. This Study Targets an Early Pubertal Cohort, as Recommended by Clinical Practice Guidelines

Avoiding the development of undesired secondary sexual characteristics by starting puberty suppression at the earliest stages of puberty is recommended in the Endocrine Society Clinical Practice Guidelines, but has never been comprehensively studied in the U.S. and has never been studied in children under the age of 12 years. This study proposes to enroll transgender children eight years or older in the earliest stages of puberty to start treatment with GnRH agonists for puberty suppression, which will provide a critically important extension to the base of empirical knowledge about treatment outcomes.

B4. Early Initiation of Cross-sex Hormone Therapy in Transgender Adolescents

Despite the knowledge that transgender identity is stable by the time youth reach adolescence,[7] The Endocrine Society Clinical Practice Guidelines recommend introducing cross-sex hormones "around" the age of 16. This study proposes to evaluate the effects and document the tolerability and safety of cross-sex hormones in youth in Tanner stages 4 and 5, including those younger than 16 years. While it is common for this team of experts to initiate cross-sex hormone therapy in transgender youth younger than age 16, there are no available data on this younger population.

B5. Groundwork for Future Investigation

The development of this four-site network with the capacity to enroll hundreds of transgender children and adolescents in clinical research paves the way for ongoing longitudinal investigation of this unique population as they age into adulthood. Clinical trials investigating best practices on hormone regimens, optimizing growth, predicting persistence of gender incongruence from childhood into adolescence, identifying resiliency factors, and investigating treatment as prevention from HIV acquisition are just a few of the future research endeavors that will be possible with the existence of this new network. *[The investigators acknowledge it is highly likely that cultural values and beliefs impact families' decision-making around seeking treatment for gender dysphoria. Although the specific study of cultural differences that impact decision-making around care are beyond the scope of what is proposed herein, it is the PI's intent to attune to these issues as they arise and develop sub-studies that the four city network is well poised to undertake.]*

B6. Summary of Innovation

This longitudinal, observational study proposes to collect critical data on the existing models of care for transgender youth that have been commonly used in clinical settings for close to a decade, although with very limited empirical research to support them. The gap in existing knowledge about the impact of these practices leaves providers and caretakers uncertain about moving forward with the recommended medical interventions for transgender youth seeking phenotypic transition. The proposed research is a direct response to the IOM report calling for such studies, as well as the needs of clinicians and patients. **The findings from this research have the capacity to substantially expand treatment across the country by providing rigorous evidence to demonstrate the benefits of early treatment and ultimately decrease the health disparity currently existing for transgender youth.**

C. APPROACH

C1. Study Objectives

The primary objective of this observational, longitudinal, multicenter study is to investigate the impact of medical treatments for gender dysphoria in two developmental and multi-ethnic cohorts of transgender youth recruited from across the nation via a network of Gender Centers dedicated to their care (Children's Hospital Los Angeles/University of Southern California, Boston Children's Hospital, Lurie Children's Hospital of Chicago/Northwestern University, and the Benioff Children's Hospital/University of California San Francisco). The proposed project aligns with the objectives outlined by the Institute of Medicine in "The Health of Lesbian, Gay, Bisexual, and Transgender People." Long-term follow-up on this ethnically diverse population is critical for generating the scientific evidence required to maximize treatment protocols and generate standards of care for the U.S. Results for this study are sorely needed to expand the body of evidence-based knowledge surrounding the practice of puberty suppression and cross-sex hormone use in adolescence and constitute the basis for further follow-up of these cohorts.

C2. Study Sites/Preliminary Data

Dr. Johanna Olson (Pediatrics and Adolescent Medicine) is the Medical Director for the Center for Transyouth Health and Development and PI at CHLA/USC. The Center has provided transgender youth care services for over 20 years and currently has 335 transgender youth in active care. Each month, this site enrolls 8-10 new transgender youth in services at the Center. **Dr. Norman Spack** (Pediatric Endocrinology) is the Medical Director of the Gender Management Service (GeMS) and is the PI at Boston Children's Hospital. GeMS was the first pediatric academic program in the Western Hemisphere to treat early adolescents with gender dysphoria. GeMS provides clinical services for 75 transgender youth and enrolls two new patients into care each month. **Dr. Robert Garofalo** (Pediatrics and Adolescent Medicine) is Co-Director of the Gender and Sex Development Program and the PI for Lurie Children's Hospital of Chicago/ Northwestern University. He has considerable experience leading and working on NIH-funded research and has been providing clinical services for transgender youth for more than a decade. The program currently has over 125 gender non-conforming children and transgender adolescents in care and on average enrolls 3-5 new patients each month. **Dr. Stephen M. Rosenthal** (Pediatric Endocrinology) is the Medical Director of the Child and Adolescent Gender Center (CAGC) and the PI at Benioff Children's Hospital/UCSF. He has significant experience conducting multi-center trials and is currently site PI for NIH/NICHD Disorders of Sex Development: Platform for Basic and Translational Research. The UCSF CAGC team has been providing multi-disciplinary care for gender non-conforming/transgender youth and adolescents for the past six years. Currently, the program has 125 youth in clinical services and is enrolling 8-10 new patients into care each month.

A pilot study funded by The Saban Research Institute conducted by Dr. Olson (CHLA) included 70 transgender youth between the ages of 12 and 24 years treated with cross-sex hormones for gender transition. Of the youth approached to participate, 99% agreed to take part in this study. The initial baseline data from this cohort confirmed high rates of suicidal ideation, suicide attempts, and drug use in this population. Fifty-four percent of participants reported thinking about suicide, and 33% had attempted suicide at least once in their lives. These numbers are three and four times higher, respectively, than the rates for general youth reported in the Youth Risk Behavior Survey (YRBS) data in 2011.[20] The majority of participants reported using alcohol, tobacco, and cannabis (78.5%, 68%, and 68% respectively). Six of the youth reported trading sex for money, food, drugs, or a place to live (survival sex). These results underscore that transgender youth remain at high risk for psychosocial morbidity. This initial pilot study, funded via a short term clinical research career development award, does not allow for longitudinal follow-up of the cohort. Additionally, this pilot cohort was primarily Caucasian and Latino/a. In order to better inform current guidelines and clinical care, the proposed project intends to include a more geographically and ethnically diverse sample; will collect expanded information about baseline mental health, comprehensive anthropometrics, and physiologic and metabolic parameters; and report follow-up results and changes over longer periods of time after treatment is initiated.

C3. Study Design

The study has a longitudinal observational design for both the early pubertal and late pubertal cohorts. *[Comparing a treated vs. an untreated control group would be the ideal mechanism to study the impact of existing recommendations for care of transgender youth, including administration of GnRHa's for younger youth and cross sex hormones for older youth. However, the current standards of care from the Endocrine Society and the World Professional Association of Transgender Health (WPATH) were both developed from a panel of scientific experts and a consensus-building process based largely upon clinical experience and the existing minimal, predominantly non-U.S. body of research, and each supports the positive impact of intervention and the negative impact of no intervention. Proceeding through an undesired puberty without treatment causes distress for transgender youth. Thus, an untreated control group does not represent a "neutral" option, but in actuality places transgender youth at risk for negative health outcomes. Inclusion of a non-intervention control group or any control group as part of a traditional randomized trial would be both impractical and unethical. Letters of support regarding our cohort design from both the Endocrine Society and WPATH are included in Appendix A. The study does include collecting longitudinal outcome data from what might be considered a "natural control" – those gender nonconforming youth who meet diagnostic criteria and get offered GnRHa's for suppression but who elect or refuse treatment as part of the informed consent process. In a small, but not rare, number of cases, parents and/or the children may elect under certain circumstances (e.g. cost, fears given a lack of scientific evidence, etc.) to not initiate pubertal suppression. For this cohort, we propose enrolling these patients and collecting and capturing outcome data for comparison along the same visit schedule as our treated cohort. In addition, as part of our original study design we will collect data on age and Tanner staging to be able to examine if early vs. delayed treatment in these young*

people affects health outcomes.] The anthropometric and physiologic parameters in the study are those routinely collected within the constructs of the clinical visit at each site. Audio computer-assisted self-interviewing (ACASI) survey instruments will be used to collect demographic, mental health, psychosocial, and behavioral data from 1) early pubertal cohort youth and their parent/caretaker and 2) late pubertal youth.

Youth participants will be recruited from patients seeking care at any of the four study sites. Because presentation of gender dysphoric youth in Tanner stage 2 or 3 is less common than presentation in later Tanner stages, we will enroll 88 youth in the early pubertal cohort, which allows for 10% anticipated attrition across the follow-up assessments. In the late pubertal cohort, 240 participants will be enrolled, which takes into account an expected 20% attrition across follow-up assessments in order to obtain a sample of 200 participants. While patients between 8 and 21 years old will be eligible for enrollment in one or the other cohorts depending on their Tanner staging, the focus of this investigation is *early treatment*. Therefore, we will not enroll more than 20% of youth age 19 or older in the late pubertal cohort. We will aim to enroll equal numbers of each gender for both cohorts. Clinical observation indicates that equal number of girls and boys seek care for gender dysphoria in the specialty clinics; thus, we do not anticipate overrepresentation of either gender.

C4. Early Pubertal Cohort

C4a. Early Pubertal Cohort - Study Enrollment and Inclusion/Exclusion Criteria

The early pubertal cohort will be recruited from those youth in early stages of puberty presenting for care at any of the four sites along with their parent/primary caretaker. Transgender children and adolescents in the first stages of pubertal development will be screened by the primary medical provider at each site for participation in the study with the following criteria:

Inclusion criteria: 1) gender dysphoria as defined by DSM-V;[21] 2) Tanner stage 2 or 3 of sexual development; 3) desire to undergo puberty suppression; and 4) *[ability to read and understand English or Spanish.]* Parent/Caretaker inclusion criteria includes reading and understanding English or Spanish.

