similar approaches to model general LGCM and its variants as described above to examine trajectories of psychosocial well-being and mental health by age. Partially missing data (e.g., in the lower and higher age range) inherent to using this approach can be addressed by Maximum Likelihood estimation for continuous and normally distributed outcomes or the use of multiple-imputations, which involves pooling of parameter estimates from imputed datasets.

Psychological well-being/mental health as a function of time since initiation of GAH (Aim 2)

HYP 2a: Patients treated with GAH will exhibit decreased symptoms of depression (anxiety, suicidality) over time.
HYP 2b: These trajectories will vary as a function of age of initiation of GAH and will differ based on sex assigned at birth (AMAB or AFAB).

To address **HYP 2a** and **HYP 2b**, we will utilize data from the original and newly enrolled GAH cohort across 6 waves (36 months) (projected N=492 using 83% retention). We will develop LGCM that estimate trajectories of each of the outcomes across time for the subsample of existing cohort (projected N=262) by end of wave 9 (83% retention of existing cohort). We will follow the approach outlined above for **HYP1a** and **HYP1b** to capture the overall trajectory of change in psychological and mental health outcomes of interest over time and inserting significant time-variant (e.g., gender minority stress and resilience) and time-invariant predictors (e.g., getting surgery) to predict how these trajectories change over time. We will explicitly model these trajectories based on sex assigned at birth and age of GAH initiation. We will then move onto examining these changes by age (aged 11 to 27 for GAH cohort) using the cohort-sequential approach, to create a common trajectory to determine the common underlying developmental trend for this cohort, which spans up to sixteen years.

Psychological well-being/mental health as a function of history of GnRHa and age initiating GAH (Aim 3)
HYP 3a: Patients receiving GAH with a history of GnRHa (GnRHa + GAH) will exhibit greater decreased symptoms of depression (anxiety, suicidality) over time compared to those with no prior history of GnRHa (GAH Cohort).
HYP 3b: These trajectories will vary as a function of age of initiation of GAH, and sex assigned at birth.

To address HYP 3a and HYP 3b that are focused on comparing the two age- and sex assigned at birth created groups, we will identify the GnRHa plus GAH group when they initiated GAH from the a) GnRHa participants 13-18 at the time they initiated GAH during up to 36 month follow-up or were b) the 29 existing GAH participants (13-18 years) who were taking GnRHA at the time of study enrollment yielding an estimated combined total sample size of 84. We anticipate adding 21 eligible participants from the newly enrolled GnRHa cohort and GAH cohort for a total of 105 for this GnRHa + GAH group. We will draw GAH only participants (within the ages of 13-18) for matching purposes. Age categories for matching will be defined as 13-15 and 16-18 because these are meaningful distinctions in GAH provision to youth. In addition to age and sex assigned at birth we will examine the distribution of Tanner stage to make the groups more comparable. Once this newly combined dataset (N= 210) is created, we will first develop GLM models that compare psychological well-being and mental health outcomes between the two groups cross-sectionally and between waves. The variable “group”, which denotes the GnRHa + GAH vs. GAH-only will be entered into each regression model. We expect the GnRHa + GAH group to exhibit significantly fewer symptoms of depression (anxiety, and incidences of suicidality) compared to the GAH-only group, after adjusting for significant covariates (i.e., protective and risk factors at each wave). Next, we will investigate cohort differences in psychological well-being and mental health longitudinally with LGCM, modeling age as time (aged between 13 to 21) spanning up to eight years, using the cohort-sequential data analytic approach described above. This approach is particularly helpful to tease out how trajectories might vary between the two cohorts as a function of age of initiation of GAH. **C8f. Site-Clustering Effects.** We will continue to monitor potential site-specific effects by including a group identifier for each participant in the analytic dataset, and the intra-class correlation (ICC) for each outcome will be calculated prior to conducting multivariate analyses. If a significant difference in group-level variance is detected, we will specify a two-level multilevel LGCM within the SEM framework, whereby the three-level clustered longitudinal data is analyzed with a two-level model.[34-36] We can then follow with the analyses specified above for hypotheses testing. **C8g. Power Analysis and Sample Size Estimations for the Use of LGCM.** While GCM has the flexibility to fit models with unbalanced data (i.e., include participants with varying waves of data), we will first estimate power for the most stringent set of hypotheses, which is with the GnRHa cohort (**Aim 1**) that has a projected sample size of 79 by 72 months (wave 9). Estimates of power for the proposed models were generated using Monte Carlo simulations in Mplus (v7.31), keeping in mind that the level of parameter bias, standard error bias, and coverage across estimates are below acceptable cut-off levels.[36,37] Results indicated that with nine waves of data and accounting for missing data patterns based on current data, the power to detect significant effects (ranged from small to medium: Cohen’s d=0.18 to 0.35) of covariates on linear change is between 83% to over 99%. For a projected sample size of 262 of the GAH cohort (**Aim 2**) by wave 9, we estimated the power to detect small effect sizes in the range of 0.10

to 0.12 to be 8 3% to 94%. For a sample of 210 (aged-match GnRHa + GAH and GAH-only cohorts) (**Aim 3**), the power to also detect small effects (Cohen's d=0.12 to 0.15) ranged from 81% to 94%.

C9. Potential Problems and Alternative Strategies.C9a. Attrition between baseline enrollment and follow-up visits has been smaller than anticipated, and we have over-enrolled from initial target numbers. However, with extended follow-up (up to six years past enrollment) attrition could impact the validity of results and the power to detect relationships among variables. Older adolescents and young adults are migratory by nature, although continued GnRHa or hormone treatment is a compelling reason to stay engaged in care. Only a few participants have chosen to go off study. This could become more challenging as youth age out of care at any of the sites; however all sites treat youth up to 25 years of age. To date we have only enrolled twelve 19-20 year old GAH participants who could age out of care within 6 years across all four sites. Study investigators fully appreciate the challenges associated with tracking young adults during this period of their lives. We are skilled at successfully retaining participants for follow-up surveys based upon extensive experience tracking young adults in previous studies including many of whom were hard-to-reach due to homelessness, substance use, or other risk behavior. Key retention strategies include: collecting extensive tracking information and verifying contact information at each follow-up visit; storing tracking information in a retrievable Access database; linking each participant to specific staff; conducting brief monthly check-ins via email or text; and training staff on the importance of retention (see Recruitment and Retention Plan for more details). **C9b. Collecting and transmitting data** During the initial grant the 4 sites implemented strong data collection and study protocols which will continue in the new grant. To support cross-site data collection, we have budgeted for a full-time data manager at the data coordinating site (CHLA) responsible for data cleaning, ensuring data are complete, querying study coordinators about problematic data, running analyses, providing data summaries, monitoring enrollment and retention rates, and assisting analysis interpretation. Guided by Dr. Wong and (b)(6) they will continue to respond to requests for data analysis and data sets from the sites' biostatisticians. **C9c. Risk to participants**. While this study will likely cause minimal risk to participants, they could potentially experience distress and/or discomfort when asked questions of a more sensitive nature in the assessments. If participants experience distress or discomfort, as outlined in the Protection of Human Subjects, they will be directed immediately to a licensed mental health clinician for evaluation and counseling.

C10. Benchmarks of Success and Timeline. Benchmarks (see **Study Timeline**) include: 1) Recruitment and enrolling of the selective cohorts (YOC and transfeminine); 2) successful enactment of recruitment protocols; 3) convening of the CAB; 4) multisite protocol team meeting; 5) data collection at each follow-up point; 6) data management and analysis; and 7) published manuscripts and dissemination.

C11. Dissemination. The PIs will present findings to at least one national/international conference per year beginning in Year 1. Data obtained from this study will be presented at national conferences (e.g., Society for Adolescent Health and Medicine, Pediatric Academic Societies, American Psychological Association) and gender-specific conferences (e.g., WPATH, Gender Odyssey). Ongoing peer-reviewed publications will be developed pertaining to cross-sectional hypotheses and longitudinal trajectory questions in Aims 1, 2 and 3.

C12. Future Directions. The continuation of this network of investigators, and ongoing data collection is an essential step in the progress to eradicate health disparity that currently exists for transgender youth. With a newly awarded NIH grant (R01HD09712; PI: Hidalgo). We have extended our investigations to examine gender identity milestones (e.g., gender cognition), mental health, and resiliency among prepubertal TGD children. This current proposal will allow us to continue observation through early adulthood, covering a large spectrum of middle childhood to young adulthood development. This longitudinal outcome research is sorely needed for understanding and optimizing medical interventions for TGD youth. Within this proposal, our network is seeking to answer some of new and unanticipated questions as they have arisen within the context of the previous work. This proposal sets up an ideal framework to continue collecting longitudinal data from the cohorts recruited for this initial work as well as understand the additional complexities of this population.

PROGRESS REPORT PUBLICATION LIST

Our group has been productive during the funding period (8/1/15-6/30/20) of this NICHD/NIH R01 HD 082554 grant. We have 31 publications, 1 paper with revisions under review, and 2 papers submitted for review demonstrating our substantial progress on all of the original aims. We have used this R01 as a platform for mentoring (* indicates author is a mentee), reflecting the commitment of the principal investigators and co-investigators to mentor early stage investigators.

Cohort Publications

1. (b)(4)

2. (b)(4)

3. **Chen, D.**, Lash, B., Kim, E. **Hidalgo, M.A.**, Muldoon, A.L., Liu, E., Jensen, J., Grabert, R., **Chan, Y.M.**, **Garofalo, R.,** & **Tishelman, A.** (Under review). A comparison of psychosocial characteristics between transgender youth enrolling versus not enrolling in a multisite research study. Under review at *LGBT Health*

4. **Olson-Kennedy J**, **Chan YM**, **Garofalo R**, Spack N, **Chen D**, **Clark L**, **Ehrensaft D**, **Hidalgo M**, **Tishelman A**, **Rosenthal S**. Impact of Early Medical Treatment for Transgender Youth: Protocol for the Longitudinal, Observational Trans Youth Care Study. *JMIR Res Protoc* 2019;8(7):e14434. PMCID: 6647755

5. **Olson-Kennedy J, Chan YM, Rosenthal S, Hidalgo MA, Chen D, Clark L, Ehrensaft D, Tishelman A, Garofalo R.** Creating the Trans Youth Research Network: A Collaborative Research Endeavor. *Transgend Health*. 2019 Nov 1;4(1):304-312. PMCID: PMC6830532.

Shared Resource Publications (grant supported time and effort)

6. **Hidalgo MA**, Petras H, **Chen D**, Chodzen G*. (2019) The Gender Minority Stress and Resilience Measure: Psychometric validity of an adolescent extension. *Clinical Practice in Pediatric Psychology, 7,* 278-290.

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PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001 and 0925-0002

Expiration Date: 03/31/2020

Are Human Subjects Involved	● Yes ○ No
Is the Project Exempt from Federal regulations?	○ Yes ● No
Exemption Number	❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8
Other Requested Information	

Human Subject Studies

Study#	Study Title	Clinical Trial?
1	The Impact of Early Medical Treatment in Transgender Youth	No

Section 1 - Basic Information (Study 1)

OMB Number: 0925-0001 and 0925-0002

Expiration Date: 03/31/2020

1.1. Study Title *

The Impact of Early Medical Treatment in Transgender Youth

1.2. Is this study exempt from Federal Regulations * ❍ Yes ● No

1.3. Exemption Number ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8

1.4. Clinical Trial Questionnaire *

1.4.a. Does the study involve human participants?	● Yes	❍ No
1.4.b. Are the participants prospectively assigned to an intervention?	❍ Yes	● No
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?	❍ Yes	● No
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?	❍ Yes	● No

1.5. Provide the ClinicalTrials.gov Identifier (e.g. NCT87654321) for this trial, if applicable

Section 2 - Study Population Characteristics (Study 1)

2.1. Conditions or Focus of Study

- Gender Dysphoria

2.2. Eligibility Criteria

GnRHa YOUTH COHORT
Inclusion Criteria
- Presence of gender dysphoria as determined by a clinician;
- Tanner stage 2, 3, or 4 of sexual development
- Appropriate to undergo puberty suppression with GnRH agonists;
- Ages 8 through 16 years inclusive;
- Ability to read and understand English;
- Receiving or planning to receive services at a study site clinic; and
- Willing and able to provide informed assent.

