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

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

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)

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

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

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)

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

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

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**

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

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

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

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

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)

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.

Sincerely yours,

(b)(6)

Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

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	$	$	$
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)

(b)(4)

(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)

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.

Sincerely yours,

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

Additional information follows

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

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	$	$	$	$
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	$	$	$

(b)(4)

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)

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.

Sincerely yours,

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

Additional information follows

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.

****

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	$	$	$	$

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)

RESEARCH

Federal Award Date: 07/31/2015

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

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

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	$	$	$	$	$
Fringe Benefits	$	$	$	$	$
Supplies	$	$			
Travel Costs	$	$	$	$	$
Other Costs	$	$	$	$	$
Consortium/Contractual Cost	$	$	$	$	$
TOTAL FEDERAL DC	$732,833	$	$	$	$
TOTAL FEDERAL F&A	$219,709	$	$	$	$
TOTAL COST	$952,542	$	$	$	$

(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)

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

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

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* 09/01/2020
Ending Date* 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
Table Of Contents

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

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

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

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

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) . 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:

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/1r92xwjc9OIk3/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)

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)

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

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)

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)

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

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)

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)

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

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	
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)

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)

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)

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

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)

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)

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

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

Johanna L. Olson-Kennedy, MD, Contact Principal Investigator ((b)(4) 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.

Marco A. Hidalgo, PhD, Co-Investigator ((b)(4) 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)(6) **Co-Investigator ((b)(4) 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.

Carolyn F. Wong, PhD, Co-Investigator ((b)(4) calendar months years 1-2 and (b)(4) 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) **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)		

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)

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	(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 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)

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)

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

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	(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 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)

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)

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

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)

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 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)

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)

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)

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)

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

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)		

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)

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

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 1

ORGANIZATIONAL DUNS*: 0765937220000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Boston Children's Hospital

Start Date*: 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)

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)

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

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)

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)

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

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 3

ORGANIZATIONAL DUNS*: 0765937220000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Boston Children's Hospital

Start Date*: 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)	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)

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)

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

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)

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)

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

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 5

ORGANIZATIONAL DUNS*: 0765937220000
Budget Type*: ❍ Project ● Subaward/Consortium
Organization: Boston Children's Hospital

Start Date*: 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, 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)		

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)

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)

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

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, 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 (Agency Name, POC Name, and POC Phone Number): DHHS, Jeanette Lu, 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: 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)

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 (Agency Name, POC Name, and POC Phone Number) DHHS, Jeanette Lu, 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: 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)

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 (Agency Name, POC Name, and POC Phone Number): DHHS, Jeanette Lu, 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: 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)

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)

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

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, 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 (Agency Name, POC Name, and POC Phone Number): DHHS, Jeanette Lu, 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: 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 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)

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

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, 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 (Agency Name, POC Name, and POC Phone Number) DHHS, Jeanette Lu, 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: 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)(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.

UCSF Data Network Recharge ($(b)(4) 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	(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)		

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)

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

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 (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 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 (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 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)

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

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 (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 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)

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

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 (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)

Budget Justification: Callen-Lorde Community Health Center

Personnel

Asa Radix, MD (Yrs 1-5, (b)(4) 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)		

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)

Tracking Number: GRANT13040415

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

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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
10. Resource Sharing Plan(s)	Data_Sharing_Plan.pdf
11. Authentication of Key Biological and/or Chemical Resources	
Appendix	
12. Appendix	Appendix_A.pdf

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).

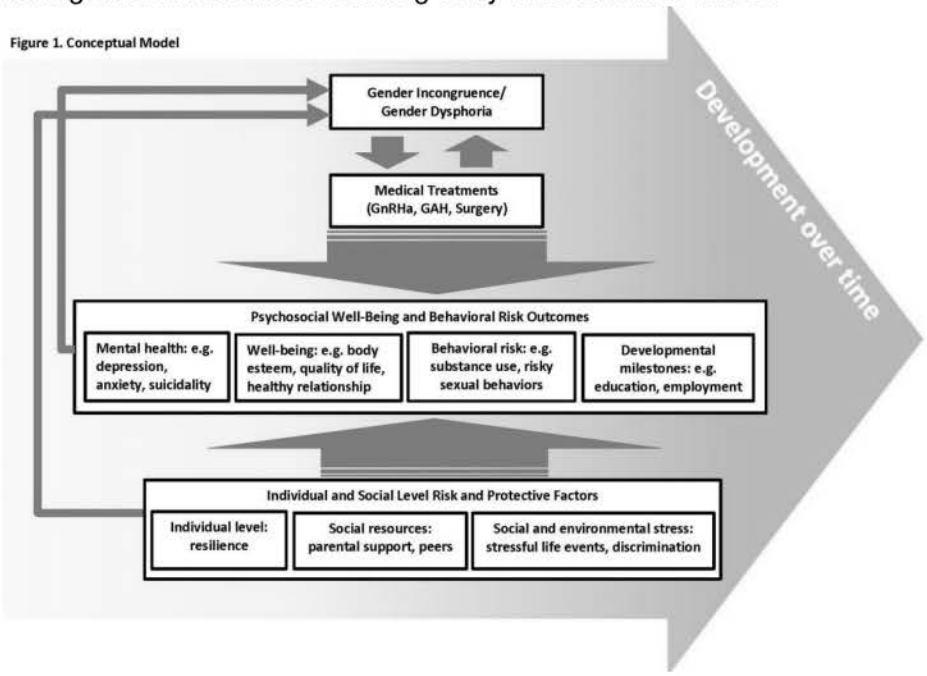
A2. No U.S. data have been collected on the longer-term physiological impact on TGD youth initiating GnRHa in early puberty. In youth with gender dysphoria who are just entering puberty, the Endocrine Society and the World Professional Association for Transgender Health (WPATH) recommend pubertal suppression 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) transgender specific experiences including gender identity, gender dysphoria, gender expression, age of realization, gender transition; 2) mental health assessment including depression, anxiety, quality of life, suicidality, self-harm, trauma events, autism symptoms, body esteem and self-perception; 3) risk and protective factors 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