Exclusion criteria: 1) prior utilization of GnRHa's; 2) precocious puberty (natal males younger than 9 years or natal females younger than 8 years); or 3) pre-existing osteoporosis.

Youth who meet inclusion criteria will provide assent, and their parent/caretaker will provide informed consent for participation in the study. (For consent forms, see Appendix B: Consent Forms.)

C4b. Early Pubertal Cohort: Treatment Plan and Data Collection

Medications used in the course of this study are the standard of care for puberty suppression at the four study sites and include the GnRHa's leuprolide acetate and histrelin acetate. The study will not influence prescription patterns among the clinical providers. Decisions about GnRHa dosing will be individually determined based on subjects' adequate and appropriate response to medications, as well as tolerability of side effects. Patients who experience intolerable side effects will have medication adjustments made according to the discretion of the medical provider at the site where they are receiving care.

***[Demographic data** including age, ethnicity, religion, educational level, relationship to child (biological parent, adoptive parent) and birth city/country];* **anthropometric measures,** including height, weight, BMI, sitting height, and Tanner stage; **physiologic parameters,** including fasting lipids and glucose, blood pressure, liver enzymes, electrolytes, and glycosylated hemoglobin; and **hormone levels** used to assess adequate pubertal suppression, including ultrasensitive luteinizing hormone and estradiol or testosterone based on gender, will be collected at baseline (T0) and at 6 months (T1), 12 months (T2), and 24 months (T3) following initiation of GnRHa treatment. **Measures related to bone health,** including bone mineral density (BMD), bone age, 25-hydroxy vitamin D, calcium, phosphate, and serum bone-specific alkaline phosphatase, will be collected at baseline and at 12 months and 24 months following initiation of GnRHa treatment.

Psychosocial ACASI Assessments

The life course approach highlights the importance of adolescence as a developmental stage in which self-identity formation and validation are crucial tasks that affect the remainder of adulthood.[22] Careful attention was given to choosing age-appropriate standardized measures with strong reliability for each construct. The use of the life course approach to our choice of psychosocial assessments dictates a focus on contextual variables that will strengthen our understanding of risk and resilience within our cohorts. These measures include the experience of life stressors and traumatic events, parental and peer relationships, and quality of life. While we will use the standardized instruments described in Table 1, we will also add events and experiences specific to the age range of our respondents, based on our teams' experiences as physicians and psychologists treating these youth, as well as information from youth and their parents. Table 1 lists the

measures, the intended respondent: Parent (P), Child (C), or both (P/C), the number of items (#), and the Cronbach alpha value. The measures in the ACASI survey fall into four domains: 1) demographic 2) transgender-specific experiences including gender dysphoria, 3) mental health and trauma assessments, and 4) additional psychosocial information including quality of life and relationships with parents and peers. ACASI survey instruments for youth and for parent/caretaker will be administered at the initial visit (T0) and 6 months (T1), 12 months (T2), and 24 months (T3) following initiation of GnRHa treatment (Table 2).

Table 1. ACASI Survey Instruments: Early Pubertal Cohort

Construct	Scale	#	α
	Parent/Caretaker Survey		
Demographics	As described above	--	--
Gender Identity	Parent Report Gender Identity Questionnaire[23]	14	--
Social Transitioning	Social Transitioning Scale[24]	8	--
Trauma symptoms	Trauma Symptom Checklist: Young Children[25]	20	.81-.88
Child Anxiety	Screen for Child Anxiety Related Disorders [26]	41	.78-.90
Child's Life events	Life Incidence of Traumatic Events [27]	16	--
Child's Resilience	Strengths & Difficulties[28]	25	.76
	Child Survey		
Gender Identity			
Body Esteem	Revised Body Esteem 8-10.5[29]	20	.73-.77
Body Image	Body Image Scale[30]	30	
Anxiety	Screen for Child Anxiety Related Disorders[26]	41	.78-.90
Depression	Beck Depression Inventory[31] Youth (7-12)	20	
Self injury/Suicide	Suicide and self-harm[32]	6	--
Quality of Life	Health-related Quality of Life in Children (KINDL)[33]		
Peer relationships	Harter Social Competence[34]		

Parent/Caretaker ACASI Instrument

Transgender experience will be assessed as child gender identity, child's age of realization of transgender status, child's age of first living in the desired gender role, domains where the child is living in their desired gender role, social transitioning, parental/guardian support, and disclosure of child's transgender status to others. Mental health and trauma assessments include parent reports of child's anxiety, child's experience of trauma and trauma symptoms (including those associated with impending or beginning pubertal development), child's suicide (ideation and attempts), and self-harm. Additional psychosocial measures include child's quality of life and child's strengths and difficulties.

Child ACASI Instrument

Transgender experience includes age of realization of transgender status, social transitioning, gender identity, and gender dysphoria. Additional measures will assess body esteem and body image. Mental health assessments will include anxiety, depression, suicide (ideation and attempts), and self-harm. Additional psychosocial measures include peer relationships. (See Appendix C: Transgender Specific Measures – Early Pubertal Cohort.)

Table 2. Data Collection Schedule – Early Pubertal Cohort

Measure	T0 (Baseline)	T1 (6 mo)	T2 (12 mo)	T3 (24 mo)
Anthropometric Measures - height, weight, BMI, sitting height, and Tanner stage	X	X	X	X
Physiologic Parameters - fasting lipids and glucose, blood pressure, liver enzymes, electrolytes, prolactin level, and glycosylated hemoglobin	X	X	X	X
Hormone Levels - luteinizing hormone via ultrasensitive assay, and estradiol or testosterone via ultrasensitive assay based on gender	X	X	X	X
Measures of Bone Health - Bone mineral density (BMD), bone age, 25-hydroxy vitamin D, calcium, phosphate, and serum bone-specific alkaline phosphatase	X		X	X
Parent/Caretaker and Child Demographic, Transgender Experience, and Psychosocial ACASI - (see Table 1)	X	X	X	X

C5. Late Pubertal Cohort

C5a. Late Pubertal Cohort - Study Enrollment and Inclusion/Exclusion Criteria

Transgender adolescents in later stages of puberty (Tanner stage 4 or 5) seeking medical treatment for the purpose of phenotypic gender transition at any of the four sites will be screened by the primary medical provider at each site for participation in the study with the following criteria:

Inclusion criteria: 1) the presence of gender dysphoria as defined by the DSM-V;[21] 2) Tanner stage 4 or 5 of sexual development; 3) interested in pursuing a phenotypic gender change with cross-sex hormones; and 4) *[ability to read and understand English or Spanish.]*

Exclusion criteria: 1) <13 or >21 years old or 2) prior utilization of cross-sex hormones. Youth who are under the age of 18 will provide assent for participation, and their parents/legal guardian will provide consent. Youth age 18 or older will provide consent for participation. (For consent forms, see Appendix B: Consent Forms.)

C5b. Late Pubertal Cohort: Treatment Plan and Data Collection

Medications used in the course of this study (i.e., feminizing agents for transgender females and masculinizing agents for transgender males) are the standard of care at the four study sites. As the study is observational, it will not influence prescription patterns among the clinical providers. Decisions about medication doses are individually determined based on adequate and appropriate response to medications, as well as tolerability of side effects. Feminizing medications include oral, transdermal, or intramuscular 17B-estradiol. Spironolactone, commonly used to suppress testosterone synthesis and action in natal males, is often used in combination with estradiol to further assist in feminization. Medroxyprogesterone is occasionally used in patients to further breast development. Masculinization medications include injectable or transdermal testosterone esters. Data on specific hormone type and dosing will be collected to evaluate differences as part of the analysis.

*[**Demographic data** including age, ethnicity, race, religion, sexual orientation educational level and birth city/country];* **anthropometric measures** including height, weight, BMI, and Tanner stage and **physiologic parameters** including fasting lipids and glucose, blood pressure, liver enzymes, electrolytes, prolactin level, hemoglobin, glycosylated hemoglobin and hormone levels will be collected at baseline (T0) and 6 months (T1), 12 months (T2), and 24 months (T3) following initiation of treatment with cross-sex hormones.

Psychosocial ACASI Assessments

As mentioned above, the life course approach highlights the importance of adolescence as a developmental stage in which self-identity formation and validation are crucial tasks as well as the importance of social environments.[22] Age-appropriate standardized measures with strong reliability were chosen wherever possible. As with the younger cohort, we will add events and experiences specific to the age range of our respondents, based on our teams' experience as well as information from youth themselves. Table 3 lists the measures chosen for the late pubertal cohort, the number (#) of items, and the Cronbach's alpha value. Our choice of measures to use in the ACASI survey fall into five domains: 1) demographics; 2) transgender-specific experiences including gender dysphoria; 3) mental health and trauma assessments; 4) additional psychosocial information including quality of life and relationships with parents and peers; and 5) behavior risk including alcohol/drug use, sex work and high-risk sexual activities.

Table 3. ACASI Survey Instruments: Late Pubertal Cohort

Construct	Scale	#	α
Transitioning	Transitioning Scale	8	--
Gender Dysphoria	The Gender Identity/Gender Dysphoria Questionnaire for Adolescents and Adults[35]	12	.74-.86
Body Esteem	Body Esteem[36]	30	.81-.94
Body Image	Body Image Scale[30]	30	
Depression	BDI II (Adolescent)[37]	21	.90
Anxiety	Manifest Anxiety Scale[38]	36	.91
Trauma Symptoms	Trauma Symptom Checklist[39]	17	--
Life events	Life Events Checklist[40]	21	--
Self Injury/Suicide	Suicide and Self-Harm[32]	6	--
Quality of Life	Health-related Quality of Life[41]	17	.74-.82
Stress/Connectedness	Gender Minority Stress[42]	55	.71-.93
Social Support	Multi-Dimensional Social Support [43]	12	.92
Drug Use	Alcohol, Smoking, and Substance Involvement Screening Test[44]	48	--
Sexual Risk	Adolescent Sexual Activity Index[45]	13	--

Transgender experience questions will include gender identity (age of realization of transgender status), transitioning (age of first transitioning or "real life experience" in the desired gender role), gender dysphoria, previous hormone use, and length of treatment. Additional measures will assess body esteem, and body image, Mental health and trauma assessments will include depression, anxiety, experience of trauma and trauma symptoms (including those associated with being transgender), suicide (ideation and attempts) and self-harm. Additional psychosocial measures include quality of life, social support from peers and family. In addition, stress will be captured by the Life Events and Gender Minority Stress Scales, including additions specific to transgender experience. (See Appendix D: Transgender Specific Measures - Late Pubertal Cohort). Behavioral risk will include assessment of drug use and sexual activity, including high-risk sexual behavior such as sex work.