Additional Inclusion Criteria for New Enrollments in the Renewal Period
- Youth of color with an emphasis on non-Hispanic/Latinx youth

Exclusion Criteria
- Prior utilization of GnRH agonists;
- Precocious puberty (natal males younger than 9 years or natal females younger than 8 years);
- Pre-existing osteoporosis;
- Presence of serious psychiatric symptoms (e.g., active hallucinations, thought disorder) that would impair the individual's ability to provide true informed consent or participate in the baseline survey;
- Visibly distraught (e.g., suicidal, homicidal, exhibiting violent behavior) at the time of consent or the baseline survey; or Intoxicated or under the influence of alcohol or other substances to such an extent that in the opinion of the study staff, the ability to give true informed consent or to understand and answer the questions is impaired.

GnRHa PARENT/CAREGIVER COHORT
Inclusion Criteria
- Parent or caregiver of a child who meets the GnRHa Youth Cohort inclusion/exclusion criteria;
- Ages 18 and above;
- Ability to read and understand English; and
- Willing and able to provide signed informed consent.

Exclusion Criteria
- Presence of serious psychiatric symptoms (e.g., active hallucinations, thought disorder) that would impair the individual's ability to provide true informed consent or participate in the baseline survey;
- Visibly distraught (e.g., suicidal, homicidal, exhibiting violent behavior) at the time of consent or the baseline survey; or
- Intoxicated or under the influence of alcohol or other substances to such an extent that in the opinion of the study staff, the ability to give true informed consent or to understand and answer the questions is impaired.

GENDER-AFFIRMING HORMONE COHORT
Inclusion Criteria
- The presence for gender dysphoria as determined by a clinician;
- Appropriate for initiating phenotypic gender change with gender-affirming hormones;
- Ages 8 through 20 years inclusive;
- Ability to read and understand English;
- Receiving or planning to receive services at a study clinic; and
- Willing and able to provide signed informed consent or assent.

Additional Inclusion Criteria for New Enrollments in the Renewal Period
- Transmasculine participants - identify as a youth of color with an emphasis on non-Hispanic/Latinx youth
- Transfeminine participants - no race or ethnicity requirements

Exclusion Criteria
- Prior utilization of gender-affirming hormones;
- Previously or currently enrolled in the GnRHa cohort;
- Presence of serious psychiatric symptoms (e.g., active hallucinations, thought disorder) that would impair the individual's ability to provide true informed consent or participate in the baseline survey;
- Visibly distraught (e.g., suicidal, homicidal, exhibiting violent behavior) at the time of consent or the baseline survey; or
- Intoxicated or under the influence of alcohol or other substances to such an extent that in the opinion of the study staff, the ability to give true informed consent or to understand and answer the questions is impaired.

2.3. Age Limits	Min Age: 8 Years	Max Age: N/A (No limit)
2.4. Inclusion of Women, Minorities, and Children	Inclusion_of_Women_Minorities_and_Children.pdf	

2.5. Recruitment and Retention Plan	Recruitment_and_Retention_Plan.pdf	
2.6. Recruitment Status	Enrolling by invitation	
2.7. Study Timeline	Study_Timeline.pdf	
2.8. Enrollment of First Subject	07/25/2016	Actual

INCLUSION OF WOMEN, MINORITIES, AND CHILDREN

Inclusion of Women and Minorities

This project meets standards for inclusion of women and minorities.

As a study of transgender children, youth, and young adults, potential participants who identify with a gender that is incongruent with the sex they were assigned at birth may be eligible to be enrolled in this study. These individuals will be recruited to participate in the proposed study and may identify with any number of gender identity labels including, but not limited to transgender, gender fluid, nonbinary, genderqueer, female, transgender female, male, and transgender male. The goal of the study is to have equal numbers of transfeminine and transmasculine participants in the youth cohorts. Currently, the gender identity percentages are relatively similar within the GnRHa cohort with 43.2% identifying as transmasculine; 47.4% transfeminine; and 9.6% nonbinary, genderqueer, or gender fluid (48% assigned female at birth and 52% assigned male at birth). However, within the gender-affirming hormone cohort, the participants are 60.3% transmasculine; 33.1% transfeminine; 5% nonbinary, genderqueer, or gender fluid; and 1.2% other (65% assigned female at birth and 35% assigned male at birth). Therefore, in the gender-affirming cohort, we are not limiting the recruitment of transfeminine youth to the specific race and ethnicity requirements that were implemented with the GnRHa cohort discussed below.

Initially, all racial and ethnic categories were eligible to enroll in the study during the first grant period; however, it became evident that the percentage of white youth enrolling in the study was higher than expected, reflecting the rates of youth in care at all four of the sites. To address the lack of racial/ethnic diversity, the MPIs decided at the protocol team meeting in late 2018 to restrict new transmasculine participant enrollments in the gender-affirming hormone cohort to participants of color, with an emphasis on non-Hispanic/Latinx youth. In the GnRHa cohort, enrollment was also restricted to youth of color, with an emphasis on non-Hispanic/Latinx youth. Due to the need to recruit and enroll more transfeminine youth in the gender-affirming hormone cohort, there were no race or ethnicity restrictions implemented. In our current cohorts, the gender-affirming hormone youth cohort is (b)(4); (b)(6). The GnRHa youth cohort is (b)(4); (b)(6) (b)(4);.

Inclusion of Children

This project meets standards for inclusion of children.

The research conducted thus far and during the renewal grant period will include coded data from early and late pubertal gender dysphoric children, adolescents, and young adults to understand the impact of hormone therapy to suppress puberty and assist in phenotypic transition. In the initial grant period, youth participants have ranged in age from 8 to 20, with a mean age of 11 years in the GnRHa cohort and 16 years in the gender-affirming hormone cohort at enrollment. Data will be collected from their medical charts as well as surveys and interviews; however, all data collection will be coded to help ensure confidentiality. Children and adolescents will be asked to complete surveys at baseline and every six months through the month-24 visit and annually thereafter for seven years. As described in the Research Plan, the Principal Investigator, research staff, and collaborating partners have a long history of providing care for and conducting research with transgender children and adolescents.

Parent/Caregiver participants must be at least 18 years of age; this is required due to self-consent requirements for participating in the study. It is not expected that we would have a potential participant under age 18 as the minimum age for the youth participants is 8 years.

The investigative team of MPIs and Co-Is has extensive expertise in providing medical and psychosocial care to children, adolescents, and young adults. The four study sites are children's hospitals with strong academic partnerships. The research space in the four children's hospital sites is age-appropriate, and the facilities are ideal for conducting research with children. The majority of the members of the PI and Co-I teams are active clinicians in addition to their research endeavors as university faculty.

Involvement of children in this study will be in compliance with all applicable subparts of 45 CFR 46, Subpart D – Additional Protections for Children Involved as Subjects in Research, as well as other pertinent Federal and State laws/regulations.

RECRUITMENT AND RETENTION PLAN

Recruitment is conducted through the clinics at the four study sites as inclusion criteria require that participants access care at the study site in order for the study to obtain observational data on the medical impact of a GnRHa to prevent progression beyond early puberty or gender-affirming hormones for phenotypic transition. In addition, these four clinic sites are some of the largest providers of transgender pediatric care in the country.

During the original grant period, our team noted that the diversity of the enrolled study population needed to be improved. This led to the launching of a selective recruitment strategy specifically to increase participation of youth of color with an emphasis on non-Hispanic/Latinx youth in the GnRHa cohort. In the gender-affirming hormone cohort, the same emphasis was placed on transmasculine participant recruitment; however, due to the smaller number of transfeminine participants in the GAH cohort, a focus on youth of color was not implemented. During the tenure of the first grant period, UCSF opened a second site at Benioff Children's Hospital Oakland that began providing gender care for that geographic region and is located in a more ethnically diverse neighborhood. Recruitment from this site, in addition to selective recruitment at the other sites, has provided additional diversity to the study population. In order to assist with identifying additional recruitment strategies, Dr. Asa Radix has joined the protocol team as a co-investigator. In addition, Dr. Olson-Kennedy at Children's Hospital Los Angeles obtained CTSI funding and IRB approval to conduct qualitative focus groups with transgender and gender diverse young adults of color to gather data about the challenges youth of color face in accessing care. The first three focus groups have been conducted, and funding has been sought to support additional focus groups. These strategies form the backbone of recruitment efforts to diversify the study population.

Our study coordinators who identify as transgender, non-binary, or genderqueer at each of the study sites provide unique recruitment and enrollment support. Having a study coordinator with whom the participants have a shared experience is of unquestionable value to the youth and parent/caregiver participants, especially when answering questions during the recruitment, informed consent, and enrollment processes. We have found this to also greatly benefit retention efforts as the youth appreciate this shared experience when they are responding to measures related to their gender identity and during the debrief at the end of each study visit.

Retention of participants at study follow-up visits is facilitated by the fact that study visits correspond to clinically-required medical follow-up visits. Additionally, we provide compensation to the participants to acknowledge the time required of them to participate in study visits. Currently, incentive amounts vary based on the type of study visit. For example, 6- and 18-month visits are shorter than baseline, month 12, and month 24 visits, and therefore, we provide less compensation for shorter visits than longer visits. During the renewal period, to strengthen retention, we will increase the incentives provided to participants over time to incentivize remaining in the study without providing an incentive so large as to be considered coercive. We also provide transportation assistance via ridesharing (e.g., Lyft), parking validations, or mileage reimbursement to assist participants in attending study visits.

Retention rates for the GnRHa cohort are as follows: 6 month: 83% (100% visits complete); 12 month: 78% (96% visits complete); 18 month: 73% (86% visits complete); 24 month: 89% (55% visits complete), and for the GAH cohort: 6 month: 92% (100% visits complete); 12 month: 83% (97% visits complete); 18 month: 73% (93% visits complete); 24 month: 80% (79% visits complete). We believe that through the efforts described above, we will continue to maintain a high retention rate throughout the study renewal period.

During the renewal grant period, retention efforts will be increased as study visits will decrease in frequency to be annual rather than every six months after month 24. In addition, as some participants may be on gender-affirming hormones for three or more years, their medical care visits may also be further spaced apart. Study coordinators will utilize retention strategies such as phone calls to participants, sending birthday cards, and providing small tokens of appreciation that will remind them of the study. As pediatric institutions, we recognize that some participants will age out of services during the seven-year extended follow-up period. To assist with retention, we will transition the survey to a web-based platform (REDCap) so that participants who no longer live close to the study site may be able to complete some study visits remotely. Also, we will continue to retain these participants through strategies such as scheduling study visits during trips home from college and obtaining

release of information forms to access medical data from other care providers. We update locator information at all visits, and we contact participants between study visits to correct and update contact information.

Retention will also be maintained through timely dissemination of data analysis to participants (youth and parents/caregivers) in a meaningful and digestible manner. In addition, presentations of study data are not limited to academic conferences and settings; we will continue to present at meetings that are attended by the community, which study participants and their family may be attending.

STUDY TIMELINE

	Year 1				Year 2				Year 3				Year 4				Year 5			
Quarters (Q1-Q4) Per Yr	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Multisite Protocol Team Meeting																				
Convene CAB																				
Recruit and Enroll New Cohort																				
1-Year Follow-Up New Cohort																				
2-Year Follow-Up Original/New Cohort																				
3-Year Follow-Up Original/New Cohort																				
4-Year Follow-Up Original/New Cohort																				
5-Year Follow-Up Original Cohort																				
6-Year Follow-Up Original Cohort																				
Data Management, Cleaning, and Analysis																				
Renewal Aim 1 Analyses & Papers																				
Renewal Aim 2 Analyses & Papers																				
Renewal Aim 3 Analyses & Papers																				
Conference Presentations																				

Inclusion Enrollment Reports

IER ID#	Enrollment Location Type	Enrollment Location
Study 1, IER 1	Domestic	Ann & Robert H. Lurie Children's Hospital of Chicago Boston Children's Hospital Children's Hospital Los Angeles UCSF Benioff Children's Hospital Oakland UCSF Benioff Children's Hospital San Francisco
Study 1, IER 2	Domestic	Ann & Robert H. Lurie Children's Hospital of Chicago Boston Children's Hospital Children's Hospital Los Angeles UCSF Benioff Children's Hospital Oakland UCSF Benioff Children's Hospital San Francisco
Study 1, IER 3	Domestic	Ann & Robert H. Lurie Children's Hospital of Chicago Boston Children's Hospital Children's Hospital Los Angeles UCSF Benioff Children's Hospital Oakland UCSF Benioff Children's Hospital San Francisco

Inclusion Enrollment Report 1

Using an Existing Dataset or Resource* : ● Yes ○ No

Enrollment Location Type* : ● Domestic ○ Foreign

Enrollment Country(ies): USA: UNITED STATES

Enrollment Location(s): Ann & Robert H. Lurie Children's Hospital of Chicago
Boston Children's Hospital
Children's Hospital Los Angeles
UCSF Benioff Children's Hospital Oakland
UCSF Benioff Children's Hospital San Francisco

Comments: GnRHa (BLOCKER)YOUTH COHORT PLANNED AND CUMULATIVE ENROLLMENT FOR THE CURRENT GRANT
Cumulative (Actual) data below are for youth and parent/caregiver participants enrolled in the current study through 2/29/20 based on identity reported in the baseline visit.
Data below are reported by sex assigned at birth, not gender identity.
UCSF Benioff Children's Hospital Oakland was added as a site during the initial grant period to improve racial and ethnic diversity in the study population.

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	(b)(4); (b)(6)				
Asian					
Native Hawaiian or Other Pacific Islander					
Black or African American					
White					
More than One Race					
Total					

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	(b)(4); (b)(6)									
Asian										
Native Hawaiian or Other Pacific Islander										
Black or African American										
White										
More than One Race										

Unknown or Not Reported	(b)(4); (b)(6)
Total	

Inclusion Enrollment Report 2

Using an Existing Dataset or Resource* : ● Yes ○ No

Enrollment Location Type* : ● Domestic ○ Foreign

Enrollment Country(ies): USA: UNITED STATES

Enrollment Location(s): Ann & Robert H. Lurie Children's Hospital of Chicago
Boston Children's Hospital
Children's Hospital Los Angeles
UCSF Benioff Children's Hospital Oakland
UCSF Benioff Children's Hospital San Francisco

Comments: GnRHa (BLOCKER) PARENT/CAREGIVER COHORT PLANNED AND CUMULATIVE ENROLLMENT FOR THE CURRENT GRANT
Cumulative (Actual) data below are for youth and parent/caregiver participants enrolled in the current study through 2/29/20 based on identity reported in the baseline visit.
Data below are reported by sex assigned at birth, not gender identity.
UCSF Benioff Children's Hospital Oakland was added as a site during the initial grant period to improve racial and ethnic diversity in the study population

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	(b)(4); (b)(6)				
Asian					
Native Hawaiian or Other Pacific Islander					
Black or African American					
White					
More than One Race					
Total					

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	(b)(4); (b)(6)									
Asian										
Native Hawaiian or Other Pacific Islander										
Black or African American										
White										
More than One Race										

Unknown or Not Reported	(b)(4); (b)(6)
Total	

Inclusion Enrollment Report 3

Using an Existing Dataset or Resource* : ● Yes ○ No

Enrollment Location Type* : ● Domestic ○ Foreign

Enrollment Country(ies): USA: UNITED STATES

Enrollment Location(s): Ann & Robert H. Lurie Children's Hospital of Chicago
Boston Children's Hospital
Children's Hospital Los Angeles
UCSF Benioff Children's Hospital Oakland
UCSF Benioff Children's Hospital San Francisco

Comments: GENDER AFFIRMING HORMONE (GAH) COHORT PLANNED AND CUMULATIVE ENROLLMENT FOR THE CURRENT GRANT
Cumulative (Actual) data below are for youth and parent/caregiver participants enrolled in the current study through 2/29/20 based on identity reported in the baseline visit.
Data below are reported by sex assigned at birth, not gender identity.
UCSF Benioff Children's Hospital Oakland was added as a site during the initial grant period to improve racial and ethnic diversity in the study population.

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	(b)(4); (b)(6)				
Asian					
Native Hawaiian or Other Pacific Islander					
Black or African American					
White					
More than One Race					
Total					

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	(b)(4); (b)(6)									
Asian										
Native Hawaiian or Other Pacific Islander										
Black or African American										
White										
More than One Race										

Unknown or Not Reported	(b)(4); (b)(6)
Total	

Section 3 - Protection and Monitoring Plans (Study 1)

3.1. Protection of Human Subjects	Protection_of_Human_Subjects.pdf
3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?	● Yes ○ No ○ N/A
If yes, describe the single IRB plan	Single_IRB_Plan.pdf
3.3. Data and Safety Monitoring Plan	Data_and_Safety_Monitoring_Plan.pdf
3.4. Will a Data and Safety Monitoring Board be appointed for this study?	○ Yes ● No
3.5. Overall structure of the study team	Overall_Structure_of_the_Study_Team.pdf

PROTECTION OF HUMAN SUBJECTS

Risks to Human Subjects

a. Human Subjects Involvement, Characteristics and Design

The primary objective of this observational, longitudinal, multicenter renewal study is to extend the initial 2-year follow-up period for an additional 4 years to evaluate the longer-term physiological and psychological impact of early medical treatment in two cohorts of dysphoric youth: 1) Those treated with puberty suppression initiated in early puberty who go on to receive gender-affirming hormones (estrogen or testosterone), and 2) those treated initially in later puberty with gender-affirming hormones. The sample of children, adolescents, and young adults will be recruited from patients presenting for care at any of the four sites along with one parent/primary caregiver for the children and youth accessing a GnRHa.

We will enroll 138 early pubertal youth participants in the GnRHa cohort (an additional 43 participants) who will meet the following inclusion and exclusion criteria:

Inclusion Criteria

- Presence of gender dysphoria as determined by a clinician;
- Tanner stage 2, 3, or 4 of sexual development
- Appropriate to undergo puberty suppression with GnRH agonists;
- Ages 8 through 16 years inclusive;
- Ability to read and understand English;
- Receiving or planning to receive services at a study site clinic; and
- Willing and able to provide informed assent.

Additional Inclusion Criteria for New Enrollments in the Renewal Period

- Youth of color with an emphasis on non-Hispanic/Latinx youth

Exclusion Criteria

- Prior utilization of GnRH agonists;
- Precocious puberty (natal males younger than 9 years or natal females younger than 8 years);
- Pre-existing osteoporosis;
- Presence of serious psychiatric symptoms (e.g., active hallucinations, thought disorder) that would impair the individual's ability to provide true informed consent or participate in the baseline survey;
- Visibly distraught (e.g., suicidal, homicidal, exhibiting violent behavior) at the time of consent or the baseline survey;
- or Intoxicated or under the influence of alcohol or other substances to such an extent that in the opinion of the study staff, the ability to give true informed consent or to understand and answer the questions is impaired.

We will enroll as study participants 138 parents or caregivers (an additional 43 participants) of the early pubertal participants who will meet the following inclusion and exclusion criteria:

Inclusion Criteria

- Parent or caregiver of a child who meets the GnRHa Youth Cohort inclusion/exclusion criteria;
- Ages 18 and above;
- Ability to read and understand English; and
- Willing and able to provide signed informed consent.

Exclusion Criteria

- Presence of serious psychiatric symptoms (e.g., active hallucinations, thought disorder) that would impair the individual's ability to provide true informed consent or participate in the baseline survey;
- Visibly distraught (e.g., suicidal, homicidal, exhibiting violent behavior) at the time of consent or the baseline survey; or
- Intoxicated or under the influence of alcohol or other substances to such an extent that in the opinion of the study staff, the ability to give true informed consent or to understand and answer the questions is impaired.

We will enroll 472 late pubertal cohort participants in the GAH cohort (an additional 156 participants) who will meet the following inclusion and exclusion criteria:

Inclusion Criteria

- The presence for gender dysphoria as determined by a clinician;
- Appropriate for initiating phenotypic gender change with gender-affirming hormones;
- Ages 8 through 20 years inclusive;
- Ability to read and understand English;
- Receiving or planning to receive services at a study clinic; and
- Willing and able to provide signed informed consent or assent.

Additional Inclusion Criteria for New Enrollments in the Renewal Period

- Transmasculine participants – identify as a youth of color with an emphasis on non-Hispanic/Latinx youth
- Transfeminine participants – no race or ethnicity requirements

Exclusion Criteria

- Prior utilization of gender-affirming hormones;
- Previously or currently enrolled in the GnRHa cohort;
- Presence of serious psychiatric symptoms (e.g., active hallucinations, thought disorder) that would impair the individual's ability to provide true informed consent or participate in the baseline survey;
- Visibly distraught (e.g., suicidal, homicidal, exhibiting violent behavior) at the time of consent or the baseline survey; or
- Intoxicated or under the influence of alcohol or other substances to such an extent that in the opinion of the study staff, the ability to give true informed consent or to understand and answer the questions is impaired.

The research is being conducted at Children's Hospital Los Angeles (CHLA), Ann & Robert H. Lurie Children's Hospital of Chicago, Boston Children's Hospital, and University of California San Francisco Benioff Children's Hospitals San Francisco and Oakland. These four academic hospitals are situated strategically across the country and have dedicated transgender youth clinics. They are considered the national leaders in the care of transgender children, adolescents, and young adults. All four sites employ a similar model for care that includes medical and mental health professionals and represent some of the most experienced providers in the country doing this work.