Table 4. Data Collection Schedule – Late Pubertal Cohort

Measure	T0 (Baseline)	T1 (6 mo)	T2 (12 mo)	T3 (24 mo)
Anthropometric Measures - height, weight, BMI, and Tanner stage	X	X	X	X
Physiologic Parameters - fasting lipids and glucose, blood pressure, liver enzymes, electrolytes, prolactin level, hemoglobin, glycosylated hemoglobin, estradiol, and free and total testosterone	X	X	X	X
Demographic, Transgender Experience, Psychosocial, and Behavioral Risk ACASI - see Table 3	X	X	X	X

C6. Data Management

The PIs from the four sites will collaborate with relevant Co-Investigators to create and finalize a cross-site study implementation protocol for each site to carry out the project in a consistent manner. The data coordination staff, housed at CHLA, will support all PIs with the generation of a cross-site protocol for data collection and templates for the Institutional Review Boards at each site. The final data collection instruments, vetted by each site PI/Co-I, will be programmed into the ACASI software by core staff. Programming will be overseen and ACASI logic (skip patterns, etc.) will be tested by Dr. Schrager. Once piloted by core staff, computers for each site will be loaded with survey data collection and data housing software. In the event of changes to future surveys, the study core will release updated survey versions and instructions for loading onto site computers to the study coordinator at each site.

Data will be collected systematically at each site using identical operating procedures, including case report forms (CRFs) for abstracting physiological parameters from medical chart data, ACASI programming, and data flow sheets to facilitate the creation of a data repository that is suitable for analysis and available for all four sites to explore. The data will be owned equally by each of the four participating sites. Data will be stored at each site and transferred to CHLA. Study-wide data management procedures, including integration and verification of multi-site data, will take place at CHLA under the direction of Dr. Schrager (CHLA Co-I).

The data manager at the coordinating site will be responsible for ensuring that site data are safely transferred via secure protocols to CHLA for cleaning and merging. The data manager will generate tracking reports regarding the accrual of participants at each site, as well as specific characteristics of the emerging cross-site data file (such as balance of male and female transgender respondents, respondent ages or age categories, etc.). The data manager will work with site staff to facilitate the receipt of data, provide technical assistance as necessary, and meet regularly via telephone with the staff person responsible for site-specific quality assurance. In addition, the data manager will manage the overall dataset, merging elements, cleaning data, creating composite variables and scales, and running descriptive statistics such as characteristics of subjects for the entire sample (male v. female, other demographics, etc.) for the larger study group.

Cleaned and coded data from all four sites, including scored measures and created scales, will be made readily available to all PIs. To meet NIH obligations for data sharing, other investigators not affiliated with the study will also be able to access de-identified study data pursuant to a signed Data Use Agreement. The core staff will be responsible for maintaining Data Use Agreement records and secure transmission of data to outside investigators.

C7. Analytical Plan and Power Analysis

C7a. General Analytical Framework for Aims 1 and 2

The analysis plan of categorical and continuous variables consists of the following: descriptive analyses; psychometric analyses of scales; and use of generalized linear models to evaluate study hypotheses (including, but not limited to multiple linear and logistic regression, path analyses, and structural equation

modeling). SPSS (version 22) and Mplus (version 7.11) will be used for data management and all preliminary and formal hypothesis-testing analyses. Prior to beginning hypothesis testing, we will undertake the following activities with all waves of psychological and physiological data from both cohorts.

C7b. Data Checking, Cleaning, and Management

Procedures to clean and screen the survey data will include univariate analyses (e.g., mean, standard deviation, plausible range and value, skewness, and kurtosis), patterns of correlation and covariance, and checks for multicollinearity and singularity of variables. These procedures will facilitate the identification of multivariate outliers and check assumptions of multivariate normality (e.g., normal distribution, linearity, and homoscedasticity). Transformation of variables (e.g., log transformation) will be conducted as needed to reduce the effects of valid outliers or violations of multivariate normality. Univariate statistics will be used to broadly examine the characteristics of the sample, including demographics, mental health, physiological parameters, substance use, and other risk behaviors (e.g., sexual risk), social support, and parental measures for the early puberty cohort. Bivariate analyses (e.g., correlation analyses) will examine relationships among variables of interest and identify potential covariates for inclusion in later multivariate models. Data reduction techniques such as factor analysis will be used to identify and/or verify scale structure of constructs of interest. Scale scores will be created as means or sums of unweighted composite scores or composite scores weighted by factor loadings, as appropriate. Confirmatory factor analysis will be considered for evaluating the stability of composite scores over time. Psychometric properties (e.g., Cronbach's alpha) of all scale measures will be evaluated at each assessment time point.

Following these preliminary analyses, formal hypothesis testing to address **Specific Aims 1 (early pubertal youth) and 2 (late pubertal youth)** will proceed as follows:

Effects of Hormonal Interventions on Mental Health and Psychological Well-Being

Hypothesis 1a: Patients treated with GnRHa's will exhibit decreased symptoms of gender dysphoria, depression, anxiety, trauma symptoms, self-injury, and suicidality and increased body esteem and quality of life over time.

Hypothesis 2a: Patients treated with cross-sex hormones will exhibit decreased symptoms of anxiety and depression, gender dysphoria, self-injury, trauma symptoms, and suicidality and increased body esteem and quality of life over time.

Hypotheses 1a and 2a will be tested in the early-puberty and late-puberty cohorts, respectively, using repeated measures multivariate analysis of variance (MANOVA) to assess the trajectories of continuous mental health outcomes and psychological well-being over time within each cohort. The MANOVA approach will preserve statistical power to detect significant effects among this set of related continuous outcomes without the inflated Type I error rates associated with a series of individual ANOVA or regression analyses. The MANOVA analyses will investigate the changes over time in gender dysphoria, depression, anxiety, trauma symptoms, self-injury, suicidality, body esteem, and quality of life. The model will incorporate time (i.e., measurement time point: baseline, 6-month, 12-month, or 24-month survey) as a within-subjects factor. Asserted gender, age, ethnicity, and other socio-demographic variables may additionally be entered as possible covariates (i.e., ANCOVA) to improve statistical power to detect significant time effects. However, we do not propose any *a priori* hypotheses about demographic effects on these outcomes, and any demographic variables that do not contribute significantly to the model will be removed from the analysis in order to preserve power and increase model parsimony.

In keeping with conventional practice, analysis will first proceed with a review of Box's test for the equality of covariance matrices. Violations of this assumption would require the use of Pillai's trace, as opposed to Wilks' Lambda, to determine multivariate statistical significance. If, as hypothesized, the within-subjects time variable demonstrates significant multivariate effects, the follow-up univariate results will be inspected as appropriate. The assumption of sphericity via Mauchly's test will be checked for each measured outcome; if sphericity is violated, the Huyhn-Feldt correction for degrees of freedom will be applied to that outcome. Finally, for outcomes showing significant time effects, linear and quadratic contrasts will be checked for significance and marginal means will be computed and plotted to create a visual display of significant trajectories. An *a priori* p-value of 0.05 will be applied as the criterion for statistical significance in all analyses.

Safety of Hormonal Interventions

Hypothesis 1b: GnRH agonists are tolerable and safe for early-pubertal transgender youth, i.e., lipids, glucose, liver enzymes, electrolytes, insulin, and HgbA1c will not increase above clinically safe ranges.

Hypothesis 2b: Cross-sex hormones are tolerable and safe to use with late-pubertal transgender youth initiating phenotypic transition, i.e., will not increase lipids, glucose, liver enzymes, electrolytes, hemoglobin A1c and hemoglobin above clinically safe ranges.

Unlike the mental health and psychological well-being measures, the question of interest for these metabolic and physiological parameters is not whether they show significant fluctuation over time (which may or may not be meaningful), but rather whether development after initiation of hormonal interventions pushes any physiological indicator above the clinically safe range for that indicator, i.e., above predetermined safety cutoff values based on previous literature and clinical guidelines. Safety will be assessed cross-sectionally with one-sided one-sample t-tests comparing cohort mean scores to the cutoff value. We hypothesize that the cohort means will be significantly lower than the cutoff score. We will use the Benjamini-Hochberg procedure[46] to account for inflated family-wise alpha due to multiple comparisons at each time point.

Additionally, ranges of raw scores from all patient labs will be computed at each time point as part of the preliminary data cleaning and descriptive analysis phase. This will provide an immediate assessment whether the indicator value for any individual patient has crossed the safety threshold for that indicator as data are collected at each time point. In the event any patient experiences an individual increase in laboratory values above the threshold, medication adjustments will be made to protect the well-being of the patient according to the discretion of the medical provider at the site where they are receiving care regardless of the whole-cohort significance test results for that time point.

Bone Density in Early Pubertal Youth

Hypothesis 1c: Raw bone density scores will remain stable for early-pubertal transgender youth receiving GnRH agonists; however, age-matched z-scores may decrease.