The four collaborating sites will recruit and enroll child and parent/caregiver participants, conduct study activities, and provide data to the data core at CHLA. The principal investigators will oversee all aspects of the study process and will monitor implementation of study activities. They will maintain ongoing communication through conference calls in order to be responsive to any issues that may arise and will modify the protocol if needed.

b. Study Procedures, Materials, and Potential Risks

Data will be collected directly from participants and their parents or caregiver via a computerized survey or by interview to minimize concerns about confidentiality, encourage honest responses to sensitive issues, and allow completion of the survey at the participants' own pace. Demographic data collected will include items such as age, ethnicity, educational level and birth city/country, as well as data specific to the transgender population, such as age parents realized their child's transgender identity, age of youth participant first living in the desired gender role, and contexts in which the child is living in their desired gender role, if any. The computerized survey will also collect information from the parents and youth regarding data such as physical activity and dietary calcium intake and psychosocial assessments such as the degree of social gender transition, parental support for gender diversity, parenting stress, quality of life, resiliency, anxiety, self-harm, social connectedness, etc. Interviews will be used for obtaining mental health diagnosis information through the use of the MINI and MINI Kid and for obtaining information regarding diagnoses and medications that may not be detailed in the electronic health record. In addition, case report forms (CRFs) will be used for items such as tracking the Modified Ferriman-Gallwey score, Tanner staging, medication information, diagnoses, etc.

Only site-specific research staff and local institution IRB personnel conducting quality assurance activities will have access to individually identifiable private information about the participants. The CHLA coordinating

center staff may have access to individually identifiable private information about the participants when providing on-site technical assistance for study implementation and quality assurance activities.

No personal identifying information (e.g., name, tracking information, etc.) will be placed on any of the CRFs or collected within the computerized survey. All study-specific records will be identified by a coded number only, to maintain confidentiality. Only the research staff will have access to the database linking the participant's unique ID code and name in a secure network, password-protected file or in a secure location under double-lock when not in use and with restricted access during work hours and/or when unattended.

For the computerized baseline and follow-up surveys each participant will be assigned a code and their surveys will be linked via this code. A master list of the codes assigned to participants will be kept in a secure, password protected file at each site or in a secured location under double-lock when not in use and with restricted access during work hours and/or when unattended. The coordinating center staff will not have access to the sites' key to the codes.

Computerized data will be collected via QDS software and web-based services (e.g., REDCap, ASEBA) at the collaborating sites. Upon transfer of the encrypted data to CHLA, the data will be stored on CHLA's secured network (with firewall protection), which cannot be accessed by anyone outside of CHLA. All case report forms (CRFs) will be entered into password protected databases at the site and be transmitted securely with an ID to CHLA. A password will be used to access survey data and will be made accessible only to the MPIs and study staff. These data will be archived in a password-protected database on the local network on a daily basis. The data coordination staff, housed at CHLA, will support all PIs with the generation of a cross-site protocol for data collection and templates. Study-wide data management procedures, including integration and verification of multi-site data, will take place at CHLA.

The potential risks of participation in this study are minimal and are not greater than those that would be accepted by other persons not participating in the study. Participants are expected to be exposed only to minimal risk based on questions asked and the confidential system of data collection. While all safeguards will be in place to protect their identity, there is also potential risk that identifying information collected could be accessed by someone other than the research team. A number of precautions and safeguards have been developed in order to protect the confidentiality of individuals who participate in the study. No personal identifying information will be used on the CRFs or surveys. Consent forms will be filed and stored separate from the raw data in a secured location under double-lock when not in use and with restricted access during work hours and/or when unattended.

As this is an observational study, there are no alternative treatments or procedures.

Adequacy of Protection against Risks
a. Informed Consent and Assent
Study team members will recruit participants for the study by speaking with patients and their parents/legally authorized representatives face-to-face or by telephone. Information regarding the study will be provided and interest in participation will be assessed.

If potential participants are interested in enrolling in the study, staff members from Children's Hospital Los Angeles, Lurie Children's Hospital of Chicago, Boston Children's Hospital, and University of California at San Francisco who have received IRB certification will consent participants. All research participants will review and sign an informed consent/permission/assent form. The informed consent/permission/assent form covers information about the overall purpose of the study, what the study entails, potential risks, potential benefits to participating individuals and society, the confidentiality of data, and contact information for the site Principal Investigator and the IRB. A waiver of some or all of the elements of informed consent will not be sought.

For child participants aged 8 to 17 years old, the participant will sign an assent form and the parent/legally authorized representative will sign a parental permission form. Young adult participants 18 and older will sign a consent form. If a youth participant turns 18 while on the study, they will sign a consent addendum. All

parent/caregiver participants will provide written consent for their own participation in the study. Informed consent, assent, permission will be obtained before any research activities are conducted.

Once informed consent/permission/assent has been obtained, the research staff will have the form reviewed by a fellow research team member, who will confirm that it is fully completed before it is filed in a secure location under double-lock when not in use and with restricted access during work hours and/or when unattended.

Project staff will inform participants that they have the right to skip any questions during the computerized survey or face-to-face interview that make them feel uncomfortable. Participants will be informed that participation is completely voluntary and that they are free to stop their involvement in the study at any time without any negative consequences. They will be informed of their rights to privacy and confidentiality and will be told that their answers to the survey will be kept confidential and not shared with others outside of the research staff. They will be informed that no information about them or provided by them during the research will be disclosed to others without their written permission, except if necessary to protect their rights or welfare (for example, if they are injured and need emergency care) or if required by law (i.e., child or elder abuse, harm to self or others, or reports of certain infectious diseases).

b. Protection Against Risk

A number of precautions and safeguards have been developed in order to protect the confidentiality of individuals who participate in the study.

No personal identifying information (e.g., names or medical record numbers) of the participants will appear in any computer or paper files associated with this research project in any location. Participants will be assigned a unique identification number code. A key file that matches the ID number to the participant and organization will be maintained in a secure data repository within the project offices at each of the four sites. Data will be kept strictly confidential, except as required by law, and stored on a secure network, with password protection such that only authorized users will have access to the file server. All computers will be located in locked facilities, and consent forms will be filed and stored separate from the raw data in a secured location under double-lock when not in use and with restricted access during work hours and/or when unattended. Any temporary data files kept on removable storage devices, as well as printouts derived from data analysis, will be stored in a locked compartment when not in use.

Data will remain on the CHLA server or secure, HIPAA compliant web applications (REDCap and ASEBA) during data collection, verification, cleaning, and analysis. CHLA will continue to serve as the repository for intact versions of the study's comprehensive data sets. The most up-to-date data set (as well as site-specific data), including scored measures and created scales, will be made readily available to all PIs. To meet NIH obligations for data sharing, other investigators not affiliated with the study will also have access de-identified study data pursuant to a signed Data Use Agreement. The Contact PI (Dr. Olson-Kennedy of CHLA) will be responsible for maintaining Data Use Agreement records and secure transmission of data to outside investigators.

As this is an observational study, adverse events are not anticipated. However, there is some risk that answering questions about some of the topics may be uncomfortable or upsetting. In the event of discomfort or upset, there are medical and psychological professionals on the research team who can provide ongoing support as needed. All of the sites have licensed psychologists who provide clinical care to transgender and gender nonconforming children. Participants do not have to answer any question in the computerized or face-to-face interview that they do not want to answer. Furthermore, participants will be informed that at any point, they may stop if they do not wish to continue the questionnaire. In the event of an adverse event, it will be reported to the IRB as per protocol to ensure the safety of participants.

A possible adverse event that is anticipated includes the need to violate participant confidentiality due to risk of harm to self or child abuse. Study personnel will be trained regarding the limits of confidentiality. This training will include reviewing possible scenarios and knowledge of key questions to assess risk. We will train staff to err on the side of caution and to contact a supervisor as needed. Supervisors will be available by

phone 24 hours a day should staff need to consult regarding an emergency. In this situation, we will train staff members to leave participants in the company of study personnel and immediately contact supervisors before participants leave. Under the guidance of supervisors, staff will be trained either to ensure the safety of participants (i.e. call the police, or if appropriate, to escort participants to the emergency room).

Unanticipated adverse events will be brought to the attention of the MPIs and reported immediately to all relevant IRBs. The IRBs will determine whether it is appropriate to stop the study protocol temporarily or will provide suggestions/modifications to the study procedures. Any recommendations from local IRBs will be communicated to the IRB of Record at CHLA. Possible modifications include adding these possible adverse events to the consent form and re-consenting all study participants. The PI will be responsible for monitoring participant safety on a monthly basis at regularly scheduled research meetings. They will keep a written log of all adverse events and ensure that the IRB is contacted immediately. They will also keep a log of the outcome of IRB decisions regarding adverse events and apprise the research team of any changes that need to be made as a result of IRB decisions.

c. Vulnerable Subjects

This proposal involves children, a vulnerable subject population. The protocol will be certified through the IRB of Record, which is located at a children's hospital, and the research staff will be certified through the local IRB at each of the four sites to conduct research on human subjects, especially as related to children. This observational study is 46.404, research not involving greater than minimal risk, and 46.408 requirements for permission by parents or legally authorized representatives and for assent by children will be followed. All HHS Subpart D – Additional Protections for Children will be followed. Within the first two months of funding, the project staff will submit an application to the single IRB for protocol approval. Throughout the project, staff will continue to work with the IRB to protect the rights and confidentiality of all individuals who participate in data collection.

Potential Benefits of the Proposed Research to Research Participants and Others

While there are no potential direct benefits to the research participants, possible risks (i.e. discomfort answering questions, potential confidentiality breeches) are minimal and are outweighed by the anticipated societal benefits.

Importance of the Knowledge to be Gained

The proposed research provides the opportunity to obtain a better understanding of transgender youth, improve their care, and share information on a local and national level about how to provide care and hormone therapy for gender dysphoric children and adolescents. The information that is learned from this project will support innovative approaches to identifying, understanding, and providing optimal care for early pubertal and late pubertal, multi-ethnic transgender youth.

SINGLE IRB PLAN

During the current grant cycle, the study has been reviewed and approved by all of the four institutional IRBs. For the renewal grant period, the study will transition to a single Institutional Review Board (sIRB), and Children's Hospital Los Angeles (CHLA) will fulfill the role of IRB of Record for this study. CHLA has extensive experience as a single IRB (sIRB) and as an IRB of record for pediatric research consortia. It obtained accreditation from the Association for the Accreditation of Human Research Protection Programs, Inc., in 2012, recognizing its commitment to the protection of human research participants through the highest ethical standards. CHLA sIRB activities are supported through the CHLA Human Subjects Protection Program, which follows all regulatory requirements including those from the Department of Health and Human Services (DHHS) at 45 CFR 46, the Food and Drug Administration (FDA) at 21 CFR 50 and 56, the Health Insurance Portability and Accountability Act (HIPAA) at 45 CFR 160 and 64 and any and all other regulatory requirements affecting research with humans including local and state laws and ordinances. The CHLA IRB is well qualified to meet the Final NIH Policy on the Use of a Single Institution Review Board for Multi-Site Research.

All sites have agreed that the Children's Hospital Los Angeles IRB will serve as the sIRB of record and to rely on the proposed sIRB. If an additional site was to be added after award, it will rely on the sIRB.

Communication between sites and the sIRB will be conducted at two levels. The Director of the Human Subjects Protection Program at CHLA and the sites will communicate to establish a reliance agreement. All sites are members of the SMART IRB Reliance platform, which will facilitate communication during the reliance process. The CHLA Clinical Research Manager will communicate with each site's study coordinator/research associate regarding information that needs to be relayed to the local IRB or vice versa. Communication will support the local context for research, ensuring that the research teams follow local laws and regulations where they will be conducting research. In addition, information may be needed regarding local customs and literacy. Documentation will be provided to the relying sites of all amendments to the protocol to ensure that all sites are implementing the protocol with fidelity and that relying IRBs have accurate information regarding research activities being conducted at their institution. Locally-relevant reportable events (such a serious adverse events or protocol deviations) will be submitted to both the local IRB and the CHLA sIRB. CHLA and the sites are experienced in this relationship as CHLA is the coordinating center for the current multi-site R01HD097122, A Longitudinal Study of Gender Nonconformity in Prepubescent Children.

All participating sites will, prior to initiating the study, sign an authorization/reliance agreement that will clarify the roles and responsibilities of the sIRB and participating sites.

CHLA will maintain records of the authorization/reliance agreements and of the communication plan.

DATA AND SAFETY MONITORING PLAN

This study is a minimal risk, observational study and does not meet the NIH definition of a clinical trial. Nevertheless, there still remains a risk of an adverse event. The most likely occurrence would be related to answering or responding to questions about sensitive topics that may be uncomfortable or upsetting. In the event of said situation, the study coordinators are trained to contact a licensed clinician to respond to the situation immediately. Any adverse events or unanticipated problems are reported to the coordinating center clinical research manager in order for them to be reported to the IRB of record. In addition, as a DSMB is not required of this study, any unanticipated problem or adverse events are discussed on the monthly MPI call to ensure awareness and oversight.

Data monitoring is conducted by the data manager and the data analyst at the Coordinating Center. Data that are submitted by the sites are reviewed for completeness and accuracy and to ensure incoming data are of high quality. The data analyst will run ongoing analyses as the cohorts move through the data points. If any data items are unclear or of concern, the data analyst sends a query to the study coordinator and tracks the query until the response is complete. The data manager provides updates regarding the data and analyses being conducted to the MPIs during the monthly MPI calls, and if a concern was found during an analysis of the observational, clinical data, it would be reported to the MPIs for safety discussions.

OVERALL STRUCTURE OF THE STUDY TEAM

The overall structure of the study team is as follows. Also, please reference the Multiple Principal Investigator Leadership Plan.

Four Study Sites

- Principal Investigator – responsible for all study activities occurring at the site and for coordinating with the other MPIs for overall study communication regarding: human subjects protection, NIH reporting, study implementation, data analysis, and publication. Please see the MPI Leadership Plan for more detail.
- Co-Investigator – collaborate with the Co-Is at the other sites to obtain meaningful mental health information form the youth, young adult, and parent/caregiver participants; conduct data analysis; and disseminate results.
- Study Coordinator – recruit and enroll study participants, conduct informed consent conferences, conduct study activities, accurately obtain and record data, participate in monthly study coordinator calls, report concerns to the site PI.
- Biostatician – collaborate with the PIs and Co-Is to conduct analyses of the medical and mental health data for publication.

Coordinating Center & Subaward Site

- Contact Principal Investigator – responsible for coordination of the MPIs and overseeing the coordinating center.
- Co-Investigators – responsible for making final decisions regarding instruments and data collection tools; oversee and direct quantitative data management and analysis and provide advanced statistical consultation to the project, including developing and executing analytical plans and advising the data team on appropriate longitudinal data analysis methods and procedures. Work closely with the biostaticians to ensure clear communication and coordination between sites on analytical and data-related issues. Provide guidance regarding strategies to diversify the study population.
- Data Analyst – conduct activities such as data cleaning, ensuring that data are complete, querying the study coordinators about problematic data, running analyses, providing data to the protocol team, and assisting with interpretation of analysis results.
- Research Manager – oversees the data management system, data cleaning and merging, and data analysis activities; coordinates the Data Coordination Committee.
- Clinical Research Manager – responsible for all activities related to the sIRB; amends the protocol as needed; communicates with all of the study coordinators regarding the study protocol through facilitating monthly calls; provides technical assistance; conducts quality assurance activities.
- Database Manager – maintains and updates the database that collects participant clinical data and creates reports to support study implementation and data analysis.

Section 4 - Protocol Synopsis (Study 1)

4.1. Brief Summary

4.2. Study Design

4.2.a. Narrative Study Description

4.2.b. Primary Purpose

4.2.c. Interventions

Type	Name	Description

4.2.d. Study Phase

Is this an NIH-defined Phase III Clinical Trial? ❍ Yes ❍ No

4.2.e. Intervention Model

4.2.f. Masking ❍ Yes ❍ No

❑ Participant ❑ Care Provider ❑ Investigator ❑ Outcomes Assessor

4.2.g. Allocation

4.3. Outcome Measures

Type	Name	Time Frame	Brief Description

4.4. Statistical Design and Power

4.5. Subject Participation Duration

4.6. Will the study use an FDA-regulated intervention? ❍ Yes ❍ No

4.6.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/ Investigational Device Exemption (IDE) status

4.7. Dissemination Plan

Delayed Onset Studies

Delayed Onset Study#	Study Title	Anticipated Clinical Trial?	Justification
The form does not have any delayed onset studies			

MULTIPLE PI/PD LEADERSHIP PLAN

Rationale

Johanna Olson-Kennedy, M.D., Robert Garofalo M.D., M.P.H., Stephen Rosenthal, M.D., and Dr. Yee-Ming Chan, M.D., Ph.D. will continue to serve as the Multiple Principal Investigator team on this study. Each PI is responsible and accountable to the National Institutes of Health (NIH) for the proper conduct of the research. The rationale for the decision to act as a multiple PI team was based on the fact that these four investigators bring unique experiences and knowledge that have complemented one another in the implementation of this project. We believe that continuing the MPI structure is a strength because it ensures a PI at each site, which is highly beneficial and particularly important because each site operates independently from the others, with each embedded differently within very large academic-hospital systems. PIs at each site, with institutional and community knowledge particular to their site, have effectively (and efficiently) managed the intricacies of study protocol implementation within each of these unique sites and regions. In addition, the MPIs have carefully developed trusted partnerships with local community-based organizations (CBOs) that serve transgender youth, and their MPI status has largely benefitted engagement of these CBOs in referral/promotion efforts. Our four sites are proposing to continue our collaboration for the proposed study due to our successful collaboration to date, as well as the possibility of enrolling a larger sample size than could be collected by a single site for the proposed research endeavor seeking to understand an uncommon experience in an understudied population.

Dr. Johanna Olson-Kennedy, M.D. (Pediatrics and Adolescent and Young Adult Medicine), is the Medical Director of the Center for Transyouth Health and Development at Children's Hospital Los Angeles (University of Southern California). She and her team based at CHLA, including Co-Is (b)(6) and Marco Hidalgo, Ph.D., lead the largest transgender youth program in the United States. Dr. Hidalgo is the Contact PI of a recently-funded NICHD study (R01HD097122). This study is the first of its kind to establish a US national cohort of prepubertal TGNC children. The primary objective of this longitudinal, multisite, observational study is to provide empirical evidence to inform clinical care by characterizing developmental patterns of gender identity and gender-role behavior, mental health outcomes at baseline and over time, and the impact of social gender transition (when present) in a cohort of prepubertal TGNC children. (b)(6) has extensive experience in multi-site and multi-partner studies as PI or Co-investigator including the 13 site Community Intervention Trial for Youth (CITY Project CDC PI), HIV couples testing in two African Capitols (NIH Co-I), Project AIM in 3 School Districts (CDC overall PI), Project Legacy for Homeless Youth and those at-risk for homelessness (Los Angeles, San Diego (HHS PI), and provision of start-up support for the NICHD funded ATN Connect to Protect Project ((b)(4) . The combined expertise of this team provides both comprehensive clinical knowledge and extensive research expertise in the area of transgender adolescents.

Dr. Yee-Ming Chan, M.D. (Pediatric Endocrinology) is Director of the Boston Children's Hospital Pediatric Reproductive Hormone (PReproHormone) Program, which provides clinical care to patients with disorders of puberty, patients with differences of sex development, and transgender youth and conducts clinical and translational research in these areas. The BCH PReproHormone Program houses the Gender Management Service (GeMS), which opened in 2007 and was the first pediatric academic program in the western hemisphere to treat pubescent teens. Three-quarters of GeMS patients come from a 150-mile radius of Boston; the rest come from throughout the US and the world. Co-I (b)(6) is a clinical psychologist with significant expertise in the scholarship and clinical realms; before joining the GeMS team, she was the Director of Child Protection Clinical Services at Boston Children's Hospital and subsequently Director of Training and Research for that program. (b)(6) has decades of experience evaluating children and families and is a recognized expert in the area of trauma and interpersonal violence with an interest in helping vulnerable children and adolescents.

Dr. Robert Garofalo, M.D., M.P.H. (Pediatrics and Adolescent and Young Adult Medicine), is Co-Director of the Gender and Sex Development Program, Division Head of Adolescent Medicine at Ann & Robert H. Lurie Children's Hospital of Chicago, and Associate Professor of Pediatrics at Northwestern University's Feinberg School of Medicine. He will serve as the PI for the Chicago site. He and his team, including Co-I Diane Chen, Ph.D., bring a wealth of expertise caring for and conducting research in adolescent populations, with particular

focus on transgender and other sexual minority youth. The Chicago team has been providing clinical services to gender non-conforming youth for more than a decade. Their multidisciplinary program for gender non-conforming youth and transgender youth undergoing medical suppression of puberty or initiating cross-sex hormone therapy brings together experts in pediatrics/adolescent care, endocrinology, psychology and child development, psychiatry, surgical subspecialties, and medical ethics. The team has extensive experience conducting NIH- funded multisite clinical and behavioral research with marginalized populations of youth.

Dr. Stephen M. Rosenthal, M.D. (Pediatric Endocrinology), Professor of Pediatrics, has served as Program Director for Pediatric Endocrinology and Co-Director of the Disorders of Sex Development Clinic, and currently serves as co-founder and Medical Director of the Child and Adolescent Gender Center (CAGC) at the University of California San Francisco (UCSF) Benioff Children's Hospital. Dr. Rosenthal is an established clinical investigator with 40 years of experience in child and adolescent endocrinology. He will serve as PI for the UCSF site. His Co-Investigator, Diane Ehrensaft, Ph.D., Associate Professor of Pediatrics and Mental Health Director of the UCSF CAGC, is an internationally recognized child psychologist/gender specialist. The UCSF CAGC has been providing multi-disciplinary care for gender non-conforming/transgender youth and adolescents for the past 10 years. The UCSF CAGC is the only such multi-disciplinary gender program in Northern California and attracts patients not only from California, but from as far away as Florida and Egypt.

Primary Roles and Areas of Responsibility for Each PI

Administrative

- Upon successful funding, the award will be made to Children's Hospital Los Angeles (CHLA). All participants will be enrolled at one of the four study sites – The Center for Transyouth Health and Development (CHLA), The Child and Adolescent Gender Center (University of California San Francisco), The Gender, Sexuality and HIV Prevention Center (Ann & Robert H. Lurie Children's Hospital of Chicago), or the Gender Management Service (Boston Children's Hospital). Drs. Olson-Kennedy, Garofalo, Rosenthal, and Chan will work collaboratively to prepare reports and other requirements for submission to the NIH. Each will oversee the administrative responsibilities at each of their respective institutions.
- Although not expected, if any PI should move to a new institution or step down (such as the retirement of Dr. Spack during the current grant period), the department at the relevant institution or one of the MPIs will nominate a candidate. The candidate would need to be democratically approved by the other MPIs.