We will use repeated measures ANOVA to estimate trajectories of raw and age-matched bone density scores over time in early pubertal youth. As before, asserted gender and socio-demographic variables may be entered as possible covariates, linear and quadratic contrasts will be assessed, and marginal means will be computed and plotted to create a visual display of trajectories for both outcomes. We hypothesize that for raw scores, the linear term will *not* differ significantly from zero, indicating net stability in bone density over time. However, for age-matched z-scores, the linear term may be negative as gender non-conforming youth receiving GnRH agonists fail to add bone density at a rate comparable to their age-matched peers.[11]

Risk Behavior in Late Pubertal Youth

Exploratory Aim 3: Based on evidence of high rates of substance use and HIV infection in some transgender adolescents, we will measure substance use and sexual risk behavior over time.

We will conduct an exploratory assessment of sexual risk and substance use behavior in the late pubertal cohort, using repeated measures MANOVA to model trajectories of these risk outcomes over time. As before, asserted gender and socio-demographic variables may be entered as possible covariates. Given that sexual risk and substance use behaviors increase during adolescence in normative samples, we do not specify *a priori* hypotheses regarding the impact of hormone treatment on these risk outcomes in our transgender population. However, linear and quadratic contrasts will be assessed. Significant positive terms (indicating increased risk over time) would be indicative of a typical adolescent risk trajectory, whereas significant negative terms (indicating decreasing engagement in risky behaviors) or non-significant time effects (suggesting no net change in risk) would instead support a "treatment-as-prevention" explanation. Again, Box's test will be reviewed for equality of covariance matrices and multivariate test statistic determined accordingly, and sphericity will be assessed via Mauchly's test with the Huyhn-Feldt correction applied as needed.

C7c. Additional Analytic Considerations: Site Clustering Effects

Although the proposed observational study will take place at four sites nationwide, we do not anticipate substantial site effects. To verify this, a group identifier for each participant will be included in the merged analytic dataset, and the intra-class correlation (ICC) for each outcome will be calculated prior to conducting multivariate analyses. If, as anticipated, no significant variance is carried at the group level, we will reduce the

model to a traditional one-level model. If significant group-level variance does emerge, dummy codes to control site-specific variance will be used to enhance statistical power.

C7d. Missing Data

We will conduct missing data analyses in order to differentiate between data that are missing at random (MAR) and data that are missing related to gender or aspects of the treatment plan (e.g., hormone dosing). If missing data can be regarded as MAR, multiple imputations may be used. If the MAR assumption is not plausible, sensitivity analyses will be conducted to evaluate the impact of MAR violations on analyses by specifying models for non-ignorable missing data mechanisms.

C7e. Power Analysis to Determine Sample Size

Early Pubertal Cohort. Unique to the early puberty cohort is the need to assess the effect of GnRH agonists on bone health (Hypothesis 1c). Although we hypothesize that there is no net change in raw bone density over time (precluding power analysis), it is important to assess nontrivial lags in development compared to age-matched peers. Using G*Power version 3.1.3 to conduct an *a priori* power analysis in a repeated measures MANOVA framework with effect size f=.20 (a moderate effect size equivalent to Cohen's d=.40), alpha=.05, adequate statistical power=.80, and 4 measurement time points, a sample of 73 participants would be sufficient to detect significant decrease in age-matched z-scores over time. Thus, we propose to recruit a sample of **80 evaluable participants in the early puberty cohort**, which will yield comparable power to detect moderate changes in mental health outcomes over time (Hypothesis 1a) and good (.89) power to detect significant differences in metabolic and physiologic lab values of one-third of a standard deviation from clinical cutoffs (Hypothesis 1b).

Late Pubertal Cohort. In the absence of available longitudinal metabolic and physiological data, the proposed study will be powered to assess changes in mental health and psychological well-being (Hypothesis 2a) based on evidence from our preliminary data. Using G*Power version 3.1.3 and conducting an *a priori* power analysis in a repeated measures MANOVA framework with effect size f=.11 (a small effect size equivalent to Cohen's d=.22), alpha=.05, adequate statistical power=.80, and 4 measurement time points, with a small natural correlation among repeated measures of r=.15, a total sample of 196 participants would be needed for adequate power to detect multivariate significance. This sample would generate adequate (.80) power to detect effects as small as d=.17, or less than a fifth of a standard deviation from clinical cutoffs, in the safety analyses of Hypothesis 2b. Therefore, we propose to recruit a total sample of **200 evaluable participants in the late puberty cohort** to ensure adequate statistical power to test the two hypotheses of Aim 2 and to conduct the exploratory analysis of Aim 3.

C8. Expected Outcomes

Aim 1: Findings will determine that the treatment practice of blocking puberty in gender dysphoric youth is not only tolerable and safe, but that this practice improves the mental health of these youth by avoiding the development of secondary sex characteristics that are undesirable. We anticipate that bone density during puberty suppression will continue to accrue at a pre-pubertal rate. Collectively, these outcomes will help clinicians and caregivers make the critical decision to move forward with treatment of gender dysphoric youth. Additionally, policy makers will have expanded scientific evidence that will support the medical necessity of this treatment approach, informing policies related to gender transition.

Aim 2: In our late pubertal cohort, findings will determine that gender transition with cross-sex hormones is tolerable, safe, and improves the mental health of transgender adolescents. Additionally, cross-sex hormone treatment may lead to a decrease in high-risk behavior including sexual activity and drug use. Collectively, these outcomes will help clinicians and caregivers provide the necessary early care for transgender adolescents. Rigorous scientific evidence supporting the benefits of early treatment will help reduce the anxiety often experienced by providers and caregivers that cross-sex hormones are harmful and the fear that the irreversible changes occurring from hormones is the wrong choice for the health and well being of their children and patients. Treatment models that are proven to improve mental health outcomes and decrease life-threatening behaviors are medically necessary and need to be unequivocally framed as such.

C9. Potential Problems and Alternative Strategies

A first potential problem with the study is participant attrition between baseline enrollment and follow-up visits, which could impact the validity of results and the power to detect relationships among variables. Older adolescents are migratory by nature, although continued hormone treatment is a compelling reason to stay engaged in care. In our pilot study of transgender youth at CHLA, attrition over one year was 15%. We are over-recruiting by 20% in the late pubertal cohort to account for potential increased attrition over 2 years. For

the youth in the early pubertal cohort, we anticipate that attrition rates will be lower than in the older cohort based on clinical observation and on increased parental involvement. We are over-recruiting in this cohort by 10% to allow for potential participant attrition.

Collecting and transmitting data consistently across four participating sites can be challenging. Data must be cleaned and stored uniformly in order to perform useful analyses and generate meaningful conclusions. Therefore, we have budgeted for a data coordination core staff at CHLA, whose responsibility it is to conduct trainings of data collection personnel at each site concerning appropriate procedures for recruitment, enrollment, and use of computer assisted data collection. Additionally, core staff will be responsible for verifying that data from all sites are comparable.

While this study will likely cause minimal risk to participants, they could potentially experience distress and/or triggering of negative feelings when asked questions on the ACASI of a more sensitive nature. If patients experience discomfort or distress, as outlined in the Protection of Human Subjects attachment, they will be directed immediately to onsite mental health providers for evaluation and counseling.

[Finally, a study design that had a more scientifically robust control arm was considered, but in light of both the WPATH and the Endocrine Society's guidelines we decided against such an approach as we deemed it both unfeasible and not ethically responsive to the population served.]

C10. Benchmarks of Success and Timeline

Benchmarks (see **Timeline of Project Activities** in the Budget Justification section) include: 1) The successful completion of project protocols and human subject approvals; 2) development and piloting of the ACASI instrument; 3) standardized training of project coordinators and data collection staff; 4) successful enactment of recruitment protocols; 5) completion of baseline collection of bone density, physiologic, and psychosocial date; 6) data collection at each follow-up point; 7) data management and analysis; and 8) published manuscripts and dissemination.

C11. Dissemination

The PIs from all sites will each attend one national conference per year to disseminate findings beginning in Year 2. Data obtained from this study are of interest to and will be presented to participants at gender specific conferences such as the World Professional Association of Transgender Health, Gender Odyssey, Philadelphia TransHealth Conference, and Gender Spectrum, and also at national conferences concerning the health of children and adolescents such as the American Academy of Pediatrics, Society for Adolescent Health and Medicine, Pediatric Academic Societies, and others. Beginning in Year 3, peer-reviewed publications will be developed pertaining to cross-sectional hypotheses and research questions found in Aims 1 and 2, though the bulk of publications are longitudinal in nature and will be developed in Year 5. Dissemination of findings to State and County officials, policy makers, and organizations will begin in Year 3, when preliminary data become available.

C12. Future Directions

The development of this network of investigators is an essential step in the progress to eradicating the health disparity that currently exists for transgender youth. Together, these sites anticipate expanding investigation into the experiences and needs of transgender youth from early childhood through early adulthood. Our network of four research sites views the proposed research as only the beginning of a larger body of longitudinal outcome research needed for understanding and optimizing medical interventions for gender non-conforming children and adolescents. A distinct strength of the proposed network is that we will be well-suited to address new and unanticipated issues as they arise within the context of the proposed work in order to refine aspects of future studies. As children and adolescents who are blocked in puberty move on to cross-sex hormones, it will be critical to understand the impact of GnRH analogues on their bone mineral density, as well as neurocognitive development. We plan to extend our investigations to include the youngest cohort of gender non-conforming children in order to identify resiliency factors, understand the role of social support systems, and identify predictors of persistence of gender non-conformity from childhood into adolescence. Additionally, future investigation into the experience of parenting gender non-conforming and transgender youth is of interest and importance. This proposal sets up an ideal framework to continue collecting longitudinal data from the cohorts recruited for this initial work as well as understand the additional complexities of this population.