Technical

- Dr. Olson-Kennedy, given her experience overseeing the CHLA coordinating center for the current project, will work with Drs. Rosenthal, Chan, Garofalo and the Co-Is to revise the study protocol reflecting the aging of the cohort and the extended data collection period.
- All four PIs will finalize protocols for each cohort in the study. Each site will continue to adhere to study implementation protocols to ensure that all sites conduct the research in the same manner.
- Data will be collected systematically, with identical operating procedures including CRFs, survey programming, and data flow sheets to facilitate the creation of a data repository that is suitable for analysis and available for all four sites to explore. The data will be owned equally by each of the four participating sites.
- All PIs and Co-Is at each site, will direct recruitment, retention, and data collection, with support from the project team at each of their respective sites. Data will be directly entered into a HIPAA-compliant, web-based database or stored at each site and safely transferred via secure protocols to CHLA for cleaning and merging.
- Dr. Olson-Kennedy, (b)(6), and the CHLA Data Core will direct data management, including integration and verification at CHLA.
- PIs, Co-Is, and biostaticians will direct data analysis at their site or request data analysis from the data core.
- PIs and Co-Is will be involved in data interpretation and dissemination.

Governance/Structure

Communication plan

- These four sites are strategically positioned across the U.S., necessitating synchronization of the cross-site protocol and dissemination plans via on-site, face-to-face meetings and structured ongoing communication via regular teleconferencing. The investigators have budgeted for annual protocol meetings in which all of the teams meet at the CHLA site. This allows the protocol teams, including the study coordinators, to review study progress, discuss protocol changes that may be needed, determine data analysis priorities, conduct rich interpretation dialogs, and support manuscript writing and dissemination activities.
- The MPIs and Co-Is meet monthly by phone with the Data Core Manager and the Coordinating Center Clinical Research Manager to discuss scientific issues, recruitment, study implementation, completion of study manuscripts, dissemination activities, etc. Additional meetings will be scheduled with members of the study team as needed.
- The Study Coordinators meet monthly by phone or videoconference to discuss study implementation, challenges, and helpful hints to successfully implement the study activities.
- Decisions on scientific direction will be made during the monthly MPI phone meetings. Dr. Olson-Kennedy will make final decisions on the implementation of the study protocol, whereas (b)(6) will make final decisions regarding instruments, data collection tools, and the statistical analyses for manuscript preparation.

Procedures for Resolving Conflicts

We do not anticipate unresolvable disagreements among the MPIs as they have several years of working together under the current grant; however, if consensus is not reached for protocol implementation issues, Dr. Garofalo, the senior investigator on the investigative team, will facilitate resolution among the MPIs, and if needed, refer the issues of conflict to third party arbitration consisting of Division Chiefs or Department Chairs of the four institutions. The four sites have determined that the following domains may require third party arbitration in the event of conflict that is not resolved through discussion amongst the sites:

- Authorship dispute – Issues of conflict will be heard by an objective observer from the WPATH executive board.
- Scientific dispute – Scientific conflict will be arbitrated by a pediatric endocrinologist faculty member at Children's Hospital of Pennsylvania.

Distribution of Resources to Four Sites

CHLA will be the primary institution for the receipt of the award and the three other sites will be supported through subcontracts from CHLA. Primary responsibility for administration at the CHLA site is (b)(6) (b)(6) (Division Head), along with financial administrator (b)(6). This team has extensive experience with financial administration of multiple site projects.

To ensure all sites maintain sufficient enrollment, enrollment progress will be assessed by all MPIs every 6 months. If a site is unable to meet its enrollment goals, MPIs may decide to reallocate funds to assist other sites in over-sampling to meet the overall study sample size. This decision will be informed the site's likelihood of meeting its target enrollment, informed by the site's sample size, degree of responsiveness regarding recruitment strategies, and its rate of enrollment to date. The MPIs will democratically reach an agreement on any reallocation of funds, relying on third party arbitrations (see Procedures for Resolving Conflicts above) should this process result in a conflict that requires resolution.

Dissemination

In order to share process and outcome data from this project with the broader scientific community, abstracts will be submitted for presentation to at least one scientific conference per year. Conferences where data may be presented include annual meetings of the Society for Adolescent Health and Medicine, The American Academy of Pediatrics, The World Professional Association of Transgender Health, Pediatric Academic Societies, The Endocrine Society, The American Public Health Association, The American Psychological

Association, The American Psychiatric Association, and others. Manuscripts are planned on the following topics:

- Description of the sample and preliminary results
- Description of the intervention
- Primary outcomes

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Consortium/Contractual Arrangements

PA-18-729 Research on the Health of Transgender and Gender Nonconforming Populations (R01)
Due Date: March 5, 2020
Earliest Start Date if funded: September 1, 2020
Duration of Project Period: Five years
Project Title: The Impact of Early Medical Treatment in Transgender Youth
Primary Applicant: Children's Hospital Los Angeles
Contact Principal Investigator: Johanna Olson-Kennedy, M.D.

The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the agency's consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.

Programmatic & Administrative Arrangements:

Children's Hospital Los Angeles
Children's Hospital Los Angeles (CHLA) will be the primary institution for the receipt of the award and the four partner sites will be supported through subcontracts from Children's Hospital Los Angeles. The Contact Principal Investigator, Johanna Olson-Kennedy, M.D., will take primary responsibility for all study related activities. CHLA will act as the data center or core for the project, and the CHLA research team will have the primary responsibility for creating data protocols in partnership with the other sites and will be the IRB of Record. Programming of changes to the computer survey, modifications of CRFs, and data management, cleaning, and analysis will occur at CHLA.

Boston Children's Hospital
The Principal Investigator, Yee-Ming Chan, M.D., Ph.D., will take primary responsibility for the implementation of the scientific aims of this project at Boston Children's Hospital. Dr. Chan will take primary responsibility for the implementation of the scientific aims of this project at Boston Children's Hospital and will collaborate in the analysis, interpretation, and dissemination of findings. The key personnel at Boston Children's Hospital will collaborate with the partner sites to submit abstracts for presentation at scientific conferences and in co-authorship of publications to disseminate important research findings as a result of this study.

Ann & Robert H. Lurie's Children's Hospital of Chicago
The Principal Investigator, Robert Garofalo, M.D., will take primary responsibility for the implementation of the scientific aims of this project at Lurie Children's Hospital. Dr. Garofalo will take primary responsibility for the implementation of the scientific aims of this project at Lurie Children's Hospital of Chicago and will collaborate in the analysis, interpretation, and dissemination of findings. The key personnel at Lurie Children's Hospital will collaborate with the partner sites to submit abstracts for presentation at scientific conferences and in co-authorship of publications to disseminate important research findings as a result of this study.

University of California San Francisco
The Principal Investigator, Stephen Rosenthal, M.D., will take primary responsibility for the implementation of the scientific aims of this project at the University of California, San Francisco (UCSF). Dr. Rosenthal will take primary responsibility for the implementation of the scientific aims of this project at UCSF and will collaborate in the analysis, interpretation, and dissemination of findings. The key personnel at UCSF will collaborate with the partner sites to submit abstracts for presentation at scientific conferences and in co-authorship of publications to disseminate important research findings as a result of this study.

Callen-Lorde Community Health Center

The Co-Investigator, Asa Radix, M.D., will provide scientific insight and perspective as an experienced clinician researcher as well as a (b)(6). This expansion of our team positions us to have enhanced community engagement, ongoing evaluation of measures, and recommendations for enriched analytic approaches. He will collaborate with the MPIs and Co-Is in the analysis, interpretation, and dissemination of findings. He will also collaborate with the partner sites to submit abstracts for presentation at scientific conferences and in co-authorship of publications to disseminate important research findings as a result of this study.

Fiscal Arrangements

Children's Hospital Los Angeles: includes full project costs (CHLA site costs and consortium and subaward site costs and F&A)

	Direct	Indirect	TOTAL Per Year
Year 1	$	$	$
Year 2	$	$	$
Year 3	$	$	$
Year 4	$ (b)(4)	$ (b)(4)	$ (b)(4)
Year 5	$	$	$
TOTAL	$	$	$

Boston Children's Hospital

	Direct	Indirect	TOTAL Per Year
Year 1	$	$	$
Year 2	$	$	$
Year 3	$	$	$
Year 4	$ (b)(4)	$ (b)(4)	$ (b)(4)
Year 5	$	$	$
TOTAL	$	$	$

Ann & Robert H. Lurie Children's Hospital of Chicago

	Direct	Indirect	TOTAL Per Year
Year 1	$	$	$
Year 2	$	$	$
Year 3	$	$	$
Year 4	$ (b)(4)	$ (b)(4)	$ (b)(4)
Year 5	$	$	$
TOTAL	$	$	$

University of California San Francisco

	Direct	Indirect	TOTAL Per Year
Year 1	$	$	$
Year 2	$	$	$
Year 3	$	$	$
Year 4	$ (b)(5)	$ (b)(4)	$ (b)(4)
Year 5	$	$	$
TOTAL	$	$	$

Callen-Lorde Community Health Center

	Direct	Indirect	TOTAL Per Year
Year 1	$ (b)(4)	$ (b)(4)	$ (b)(4)
Year 2	$	$	$
Year 3	$	$	$
Year 4	$	$	$
Year 5	$	$	$
TOTAL	$	$	$

Letters of Support

Authors of the attached letters of support were approached for use of their letter for this resubmission, which they approved.

Multiple PI and Co-I Letters

1. University of California San Francisco/Benioff Children's Hospital San Francisco and Oakland (Rosenthal, MPI)
2. Boston Children's Hospital/Harvard University (Chan, MPI)
3. Boston Children's Hospital/Harvard University ((b)(6))
4. Ann & Robert H. Lurie Children's Hospital of Chicago/Northwestern University (Garofalo, MPI, and Chen, Co-I)
5. Callen-Lorde, New York, NY (Radix, Co-I)*

Clinical and Translational Science Institute (CTSI) Leadership

6. Southern California Clinical and Translational Science Institute, University of Southern California ((b)(6))
7. University of California San Francisco, Clinical and Translational Science Institute ((b)(6))
8. Northwestern University Clinical and Translational Sciences Institute ((b)(6))

Academic Medical Centers with Multidisciplinary Services for Transgender Youth

9. University of Minnesota's Program in Human Sexuality, Minneapolis, MN ((b)(6))*
10. Children's National Medical Center, Gender Development Program, Washington, DC ((b)(6))
11. MetroHealth Medical Center/Case Western Reserve University, Cleveland, OH ((b)(6))
12. Gender & Sexuality Development Clinic, Children's Hospital of Philadelphia, Philadelphia, PA ((b)(6) (b)(6))
13. Rady Children's Hospital/University of California San Diego, San Diego, CA ((b)(6))
14. Hasbro Children's Hospital/Brown University (Forcier), Providence, Rhode Island ((b)(6))
15. University of California San Francisco's Dimensions Clinic, San Francisco, CA ((b)(6))

Community Health Centers with Health Services for Transgender Youth

16. El Rio Health Center, Tuscon, AZ ((b)(6))

Organizations Focused on Policy and Health Advocacy Impacting Transgender Youth

17. Human Rights Campaign, Youth and Families Program, Washington, DC ((b)(6))
18. The Trevor Project, West Hollywood, CA ((b)(6))
19. Gender Spectrum, San Leandro, CA ((b)(6))

Public Health Researchers

20. Boston Children's Hospital/Harvard T.H. Chan School of Public Health, Boston, MA ((b)(6))*
21. Boston Children's Hospital/Harvard Medical School, Boston, MA ((b)(6))

Community-based Groups

22. Mind the Gap Trans Youth Mental Health Consortium, Oakland, CA ((b)(6))
23. Parents of Transgender Individuals Chicago/PFLAG, Chicago, IL ((b)(6))

***Co-Chair of Revision Committee, World Professional Association for Transgender Health (WPATH) Standards of Care**

University of California
San Francisco

UCSF

Department of Pediatrics
Division of Endocrinology

June 19, 2019

Maya B. Lodish, M.D., MHSc
Gina Capodanno, M.D.
Brian J. Feldman, M.D., Ph.D.
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Dear Dr. Olson:

We are delighted to continue our collaboration with you and the other members of our Multiple Principal Investigator-led teams for the continuation of the project entitled "The Impact of Early Medical Treatment in Transgender Youth" (1R01HD082554) in response to PA-18-729: Research on the Health of Transgender and Gender Nonconforming Populations. Our site, the UCSF Child and Adolescent Gender Center (CAGC) has thus far enrolled more than 100 subjects into our combined 4-site database, and, in particular we have exceeded our enrollment targets for the early pubertal cohort treated with pubertal blockers. While we will complete 24-month follow-up on our study subjects at the end of the current grant period (June, 2020), it is clear that longer-term outcomes studies beyond 24 months are essential to meaningfully assess the physiologic and mental health impact of current clinical practice guidelines for transgender youth.

For this renewal, the following key personnel will work with you and the other investigators in the long-term follow-up of the impact of early medical treatment in transgender youth:

Stephen M. Rosenthal, MD, Site Principal Investigator, will continue to take primary responsibility for the implementation of the scientific aims of this project at UCSF Benioff Children's Hospital, as well as collaborate to disseminate findings.

Diane Ehrensaft, PhD, Site Co-Investigator, will share responsibility for the scientific and fiscal integrity of the project. As a Clinical Psychologist, Dr. Ehrensaft will assist in the implementation of the scientific aims, data collection, data analysis, preparation of manuscripts, and dissemination of findings at scientific meetings. She will also assist Dr. Rosenthal with IRB submissions, and will assist in developing and overseeing recruitment strategies.

Our collaborative proposal has the potential to provide much needed outcomes studies to inform and optimize care for a population of youth that has been often marginalized and poorly understood. We continue to be deeply committed to this work, and seeing it reach its fruition.

Sincerely,

(b)(6)

Stephen M. Rosenthal, MD
Professor of Pediatrics
Division of Pediatric Endocrinology
Medical Director, Child and Adolescent Gender Center

Director, Endocrine Society
Past President, Pediatric Endocrine Society

Boston Children's Hospital
Department of Pediatrics
Division of Endocrinology

Harvard Medical School
Department of Pediatrics

Yee-Ming Chan, M.D., Ph.D.
Associate Physician in Pediatrics, Boston Children's Hospital
Assistant Professor of Pediatrics, Harvard Medical School
300 Longwood Avenue
Boston, Massachusetts 02115
phone (b)(6)
Yee-Ming.Chan@childrens.harvard.edu

June 10, 2019

Dear Jo, Rob, and Steve,

My colleagues at Boston Children's Hospital and I are delighted to continue our collaboration on the Trans Youth Care (TYC) Study. We have much to be proud of: developing a solid research infrastructure to study gender-diverse youth at our four sites, exceeding our recruitment targets, thoughtfully revising our data collection methods to be responsive to the needs of our diverse study cohort, and most of all creating a network of medical providers, mental health providers, and research staff for vibrant scientific exchange. We have been avidly analyzing the baseline data from our study, we are excited to start analyzing the follow-up data emerging from our study, and we are most excited about the prospect of following our cohorts for another five years as they reach key milestones for their physical and psychosocial development.

I anticipate many more years of productive and stimulating collaboration as we continue our vital work to enhance the health and well-being of our gender-diverse patients.

Sincerely,

(b)(6)

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

Boston Children's Hospital

HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

June 9, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I write this letter in support of our research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow us and our collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents (TGNC) beyond a 24-month period. The ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood. We also propose to expand the current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of this study.

I am a (b)(6) at Boston Children's Hospital, which serves TGNC children, adolescents and young adults. I am also on the (b)(6) child and adolescent committee and am a (b)(6). As a (b)(6) I am very aware of how necessary it is to move the field forward with research that will directly affect the care practices and well-being of transgender adolescents and youth, currently a high risk population. I anticipate that this unique and much needed research will disseminate information of high scientific and clinical value to demonstrate the diverse impacts of medical treatments on TGNC youth and young adults, and how to facilitate resilience and better outcomes in this population. Should you be awarded NIH funding, I am certain that our research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria. Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6).

Sincerely,

(b)(6)

(b)(6)

Assistant Professor
Harvard Medical School

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

Ann & Robert H. Lurie
Children's Hospital of Chicago™

July 3, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

We are delighted to continue our collaboration with you and the other members of our Multiple Principal Investigator-led teams for the continuation of the project entitled "The Impact of Early Medical Treatment in Transgender Youth" (1R01HD082554) in response to PA-18-729: Research on the Health of Transgender and Gender Nonconforming Populations. Our site, the Ann & Robert H. Lurie Children's Hospital of Chicago Gender & Sex Development Program (GSDP) has thus far enrolled more than 100 subjects into our combined 4-site database. While we will complete 24-month follow-up on our study subjects at the end of the current grant period (June, 2020), it is clear that longer-term outcomes studies beyond 24 months are essential to meaningfully assess the physiologic and mental health impact of current clinical practice guidelines for transgender youth.

For this renewal, the following key personnel will work with you and the other investigators in the long-term follow-up of the impact of early medical treatment in transgender youth:

Rob Garofalo, MD, MPH, Site Principal Investigator, will continue to take primary responsibility for the implementation of the scientific aims of this project at Lurie Children's, as well as collaborate to disseminate findings.

Diane Chen, PhD, Site Co-Investigator, will share responsibility for the scientific and fiscal integrity of the project. As a Pediatric Psychologist, Dr. Chen will assist in the implementation of the scientific aims, data collection, data analysis, preparation of manuscripts, and dissemination of findings at scientific meetings. She will also assist Dr. Garofalo with IRB submissions, and will assist in developing and overseeing recruitment strategies.

Our collaborative proposal has the potential to provide much needed outcomes studies to inform and optimize care for a population of youth that has been often marginalized and poorly understood. We continue to be deeply committed to this work, and seeing it reach its fruition.

Ann & Robert H. Lurie
Children's Hospital of Chicago™

Sincerely,

(b)(6)

Rob Garofalo, MD, MPH
Division Chief, Potocsnak Family Division of Adolescent and Young Adult Medicine
Director, Adolescent HIV Services
Director, Center for Gender Sexuality and HIV Prevention
Co-Director, Gender & Sex Development Program
Ann & Robert H. Lurie Children's Hospital of Chicago
Professor of Pediatrics and Preventive Medicine
Northwestern University Feinberg School of Medicine

(b)(6)

Diane Chen, PhD
Pediatric Psychologist
Behavioral Health Director, Potocsnak Family Division of Adolescent and Young Adult Medicine
Ann & Robert H. Lurie Children's Hospital of Chicago
Assistant Professor of Psychiatry and Behavioral Sciences, and Pediatrics
Northwestern University Feinberg School of Medicine

CALLEN-LORDE

6/12/2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood.

You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study.

My background is in internal medicine and infectious diseases, with specific training in epidemiology and public health. I am very familiar with the medical and bio-psychosocial issues affecting transgender communities. I am currently the co-chair the World Professional Association of Transgender Health Stands of Care Revision Committee as well as serving on the WPATH board. I am very familiar with the gaps in research, especially for transgender children and adolescents. The results of this study will result in much needed information to inform clinical standards. It has high scientific and clinical value. Although similar studies are underway in Europe, this is the first to be conducted in racially and ethnically diverse communities and is therefore likely to have much greater impact for the global community.

Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6).

Sincerely,

(b)(6)

Asa Radix, MD, MPH, FACP
Senior Director of Research and Education

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

Chelsea
356 West 18th Street
New York, NY 10011
212.271.7200

Thea Spyer Center
230 West 17th St
New York, NY 10011
212.271.7200

Bronx
3144 3rd Ave
Bronx, NY 10451
718.215.1800

Southern California
Clinical and Translational Science Institute
Translating Science into Solutions for Better Health

June 14, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

As (b)(6) of the Southern California Clinical and Translational Science Institute (SC CTSI) and (b)(6) in the Department of Pediatrics at Children's Hospital Los Angeles (CHLA), it is with enormous enthusiasm that I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood. You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study. To be sure, your proposed research is highly significant, innovative, and timely, and you have my full and enthusiastic support.

The University of Southern California (USC) and Children's Hospital Los Angeles (CHLA) have a large Clinical and Translational Science Award from the National Institutes of Health, called the Southern California Clinical and Translational Science Institute (SC CTSI). The SC CTSI has built an organization devoted entirely to improving the success of translational science with diverse populations, using an array of tools and programs that support researchers and their work. The SC CTSI has emerged as a valuable, multifaceted resource for pre-clinical, clinical and community-partnered translational research at USC, CHLA, and throughout Southern California. To date the SC CTSI has supported more than 900 investigators in their quest to create and apply new diagnostic and therapeutic advances, medical procedures, and behavioral interventions to improve clinical care and the health of individuals and the public.

I assure you that you and your entire team here at CHLA will continue to have the full support of our SC CTSI, which may include the availability of additional resources such as statistical support, community engagement, and any assistance needed for implementing the highest quality clinical trials and clinical and translational research. We will work with your research team to disseminate necessary scientific findings that improve the delivery of health care and medical intervention to youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6).

Sincerely,

(b)(6)

University of Southern California
2250 Alcazar Street, Suite 200, Los Angeles CA 90033

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

University of California
San Francisco

UCSF

Department of Family & Community Medicine

(b)(6)

Mailing address:

(b)(6)

Tel: (b)(6)
Fax: (b)(6)
Email: (b)(6)

June 20, 2019

Stephen M. Rosenthal, MD
Medical Director, Child and Adolescent Gender Center
UCSF Benioff Children's Hospital
Mission Hall, Global Health & Clinical Sciences
550 – 16th Street, 4th Floor
San Francisco, CA 94143

Dear Dr. Rosenthal,

I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood. You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study.

As a (b)(6)
(b)(6)
Program, I recognize the tremendous value of the research you are conducting. Clinicians, patients, and families desperately need more scientific evidence on the long-term outcomes of gender-affirming health care to guide clinical practice and shared decision making by patients and families. Critical to the success of this research is engaging the transgender and broader LGBTQ community as partners in participatory research. Our Community Engagement Program looks forward to working with you and your multicenter research team to optimize stakeholder engagement in your proposed study. I assure you that, should you be awarded NIH funding, you and your entire team here at UCSF will have the full backing and support of our CTSI, as needed. We will work with your research team to disseminate

scientific findings that improve the delivery of health care and medical intervention to youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic.

Sincerely,

(b)(6)

Cc: Johanna Olson-Kennedy, MD, Robert Garofalo MD, Yee-Ming Chan MD, Asa Radix MD

Northwestern Medicine®

NUCATS Clinical and Translational Sciences Institute

(b)(6)

(b)(6)
Tel: (b)(6)
Fax: (b)(6)
Email: (b)(6)

(date)

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

The Northwestern University Clinical and Translational Science Institute and the Stanley Manne Research Institute of Ann & Robert H. Lurie Children's Hospital of Chicago enthusiastically support your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." This funding will extend current research conducted at Lurie Children's Hospital] under the leadership of Dr. Robert Garofalo, allowing you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently funded by the NICHD) for an additional 5-year period, allowing your team to continue to examine both short and longer-term physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond your originally proposed 24-month period. As this is the only U.S cohort study of its kind, the ability to extend observation of this sample over time is imperative and will yield much-needed information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood. You research will also begin to elucidate critically important questions previously unexplored in the literature about the clinical care decisions and paradigms and as such is of considerable public health significance.