PROTECTION OF HUMAN SUBJECTS

Risks to Human Subjects

a. Human Subjects Involvement, Characteristics, and Design
Transgender children and adolescents, those who experience incongruence between assigned birth sex and internal gender identity, are a poorly understood and distinctly understudied population in the United States. The limited available data suggest that transgender youth who are gender dysphoric (persistently distressed about their gender incongruence) are at increased risk for numerous health disparities in comparison to their peers, including higher rates of anxiety, depression, suicide, and substance use. The development of undesired secondary sex characteristics during puberty intensifies the distress associated with gender incongruence and increases the risk for these conditions. Current clinical practice guidelines include strategies for treating transgender youth with the use of: 1) gonadotropin releasing hormone (GnRH) agonists to suppress endogenous puberty in early pubertal adolescents in order to avoid the development of undesired secondary sex characteristics and 2) cross sex hormones to induce masculine or feminine features in late pubertal adolescents. The goal of these interventions is to decrease gender dysphoria and ameliorate other potential negative health outcomes. These guidelines are used at academic and community-based centers across the U.S.; however, they are only partially empirically derived and based on very limited data, largely from non-U.S. sources. Further, there are no data available examining the physiologic and metabolic consequences of these treatments in adolescents. This represents an obvious gap in the literature that has significant implications for clinical practice across the U.S. The general lack of U.S. data leaves healthcare providers uncertain about optimal care for these highly vulnerable youth. This proposed research will fill gaps in knowledge, provide empirical evidence to inform clinical care, and would be the first study of its kind evaluating longitudinal outcomes of medical treatment for multi-ethnic, transgender youth in the U.S.

The proposed research study will collect data from 328 transgender youth (88 early pubertal [Tanner stages 2 and 3] and 240 late pubertal youth [Tanner stages 4 and 5]) and 88 parents of the early pubertal group in order to evaluate the impact of hormone therapy.

Potential participants will be receiving services at one of the four sites (Boston, Chicago, Los Angeles, and San Francisco) and seeking hormonal intervention to either delay the progression of puberty through the use of GnRH agonists or begin phenotypic gender transition by adding cross-sex hormones. Recruitment will be conducted by one of the care providers at the site, and ongoing retention will be supported through the participants receiving transgender care services.

Inclusion criteria for early pubertal cohort includes the presence of gender dysphoria, expressed anxiety about endogenous puberty and/or the development of undesired secondary sexual characteristics, Tanner stage 2 or 3 of sexual development, and a desire to undergo puberty suppression. Patients and parents/legal guardians must be able to read and understand English. To be eligible for enrollment, the participants cannot have utilized GnRH agonists or hormones prior to the initial visit.

Inclusion criteria for the late pubertal cohort includes transgender youth between 13 and 21 years of age with gender dysphoria, Tanner stage 4 or 5 of sexual development, and an interest in pursuing a phenotypic gender change with cross-sex hormones. Patients must be able to read and understand English. To be eligible for enrollment, the participants cannot have utilized cross sex hormones prior to the initial visit.

The involvement of children is required as this study focuses on transgender youth who are either early pubertal or late pubertal. The hormonal interventions are ideally utilized in Tanner stages 2 and 3 for puberty delay or Tanner stages 4 and 5 for phenotypic gender change. No other special vulnerable populations will be enrolled.

Physiologic, psychosocial, behavioral, and medical data will be collected at the baseline visit (T0), 6 months (T1), 12 months (T2), and 24 months (T3). The timeline for data collection is correlated with expected standard of care clinical visits so as to not overly burden the participants or their parents/legal guardians with additional

study visits. Physiologic data will be abstracted from medical records, while demographic, psychosocial, and behavioral data will be collected via Audio Computer-Assisted Self-Interviewing (ACASI) technology.

The research is being conducted at Children's Hospital Los Angeles, University of California San Francisco Benioff Children's Hospital, Lurie Children's Hospital of Chicago, and Boston Children's Hospital in order to investigate the impact of the treatment on multi-ethnic transgender youth in the United States. These four academic hospitals situated strategically across the country have dedicated transgender youth clinics and are considered the national leaders in the care of transgender children and adolescents. All four sites employ a similar model for care that includes medical and mental health professionals and represent some of the most experienced providers in the country doing this work.

ACASI data collected at the collaborating sites will be encrypted and transferred to CHLA. Upon transfer of the encrypted data to CHLA, the data will be stored on CHLA's secured network (with firewall protection), which cannot be accessed by anyone outside of CHLA. All case report forms (CRFs) will be entered into password protected databases at the site and be transmitted securely with an ID core to CHLA. A password will be used to access survey data and chart abstraction files and will be made accessible only to the Principal Investigators and study staff. These data will be archived in a password-protected database on the local network on a daily basis. The data coordination staff, housed at CHLA, will support all PIs with the generation of a cross-site protocol for data collection and templates for the Institutional Review Boards at each site. Study-wide data management procedures, including integration and verification of multi-site data, will take place at CHLA.

b. Sources of Materials

Case report forms (CRFs) for abstracting physiological parameters (height, weight, BMI, sitting height, Tanner stage), hormone levels, and bone health from medical chart data will be used.

Data will be collected directly from participants and for the early pubertal group, their parents/legal guardians, via ACASI to minimize concerns about confidentiality. Demographic data for the early pubertal group collected will include age, ethnicity, educational level and birth city/country, as well as data specific to the transgender population, such as age of realization of transgender status, age of first living in the desired gender role, and domains where they are living in their desired gender role, if any. Demographic, mental health, and behavioral data will also be collected from the parents of the youth in the early pubertal group.

Demographic data for the late pubertal group collected will include age, ethnicity, educational level, and birth city/country, as well as data specific to the transgender population, such as age of realization of transgender status, age of first transitioning or "real life experience" in the desired gender role, prior sexual activity, sexual orientation, previous hormone use, and length of treatment. Psychosocial indicators from the late pubertal group include gender dysphoria, quality of life, body esteem, depression, suicidal ideation, drug use, sex work, and high-risk sexual behavior.

Only site-specific research staff and local institution IRB personnel conducting quality assurance activities will have access to individually identifiable private information about the participants.

No personal identifying information (e.g., name, tracking information, etc.) will be placed on any of the CRFs or collected within the ACASI survey. All study-specific records will be identified by a coded number only, to maintain confidentiality. Only the research staff will have access to the database linking the participant's unique ID code and name in a secure network, password-protected file or in a secure location under double-lock when not in use and with restricted access during work hours and/or when unattended.

Anthropometric measures, hormone levels, laboratory result data, and bone health will be abstracted by trained, research staff and recorded on CRFs. All CRFs will be entered into password protected databases at the site and transmitted securely with an ID to CHLA.

For the ACASI baseline and follow-up surveys each participant will be assigned a code and their pre- and post-surveys will be linked via this code. A master list of the codes assigned to participants will be kept in a secure,

password protected file at each site or in a secured location under double-lock when not in use and with restricted access during work hours and/or when unattended.

c. Potential Risks

The risks of participation in this study are minimal and are not greater than those that would be accepted by other persons not participating in the study. Participants are expected to be exposed only to minimal risk based on questions asked and the confidential system of data collection. While all safeguards will be in place to protect their identity, there is also potential risk that identifying information collected could be accessed by someone other than the research team. A number of precautions and safeguards have been developed in order to protect the confidentiality of individuals who participate in the study. No personal identifying information will be used on the CRFs or ACASIs. Consent forms will be filed and stored separate from the raw data in a secured location under double-lock when not in use and with restricted access during work hours and/or when unattended.

As this is an observational study, there are no alternative treatments or procedures.

Adequacy of Protection Against Risks

a. Recruitment and Informed Consent

Site care members will recruit participants for the study by speaking with patients and their parents/legal guardians face-to-face or by telephone. Information regarding the study will be provided and interest in participation will be assessed.

If the potential participants are interested in enrolling in the study, staff members from Children's Hospital Los Angeles, Boston Children's Hospital, Lurie Children's Hospital of Chicago, and University of California at San Francisco who have received IRB certification will consent participants. The Institutional Review Boards at all sites requires that all research participants review and sign an informed consent/permission/assent form or be given an information sheet (if a waiver of written consent is obtained). The informed consent/permission/assent form covers information about the overall purpose of the study, what the study entails, potential risks, potential benefits to participating individuals and society, the confidentiality of data, and contact information for the Principal Investigator and the IRB. Once informed consent/permission/assent has been obtained, the research staff will have the form reviewed by a fellow research team member, who will confirm that it is fully completed before it is filed in a secure location under double-lock when not in use and with restricted access during work hours and/or when unattended.

For participants aged 7 to 13 years old, the participant will sign an age-appropriate assent form, and the parent/legal guardian will sign a consent/permission/assent form.

For participants aged 14 to 17 years old, the participant and the parent/legal guardian will sign a consent/permission/assent form.

For participants aged 18 years or older, the participant will sign a consent/permission/assent form.

Project Staff will inform participants that they have the right to skip any survey questions that make them feel uncomfortable. Participants will be informed that participation is completely voluntary and that they are free to stop their involvement in the study at any time without any negative consequences. They will be informed of their rights to privacy and confidentiality and will be told that their answers to the survey will be kept confidential and not shared with others outside of the research staff. They will be informed that no information about them or provided by them during the research will be disclosed to others without their written permission, except if necessary to protect their rights or welfare (for example, if they are injured and need emergency care) or if required by law (i.e., child or elder abuse, harm to self or others, or reports of certain infectious diseases).

Participation in all phases of the data collection process is voluntary. There will be no mandatory participation through any venue (e.g., court-ordered, condition of probation, compliance with agreement to work, or to

maintain housing). The consent/permission/assent form clearly states that participation is voluntary and that a decision to not participate is entirely up to each individual.

b. Protections Against Risk

A number of precautions and safeguards have been developed in order to protect the confidentiality of individuals who participate in the study.

No personal identifying information (e.g., names) of the participants will appear in any computer files associated with this research project in any location. Participants will be assigned a unique identification number code. A key file that matches the ID number to the participant and organization will be maintained in a secure data repository within the project offices at each of the four sites. Data will be kept strictly confidential, except as required by law, and stored on a secure network, with password protection such that only authorized users will have access to the file server. All computers will be located in locked facilities, and consent forms will be filed and stored separate from the raw data in a secured location under double-lock when not in use and with restricted access during work hours and/or when unattended. Any temporary data files kept on removable storage devices, as well as printouts derived from data analysis, will be stored in a locked compartment when not in use.

After a subject completes the ACASI survey at a site, the ACASI data will be secured by being saved in a password-protected compressed file. As each section of the survey is completed, the section will be saved and encrypted so that no one is able to look at previous screens to view the data. If the subject completing the interview requires a short break, it is possible to stop the interview and return later to complete it. Only authorized users with a login name and password will be able to open the survey on the laptop.

Data will remain on the CHLA server during data collection, verification, cleaning, and analysis. At the closure of the study, electronic and hardcopy data will be maintained for a minimum of six years per CHLA IRB policy. The local site data will be retained at the local site for the length of time as defined the local site's IRB policy. Project binders at CHLA containing archival information will be stored a minimum of six years and will then be eligible to be destroyed.

The research staff and protocol will be certified through the local IRB at each of the four sites to conduct research on human subjects, especially as related to children. This observational study is 46.404, research not involving greater than minimal risk, and 46.408 requirements for permission by parents or guardians and for assent by children will be followed. Within the first two months of funding, the project staff will submit an application to the IRB for protocol approval. Throughout the project, staff will continue to work with IRB at their respective sites to protect the rights and confidentiality of all individuals who participate in data collection.

As this is an observational study, adverse events are not anticipated. However, there is some risk that answering questions about some of the topics may be uncomfortable or upsetting. In the event of discomfort or upset, there are medical and psychological professionals on the research team who can provide ongoing support as needed. Participants do not have to answer any question in the computerized interview that they do not want to answer. Furthermore, participants will be informed that at any point, they may stop if they do not wish to continue the questionnaire. In the event of an adverse event, it will be reported to the IRB as per protocol to ensure the safety of participants.

Potential Benefits of the Proposed Research to Human Subjects and Others

While there are no potential direct benefits to the research participants, the risks involved in this study are minimal and the anticipated societal benefits outweigh them.

Importance of the Knowledge to be Gained

As described above the risks involved in this study are minimal and the anticipated societal benefits outweigh them. The proposed research provides the opportunity to obtain a better understanding of transgender youth, improve their care, and share information on a local and national level about how to provide care and hormone

therapy for gender dysphoric children and adolescents. The information that is learned from this project will support innovative approaches to identifying, understanding, and providing optimal care for early pubertal and late pubertal, multi-ethnic transgender youth.

Data and Safety Monitoring Plan

Not applicable as the proposed research does not include a clinical trial.

ClinicalTrials.gov Requirements

Not applicable as the proposed research does not include a clinical trial.

INCLUSION OF WOMEN AND MINORITIES

Inclusion of Women

As a study of transgender children and youth, those designated at birth as female or male and who identify with a gender that is inconsistent with that label will be eligible to be enrolled in this study. These individuals will be recruited to participate in the proposed study as the target population and may identify with any number of gender identity labels including, but not limited to transgender, female, transgender female, male, and transgender male.

Inclusion of Minorities

All racial and ethnic categories are eligible for our proposed study; however, our proposed sample will be predominantly White, Hispanic, and African American. This reflects the target populations of transgender individuals that are currently being served within the four sites. The inclusion criteria include monolingual Spanish speakers, and the ACASI instruments and consents will be made available in Spanish.

OMB Number: 0925-0002

Planned Enrollment Report

Study Title: The Impact of Early Medical Treatment in Transgender Youth

Domestic/Foreign: Domestic

Comments:

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/Alaska Native	(b)(4); (b)(6)				
Asian					
Native Hawaiian or Other Pacific Islander					
Black or African American					
White					
More than One Race					
Total					

Study 1 of 1

Tracking Number: GRANT11778555

Funding Opportunity Number: PA-12-111. Received Date: 2014-11-05T18:44:21.000-05:00

INCLUSION OF CHILDREN

The proposed research will include coded data from early and late pubertal, gender dysphoric children and adolescents (Tanner stages 2-5) to understand the impact of hormone therapy to suppress puberty. Data will be collected from their medical charts as well as audio computer-assisted self-interviewing surveys; however, all data collection will be coded to help ensure confidentiality. Children and adolescents will be asked to complete surveys at baseline, 6 months, 12 months, and 24 months. As described in the Research Plan, the Principal Investigator, research staff, and collaborating partners have a long history of working with and conducting research related to transgender children and adolescents.

MULTIPLE PI/PD LEADERSHIP PLAN

Johanna Olson, M.D., Norman Spack, M.D., Robert Garofalo M.D., M.P.H., and Stephen Rosenthal, M.D., will serve as a team of Principal Investigators on this application, each responsible and accountable to the National Institutes of Health (NIH) for the proper conduct of the research. The rationale for the decision to act as a multiple PI team is based on the fact that these four investigators bring unique experiences and knowledge that will integrate and complement one another in the implementation of this project. Additionally, the involvement of these four sites provides larger numbers than a single site could of potential participants for a research endeavor seeking to understand an uncommon experience. The PIs serve as the Medical Directors of four university-affiliated programs in the United States currently providing care for transgender youth.

Dr. Johanna Olson, M.D. (Pediatrics and Adolescent Medicine), is the Medical Director of the Center for Transyouth Health and Development at Children's Hospital Los Angeles (University of Southern California). She and her team based at CHLA, including Co-Is Marvin Belzer, M.D., Leslie Clark, Ph.D., M.P.H., and Sheree Schrager, Ph.D., M.S., lead the largest transgender youth program in the United States. The combined expertise of this team provides both comprehensive clinical knowledge and extensive research expertise in the area of transgender adolescents. Patients seek care at this center from as far away as Shanghai. While we acknowledge that Dr. Olson, the lead PI, is still early in her career, she is surrounded by an experienced team of mentors at her own site and at the three other sites participating in the proposed project. Dr. Belzer has extensive experience managing clinical trials, including his participation as a site PI in the NICHD supported REACH and ATN Networks for the past 20 years as well as the PACTG/IMPAACT Network for 15 years. Dr. Belzer will serve as the primary mentor for Dr. Olson, a role he has had for the past four years. Drs. Clark and Schrager bring an extensive portfolio of skills including the design and implementation of behavioral interventions, expertise in research methodology and statistical analysis, and prior experience managing multi-site studies.

Dr. Norman Spack, M.D. (Pediatric Endocrinology), and his team, including Co-I Psychologist Amy Tishelman, Ph.D., are principals in Boston Children's Hospital's Gender Management Service (GeMS) which opened in 2007. GeMS was the first pediatric academic program in the western hemisphere to treat pubescent teens. Dr. Spack treated 200 transgender adults from 1985-2006, and in 2004, GeMS' personnel were trained by the Amsterdam team and given their protocols for psychometric assessment and pubertal suppression. 75% of GeMS' patients come from a 150 mile radius of Boston; the rest come from throughout the US. His Co-Investigator, Amy Tishelman, Ph.D., is a clinical psychologist with significant expertise in scholarship and clinical realms; before joining the GeMS team she was the Director of Child Protection Clinical Services at Boston Children's Hospital and subsequently Director of Training and Research for that program. She has decades of experience evaluating children and families and is a recognized expert in the area of trauma and interpersonal violence with an interest in helping vulnerable children and adolescents.

Dr. Robert Garofalo, M.D., M.P.H. (Pediatrics and Adolescent Medicine), is Co-Director of the Gender and Sex Development Program, Division Head of Adolescent Medicine at Lurie Children's Hospital of Chicago, and Associate Professor of Pediatrics at Northwestern University's Feinberg School of Medicine. He will serve as the PI for the Chicago site. He and his team, including Co-Is Marco Hidalgo, Ph.D., Lisa Simons, M.D., Courtney Finlayson, M.D., and Scott Leibowitz, M.D., and Ethicist Joel Frader, M.D., bring a wealth of expertise caring for and conducting research in adolescent populations, with particular focus on transgender and other sexual minority youth. The Chicago team has been providing clinical services to gender non-conforming youth for more than a decade. Their multidisciplinary program for gender non-conforming youth and transgender youth undergoing medical suppression of puberty or initiating cross-sex hormone therapy brings together experts in pediatrics/adolescent care, endocrinology, psychology and child development, psychiatry, surgical subspecialties, and medical ethics. The team has extensive experience conducting NIH-funded multisite clinical and behavioral research with marginalized populations of youth.

Dr. Stephen M. Rosenthal, M.D. (Pediatric Endocrinology), Professor of Pediatrics, Program Director for Pediatric Endocrinology, Co-Director of the Disorders of Sex Development Clinic, and Medical Director of the Child and Adolescent Gender Center (CAGC) at the University of California San Francisco (UCSF) Benioff Children's Hospital, is an established clinical investigator with greater than 30 years of experience in child and adolescent endocrinology. He will serve as PI for the UCSF site. His Co-Investigator, Diane Ehrensaft, Ph.D.,

and Mental Health Director of the UCSF CAGC, is an internationally recognized child psychologist/gender specialist. His Co-Investigator, David Glidden, Ph.D., Professor of Epidemiology and Biostatistics at UCSF, brings extensive expertise in research design and statistical analysis. The UCSF CAGC has been providing multi-disciplinary care for gender non-conforming/transgender youth and adolescents for the past six years. The UCSF CAGC is the only such multi-disciplinary gender program in Northern California and attracts patients not only from California, but from as far away as Florida and Egypt.

Primary Roles and Areas of Responsibility for Each PI

- Administrative
  - Upon successful funding, the award will be made to Children's Hospital Los Angeles (CHLA). All participants will be enrolled at one of the four study sites – The Center for Transyouth Health and Development (CHLA), The Child and Adolescent Gender Center (University of California San Francisco), The Gender, Sexuality and HIV Prevention Center (Lurie Children's Hospital of Chicago), or the Gender Management Service (Boston Children's Hospital). Drs. Olson, Garofalo, Rosenthal, and Spack will work collaboratively to prepare reports and other requirements for submission to the NIH. Each will oversee the administrative responsibilities at each of their respective institutions.
- Technical
  - Dr. Olson, given her experience conducting the pilot studies that serve as the principal preliminary data for the current application, will work with Drs. Rosenthal, Spack, and Garofalo to finalize study implementation protocols at each site, so that each site carries out the project in the same manner. Data will be collected systematically, with identical operating procedures including CRFs, ACASI programming, and data flow sheets to facilitate the creation of a data repository that is suitable for analysis and available for all four sites to explore. The data will be owned equally by each of the four participating sites.
  - Dr. Olson will oversee the protocols for data collection, including physiologic and psychosocial at each site.
  - All four PIs will finalize protocols for each cohort in the study and standardize these to ensure that there is consistency in delivery across the four study sites.
  - All four PIs, with the project directors/Co-Is at each site, will direct recruitment, retention, data collection, and intervention delivery, with support from the project team at each of their respective sites. Data will be stored at all sites and safely transferred via secure protocols to CHLA for cleaning and merging.
  - Drs. Clark and Schrager will direct data management, including integration and verification at CHLA.
  - Drs. Clark, Schrager, and Glidden will direct data analysis at CHLA and UCSF.
  - Dr. Garofalo will be involved in scientific direction and support data interpretation and dissemination.

Governance/Structure

- Communication plan
  - These four sites are positioned across the U.S., necessitating ongoing communication via teleconference. The investigators have budgeted for a one-week training at the beginning of the study, in which all of the teams will meet at one of the principal sites. The investigators have also budgeted travel for mid-study team meetings that will allow the research team to review study progress and ensure successful completion. In the final year, the investigators have budgeted travel for the purpose of meeting around data analysis, interpretation, and manuscript writing.
  - During the accelerated start up phase of the study, the PIs and Co-Is will meet twice weekly via Skype/phone with the project managers at each site to discuss scientific issues, intervention sessions, recruitment, implementation, etc. Additional meetings will be scheduled with members of the study team as needed.
  - Decisions on scientific direction will be made during the weekly meetings. Dr. Olson will make final decisions on the delivery of the intervention protocol, whereas Drs. Clark and Schrager will make final decisions regarding instruments, data collection tools, and the statistical analyses for manuscript preparation.

- Procedures for resolving conflicts – The four sites have determined that the following domains may require third party arbitration in the event of conflict that is not resolved through discussion amongst the sites:
    - Authorship dispute – issues of conflict will be heard by an objective observer from the WPATH executive board.
    - Scientific dispute – scientific conflict will be arbitrated by a pediatric endocrinologist faculty member at Children's Hospital of Pennsylvania.
    - Safety – a data safety monitoring board will be established by the end of month three to provide periodic assessment of the protocol and preliminary results, and assist with conflict arising from potential safety issues.
- Distribution of resources to four sites – CHLA will be the primary institution for the receipt of the award and the three other sites will be supported through subcontracts from CHLA. Primary responsibility for administration at the CHLA site is Dr. Marvin Belzer, along with financial administrator Priscilla Brown. This team has extensive experience with financial administration of multiple site projects.

Dissemination

- In order to share process and outcome data from this project with the broader scientific community, abstracts will be submitted for presentation to at least one scientific conference per year. Conferences where data may be presented include annual meetings of the Society for Adolescent Health and Medicine, The American Academy of Pediatrics, The World Professional Association of Transgender Health, Pediatric Academic Societies, The Endocrine Society, The American Public Health Association, The American Psychological Association, The American Psychiatric Association, and others. Manuscripts are planned on the following topics:
    - Description of the sample and preliminary results
    - Description of the intervention
    - Primary outcomes

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CONSORTIUM/CONTRACTUAL ARRANGEMENTS

PA-12-111 Research on the Health of LGBTI Populations (R01)
Due Date: November 5, 2014
Earliest Start Date if funded: July 1, 2015
Duration of Project Period: Five years
Project Title: The Impact of Early Treatment in Transgender Youth
Primary Applicant: Children's Hospital Los Angeles
Principal Investigator: Johanna Olson

The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the agency's consortium agreement policy and are prepared to establish the necessary inter-organizational agreements consistent with that policy.

Programmatic Arrangement:

Children's Hospital Los Angeles
Children's Hospital Los Angeles (CHLA) will be the primary institution for the receipt of the award and the three partner sites will be supported through subcontracts from Children's Hospital Los Angeles. CHLA will act as the data center or core for the project, and the CHLA research team led by Johanna Olson, MD, will have the primary responsibility for creating data protocols in partnership with the other sites. Programming of the ACASI, creation of CRFs, and data management, cleaning, and analysis will occur at CHLA.

Boston Children's Hospital
The Site Principal Investigator, Norman Spack, MD, will implement the proposed observational study on the impact of providing treatment to early-pubertal and late-pubertal transgender youth. Dr. Spack will take primary responsibility for the implementation of the scientific aims of this project at Boston Children's Hospital and will collaborate in the dissemination of findings. The key personnel at Boston Children's Hospital will collaborate with the partner sites to submit abstracts for presentation at scientific conferences and in co-authorship of publications to disseminate important research findings as a result of this study.

Lurie's Children's Hospital of Chicago
The Site Principal Investigator, Robert Garofalo, MD, will take primary responsibility for the implementation of the scientific aims of this project at Lurie Children's Hospital of Chicago. The Co-Investigators will share responsibility for the scientific and fiscal integrity of the project, assist in protocol development, and examine ethical aspects of the implementation of clinical guidelines and issues surrounding school or voluntary organization exclusion or other discrimination based on gender nonconformity.

University of California San Francisco
The Site Principal Investigator, Stephen M. Rosenthal, MD, will implement the proposed observational study on the impact of providing treatment to early-pubertal and late-pubertal transgender youth. Dr. Rosenthal will take primary responsibility for the implementation of the scientific aims of this project at Benioff Children's Hospital at UCSF and will collaborate in the dissemination of findings. The key personnel at UCSF will collaborate with the partner sites to submit abstracts for presentation at scientific conferences and in co-authorship of publications to disseminate important research findings as a result of this study.

Fiscal Arrangement:

Children's Hospital Los Angeles: includes full project costs (CHLA site costs, consortium site costs, and CHLA's and consortium sites' F&A)

	Direct	Indirect (%)	TOTAL Per Year
Year 1	$	$	$
Year 2	$	$	$
Year 3	$	$	$
Year 4	$	$	$
Year 5	$	$	$
TOTAL	$	$	$

(b)(4)

Boston Children's Hospital:

	Direct	Indirect (%)	TOTAL Per Year
Year 1	$	$	$
Year 2	$	$	$
Year 3	$	$	$
Year 4	$	$	$
Year 5	$	$	$
TOTAL	$	$	$

(b)(4)

Lurie Children's Hospital of Chicago:

	Direct	Indirect (%)	TOTAL Per Year
Year 1	$	$	$
Year 2	$	$	$
Year 3	$	$	$
Year 4	$	$	$
Year 5	$	$	$
TOTAL	$	$	$

(b)(4)

University of California San Francisco:

	Direct	Indirect (%)	TOTAL Per Year
Year 1	$	$	$
Year 2	$	$	$
Year 3	$	$	$
Year 4	$	$	$
Year 5	$	$	$
TOTAL	$	$	$

(b)(4)

Ann & Robert H. Lurie
Children's Hospital of Chicago™
Gender and Sex Development Program

Robert Garofalo, MD, MPH
Division Chief, Adolescent Medicine
Director, Center for Gender, Sexuality and HIV Prevention
Ann & Robert H. Lurie Children's Hospital of Chicago
255 East Chicago Avenue, Box 161
Chicago, Illinois 60611-2991

October 29, 2014

Johanna Olson, MD, MPH
Assistant Professor of Clinical Pediatrics
Medical Director, Center for Transyouth Health and Development
Children's Hospital Los Angeles
5000 W. Sunset Blvd., 4th Floor
Los Angeles, CA 90027

Dear Dr. Olson:
We are delighted to join your team of investigators for the project entitled "Impact of Early Treatment on Transgender Youth" to be submitted through the R01 mechanism. We have a great deal of experience in working with transgender children and adolescents at the Center for Gender, Sexuality and HIV Prevention at Lurie Children's Hospital of Chicago. Specifically, we have focused on the collection of data, both behavioral and clinical biomarkers, in marginalized populations and the translation of this data into intervention development. I was Committee Member on the Institute of Medicine (IOM) Study on The Health of Lesbian, Gay, Bisexual and Transgender People that established as a research priority the need for longitudinal outcomes research on medical interventions for transgender people. As such, it is a distinct honor to be part of this collaborative network of research teams and investigators.
For this proposal, the following key personnel will work with you to implement an observational study of the impact of providing early treatment to peri-pubertal and post-pubertal transgender youth.

Rob Garofalo, M.D., MPH, Site Principal Investigator, will take primary responsibility for the implementation of the scientific aims of this project at Lurie Children's as well as collaborate to disseminate findings.

Lisa Simons, M.D., Co-Investigator, Pediatrician, will share responsibility for patient care as a Pediatrician and the scientific and fiscal integrity of this project and will oversee all research activities at Lurie Children's. She will also share responsibility for data analysis and dissemination of findings with Dr. Garofalo.

Marco A. Hidalgo, Ph.D., Co-Investigator, will supervise the Project Coordinator in her/his management of day-to-day tasks by coordinating IRB submissions, developing and overseeing effective recruitment strategies and providing ongoing advice regarding confidential data collection/ management procedures. He will also assist the Data Manager in refining assessment instruments, managing study databases, and creating data manuals.

Scott Leibowitz, MD., Co-Investigator/Psychiatrist, will assist in protocol development as well as conduct patient assessments at the Lurie site.

Ann & Robert H. Lurie
Children's Hospital of Chicago
Gender and Sex Development Program

Joel Frader, M.D., Ethicist, will examine ethical aspects of the implementation of clinical guidelines, including: the age and developmental/maturational characteristics of decision-making capacity of children and adolescents for treatment; the ways in which clinicians and parents manage different points of view regarding treatment, particularly when parent perspectives are based on particular religious and philosophical convictions; and ethical and legal issues surrounding school or voluntary organization exclusion or other discrimination based on gender nonconformity. Dr. Frader will also assist in protocol development.

Courtney Finlayson, M.D., Co-Investigator/Endocrinologist, will be the lead Endocrinologist at the Lurie site and will: conduct patient assessments; review laboratory results; consult with the study teams on all endocrinological issues such as bone development and growth. Dr. Finlayson will also assist in protocol development.

The key personnel at Lurie Children's Hospital will collaborate with the partner sites to submit abstracts for presentation at scientific conferences and in co-authorship of publications to disseminate important research findings as a result of this study.

In addition, along with your Division Head, Dr. Belzer, I will help co-mentor you as the contact PI as I/we have done throughout your young and promising career. Although as contact PI you may be relatively inexperienced with NIH-funded multisite clinical trials, it is my opinion that you are the emerging clinical and research leader in this field. As you are aware the proposed network of 4 sites gave very careful consideration in deciding the contact PI for this proposal. I have full confidence that with the appropriate guidance and mentoring that you are ideally suited to lead this effort. You have my full support and I am happy to provide whatever mentorship is required to make this project a success.

Lastly, reflecting back upon the recommendations of the IOM, the proposed body of research is not only innovative but of considerable public health significance as it will have a profound impact on the body of clinical evidence. This evidence is sorely needed to hone the safety and efficacy of clinical guidelines and to properly advise parents and families on proposer treatment options for their gender non-conforming and transgender children and adolescents. We look forward to doing this work as a Team Investigators from across the U.S. and in partnership with the NIH/NICHD.

Sincerely,

Rob Garofalo, MD, MPH
Co-Director of the Gender and Sex Development Program
Division Head of Adolescent Medicine, Lurie Children's Hospital
Professor of Pediatrics and Preventive Medicine
Northwestern University's Feinberg School of Medicine

Boston Children's Hospital
Department of Medicine
Division of Endocrinology
Senior Associate in Medicine

Harvard Medical School
Department of Pediatrics
Associate Clinical Professor of Pediatrics

Norman Spack, M.D.,
Boston Children's Hospital
Department of Endocrinology
Co-Director, Gender Management Service
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October 16th, 2014

Johanna Olson, MD, MPH
Assistant Professor of Clinical Pediatrics
Medical Director, Center for Transyouth Health and Development
Children's Hospital Los Angeles
5000 W. Sunset Blvd., 4th Floor
Los Angeles, CA 90027

Dear Dr. Olson:

We are delighted to join your team of investigators for the project entitled "Impact of Early Treatment on Transgender Youth" to be submitted through the R01 mechanism. We have a great deal of experience in working with transgender children and adolescents at the Gender Management Service (GeMS) at Boston Children's Hospital and Harvard Medical School. Specifically, we are the first clinic to treat transgender and gender questioning youth in North America, and have years of experience working with this population and an investment facilitating research to enhance the well-being of these youth and facilitate optimal clinical care. Some of the attributes of the children and adolescents we treat and our approaches have been recently described in papers published in the journals *Pediatrics* (Spack et al, 2012), and Professional Psychology: Research and Practice (Tishelman et al, in press) and we believe that the research proposed in this study is timely and will have a significant impact on clinical care.

For this proposal, the following key personnel will work with you to implement an observational study of the impact of providing early treatment to peri-pubertal and post-pubertal transgender youth.

Norman Spack, M.D, Site Principal Investigator, will take primary responsibility for the implementation of the scientific aims of this project at Boston Children's Hospital, as well as collaborate to disseminate findings.

Amy Tishelman, Ph.D., Co-Investigator, and Director of Clinical Research for the DSD-GeMS program, will share responsibility for the scientific and fiscal integrity of this project and will oversee research activities at Boston Children's Hospital. Along with Dr. Shumer, she will hire, train and supervise the Project Coordinator and other staff. She will assist in data collection, protocol development, and intervention implementation plans. She will collaborate in data analysis, interpretation, preparation of manuscripts, and dissemination activities. Dr. Tishelman, a Clinical Psychologist, will also provide therapeutic services and urgent assessments related to research participation.

Daniel Shumer, M.D.., Co-Investigator and endocrinologist, will share responsibility for the scientific and fiscal integrity of this project and, along with Dr. Tishelman, will help to oversee research activities at Boston Children's Hospital. He will work with Dr. Tishelman to hire, train and supervise the Project Coordinator and other staff and assist in data collection, protocol development, and intervention implementation plans. As an endocrinologist, he will help to conduct patient assessments; review laboratory results; consult with the study teams on all endocrinological issues such as bone development and growth. He will collaborate in data analysis, interpretation, preparation of manuscripts, and dissemination activities.

Sincerely,

Norman Spack, M.D.
Co-Director, Gender Management Service
Endocrine Division, Boston Children's Hospital
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Stephen M. Rosenthal, MD
Professor of Pediatrics
Program Director, Pediatric Endocrinology
Medical Director, Child and Adolescent Gender Center
University of California San Francisco, Benioff Children's Hospital

October 24, 2014

Johanna Olson, MD, MPH
Assistant Professor of Clinical Pediatrics
Medical Director, Center for Transyouth Health and Development
Children's Hospital Los Angeles
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Los Angeles, CA 90027

Dear Dr. Olson:

We are delighted to join your team of investigators for the project entitled "Impact of Early Treatment on Transgender Youth" in response to PA-12-111, to be submitted through the R01 mechanism. We have a great deal of experience working with transgender children and adolescents at the Child and Adolescent Gender Center (CAGC) at the University of California San Francisco (UCSF) Benioff Children's Hospital. The UCSF CAGC is one of the leading centers for the multidisciplinary care of transgender youth in the U.S., and serves as the Pediatric/Adolescent clinical arm of the widely recognized UCSF Transgender Center of Excellence. Our CAGC investigators have authored numerous publications on transgender youth, including a recently in-press "State-of-the-Art" invited review in *Pediatrics* and an in-press invited review in the "Approach-to-the-Patient" series in the *Journal of Clinical Endocrinology and Metabolism.* I am currently serving as the official representative of the Pediatric Endocrine Society to the Endocrine Society's Clinical Practice Guidelines Revision Task Force for the Care of Transgender individuals. In addition, as a basic and clinical investigator with > 30 years' experience in child and adolescent endocrinology, I have had significant experience conducting multi-center trials, and am currently serving as UCSF Site Principal Investigator for NIH/NICHD "Disorders of Sex Development: Platform for Basic and Translational Research". Our UCSF CAGC team strongly believes that the research proposed in this study is timely and will have a significant impact on clinical care.

For this proposal, the following key personnel will work with you to implement an observational study of the impact of providing early treatment to early-pubertal and late-pubertal transgender youth:

Stephen M. Rosenthal, M.D., Site Principal Investigator, will take primary responsibility for the implementation of the scientific aims of this project at UCSF Benioff Children's Hospital, as well as collaborate to disseminate findings.

Diane Ehrensaft, Ph.D., Co-Investigator, will share responsibility for the scientific and fiscal integrity of this project. As a Clinical Psychologist, Dr. Ehrensaft will assist in protocol development, data collection, data analysis, preparation of manuscripts, and dissemination of findings at scientific meetings. She will also assist Dr. Rosenthal with IRB submissions, and will assist in developing and overseeing effective recruitment strategies.

David V. Glidden, Ph.D., Co-Investigator and Biostatistician, will work closely with Dr. Schrager at Children's Hospital Los Angeles, and will provide advice and support on analytic approaches. Dr. Glidden will contribute expertise on the statistical design of the study and will focus on analysis of the metabolic data in this project. He will be responsible for the design, analysis plan, and execution of these analyses.

As you know, existing clinical practice guidelines for the multidisciplinary care of transgender youth and adolescents are primarily based on expert opinion, as only minimal outcomes data currently exist. Our collaborative proposal has the potential to provide such needed outcomes data to inform appropriate care for a population of youth that has been marginalized and poorly understood. We are deeply committed to this work and seeing it reach its fruition.

Sincerely,

Stephen M. Rosenthal

Stephen M. Rosenthal, MD
Professor of Pediatrics
Program Director, Pediatric Endocrinology,
Medical Director, Child and Adolescent Gender Center
University of California San Francisco, Benioff Children's Hospital

RESOURCE SHARING PLAN: DATA SHARING PLAN

The proposed research will include final data from approximately 240 transgender youth in the late pubertal group, 88 youth in the early pubertal group, and 88 parents/legal guardians of the early pubertal group. The final datasets will include self-reported demographic and behavioral data from surveys with the subjects and laboratory data from specimens provided for routine care of transgender youth. The dataset for the early pubertal group will also include demographic, behavioral, and mental health data about the youth from the parent. Although the final dataset will be stripped of identifiers prior to release for sharing, we believe that there remains the possibility of deductive disclosure of subjects with unusual characteristics. Thus, we will make the data and associated documentation available to users only under a data-sharing agreement that provides for: (1) a commitment to using the data only for research purposes and not to identify any individual participant; (2) a commitment to securing the data using appropriate computer technology; and (3) a commitment to destroying or returning the data after analyses are completed.

We wish to make our results available to the transgender community, mental and medical health providers, public health practitioners, and scientists interested in studying, providing, and receiving competent mental and medical healthcare. Thus, we will make our data available to other NIH investigators under the data-sharing agreement after a reasonable time period that includes enough opportunity to prepare and have submitted for publication four manuscripts presenting the basic outcomes of the project. Our plan also includes sharing of study findings through multiple presentations at meetings of both community oriented audiences (such as the World Professional Organization of Transgender Health and GLAMA) and national pediatric and transgender health conferences (such as the American Academy of Pediatrics, the Society for Adolescent Health and Medicine, the Pediatric Endocrine Society, and the Endocrine Society).