Your proposal to expand your current work and sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of adds significantly to its innovation and clinical/public health significance. Dr. Garofalo is uniquely positioned to be the PI of the proposed research here at Northwestern University Feinberg School of Medicine and Lurie Children's. He has 20 years of clinical experience working with transgender populations. He started and co-directs the Lurie Children's Gender & Sex Development Program and is considered to leader in the emerging academic discipline that is transgender health. He is the Editor-in-Chief of the journal Transgender Health. Dr. Garofalo also has extensive experience leading and conducting NIH funded research. He has been the PI on 13 NIH research grants and a Co-I on an additional 18 research projects funded by the NIH.

I assure you that Dr. Garofalo and his entire team here at Lurie Children's Hospital and Northwestern University will have the full backing and support of NUCATS and the Manne Institute, including but not limited to statistical support, community engagement, and any assistance required for the conduct of the highest quality clinical and translational research. With this NIH funding, we will work with your research team to disseminate necessary scientific findings that improve the delivery of health care and medical intervention to youth with gender dysphoria.

The Clinical and Translational Research Program of the Manne Children's Research Institute is a partner of the Northwestern University Clinical and Translational Sciences (NUCATS) Institute. NUCATS was launched in 2007 to create an integrated hub supporting and accelerating clinical and translational science (CTS) across Northwestern University (NU; including 6 schools), our 3 nationally-renowned clinical partners, our Chicago community and stakeholders, and across the broad consortium of CTSA-funded institutions. NU is a leading national research university affiliated with Ann & Robert H. Lurie Children's Hospital of Chicago, Northwestern Memorial HealthCare Corp., and the Shirley Ryan Ability Lab (formerly the Rehabilitation Institute of Chicago), each of which is ranked in the top 10 among its peer hospitals nationally. NUCATS was designed to leverage and advance the strengths of NU researchers and all of our partners to enhance CTS, and has been supported continuously since 2008 by ~$60 million in CTSA award funding from NIH and ~$75 million in financial and in-kind support from NU and its partners. This proposal is strongly aligned with the NUCATS and Lurie Children's mission and goals, including our strong commitments to populations underrepresented in biomedical research, and has our unqualified support.

Sincerely,

(b)(6)

(b)(6)

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Program in Human Sexuality
Department of Family Medicine and Community Health
Medical School

1300 South 2nd Street, Suite 180
Minneapolis , MN 55454
Office: (b)(6)
Fax: (b)(6)

June 17, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood.

You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study.

As (b)(6) at the University of Minnesota Medical School and have been working in the field of transgender health for 40 years, I applaud this effort recognizing the critical need for further research in this area. Also as (b)(6) (b)(6) I appreciate how valuable the findings of this research for advancing best practices of gender-affirming medical care among adolescence. This is an area that is woefully under researched.

Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact (b)(6).

(b)(6)

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD

Johanna Olson-Kennedy, MD
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles CA 90027

June 20th, 2019

Dear Dr. Olson-Kennedy:

I am writing to express my strong support for your proposal to the National Institutes of Health entitled, "The Impact of Early Medical Treatment in Transgender Youth." I am aware that this proposal extends the assessment period of the original Trans Youth Care Study. The field of youth gender care has struggled due to a lack of research and an over-focus on cross-sectional (single time point) designs. The few existing "outcome" studies of transgender youth have included extremely small samples and two or three time-points. I am confident that your proposed study will be a major contribution to the field given its: rich sampling of youth over multiple time-points and extended assessment period into later adolescence and young adulthood. Because you have already curated one of the largest and most diverse samples of well-characterized transgender youth, your current proposal to continue to follow them over time is clearly feasible. Further, your plan to expand sampling across your four sites to better represent the growing ethnic/racial diversity of adolescents seeking gender-affirming care is critical given the limited generalizability of previous gender-care studies due to mono-cultural recruitments.

As you know, I am the (b)(6) Children's National Medical Center in Washington, DC. The Gender Development Program is one of the first founded pediatric gender programs nationally, and serves the large and diverse Washington, DC metropolitan area. Findings from the Trans Youth Care Study and its proposed extension are needed to inform and refine clinical care such as that provided in our program, as the number of transgender and gender diverse youth presenting for gender care continues to increase. We must better understand both the physiological and psychosocial outcomes of gender-affirming medical intervention over time, as current care standards are understudied. Your ability to extend observation of your sample into later adolescence and young adulthood will provide key information regarding longer-term safety and side effects of gender-affirming medical care. Should your proposal be funded, I am hopeful that your group will continue to share scientific findings with the broad community to optimize the safe and effective delivery of medical care to transgender youth. Please keep me informed of ways that I may support your important work.

Sincerely,

(b)(6)

Children's National Medical Center (Washington, DC)

Cc: Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD, Robert Garofalo MD

MetroHealth

CASE SCHOOL OF MEDICINE

June 6, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

This letter is in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood.

I am pleased that you also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study.

I cannot emphasize enough how critical it is that we systematically measure the long-term outcomes in this study. As a psychologist involved with research and clinical services for gender-diverse youth since 2008, I am confident this study would provide much-needed data with high scientific and clinical value.

Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6) or (b)(6).

Sincerely,

(b)(6)

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

Children's Hospital of Philadelphia℠
PolicyLab
3401 Civic Center Blvd. • Philadelphia, PA 19104 • (b)(6) • chop.edu

June 18, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood.

You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study.

As the (b)(6)
Development we now care for more than 1300 transgender and gender-diverse children and adolescents. We each have more than 10 years of experience providing clinical care and conducting research with transgender youth. In light of our experience in the field of pediatric transgender health we find your proposed study to be of high scientific and clinical value as we have a paucity of long term data to guide clinical management.

Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6).

Sincerely,

(b)(6)

The Children's Hospital of Philadelphia
3550 Market Street, (b)(6)
Philadelphia, PA, 19104

(b)(6)

The Children's Hospital of Philadelphia
3550 Market Street, (b)(6)
Philadelphia, PA, 19104

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

Rady Children's Specialists of San Diego
A Medical Foundation

UC San Diego
SCHOOL OF MEDICINE

Advancing the future of pediatric healthcare...together.

Pediatric Endocrinology and Diabetes

Attending:
Michael Gottschalk, MD, PhD
Division Chief
Laura Barba, RNC. MS. NNP
Patricia Clark, MD
Giana Consiglieri, PNP
Carla Demeterco, MD, PhD
Kenneth L. Jones, MD
Thomas G. Kelly, MD
Jane J. Kim, MD
Karen Klein, MD
Maja Marinkovic, MD
Ron Newfield, MD
Susan Phillips, MD

Fellows:
Abigail Fruzza, MD
Audrey Briscoe, MD
Hiba Al-Zubeidi, MD

Nurses:
Karen Haddad, RN, MS, C-PNP
Andrea Huber, RN, CDE
Beth McFeely, RN, CDE
Kim McNamara, RN, BSN
Emalie Sherrell, RN
Emily Spangenberg, RN, BSN

Dietician:
Vanessa Aldaz, MPH, RD, CDE
Lisa Ameer, MSNH, RD, CDE

Social Worker:
Eleanor Lazarow, LCSW
Renee Price, LCSW

Mailing Address:
3020 Children's Way
Mail Code (b)(6)
San Diego, CA 92123

(b)(6) Fax

Regional Offices:
Encinitas
Escondido
Murrieta
Oceanside

www.RCSSD.org

June 20, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood.

You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study.

As a (b)(6) who has been providing care to transgender/gender nonconforming (TGNC) youth since 2012, I have a deep understanding of the importance of the research that you and your colleagues are conducting. In the field of transgender medicine, the long-term outcome data relevant to pediatric and adolescent population are very scarce. Therefore, it is of utmost importance for researchers such as Dr. Olson-Kennedy and colleagues to continue their work on prospective data gathering. This will enable them to provide valuable information on safety, efficacy, possible side effects and other relevant data from large and diverse cohorts.

Rady Children's Specialists of San Diego
A Medical Foundation

UC San Diego
SCHOOL OF MEDICINE

Advancing the future of pediatric healthcare...together.

Pediatric Endocrinology and Diabetes

Attending:
Michael Gottschalk, MD, PhD
Division Chief
Laura Barba, RNC. MS. NNP
Patricia Clark, MD
Giana Consiglieri, PNP
Carla Demeterco, MD, PhD
Kenneth L. Jones, MD
Thomas G. Kelly, MD
Jane J. Kim, MD
Karen Klein, MD
Maja Marinkovic, MD
Ron Newfield, MD
Susan Phillips, MD

Fellows:
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Audrey Briscoe, MD
Hiba Al-Zubeidi, MD

Nurses:
Karen Haddad, RN, MS, C-PNP
Andrea Huber, RN, CDE
Beth McFeely, RN, CDE
Kim McNamara, RN, BSN
Emalie Sherrell, RN
Emily Spangenberg, RN, BSN

Dietician:
Vanessa Aldaz, MPH, RD, CDE
Lisa Ameer, MSNH, RD, CDE

Social Worker:
Eleanor Lazarow, LCSW
Renee Price, LCSW

Mailing Address:
3020 Children's Way
Mail Code (b)(6)
San Diego, CA 92123

(b)(6) Fax

Regional Offices:
Encinitas
Escondido
Murrieta
Oceanside

www.RCSSD.org

Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6).

Sincerely,

(b)(6)

(b)(6)
Rady Children's Hospital
3030 Childrens Way
San Diego, CA 92123
Office: (b)(6)
FAX: (b)(6)

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

Rhode Island Hospital
Hasbro Children's Hospital
A Lifespan Partner

June 20 2019

Department of Pediatrics
Division of Adolescent Medicine

593 Eddy Street
Providence, RI 02903
Academic Office
Tel
Fax (b)(6)

Adolescent Clinic
3055 Coro West 1 Hoppin St
Providence RI 02903
Tel
Fax (b)(6)

Abigail A. Donaldson, MD
Patricia Flanagan, MD
Michelle Forcier, MD MPH
Sherry Gagnon, NP
Unab Khan, MD
Margaret Kozel, MD
Suzanne Palinski, MD
Jack Rusley, MD

Medicine Pediatrics Clinic
245 Chapman St
Providence RI 02903

Department of Pediatrics
The Warren Alpert Medical School of Brown University

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood. You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study.

Our clinic is a high volume academic center in New England that care for pediatric, adolescent, adult patients of all ages. We serve over 500 gender diverse patients and collaborate with a variety of training residency programs and students (medical and nurse practitioner) in Rhode Island and Massachusetts. Your research is approached with scientific integrity, attention to patient needs, and has great ongoing scientific and clinical value. We fully and strongly support continued and increased funding for this very necessary project.

Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at [PHONE].

Sincerely,

(b)(6)

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

University of California
San Francisco

UCSF

Department of Psychiatry
School of Medicine

San Francisco General Hospital
1001 Potrero Avenue
San Francisco, CA 94110
tel: (b)(6)
fax: (b)(6)

June 15, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood.

You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study.

I have been working in transgender health at UCSF for over 25 years, and for the last 16 years have worked as the (b)(6) a multiagency collaborative funded by the San Francisco Department of Public Health to care for trans youth. As a coauthor of (b)(6) and a (b)(6), I know the high scientific and clinical importance of longitudinal data on the healthcare of transgender youth. I am aware of the work that you and your collaborators of doing and I believe the continuation of this work, and the information to be derived from it, is of critical importance to guide healthcare providers and researchers in doing our work.

Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6) or (b)(6).

Sincerely,

(b)(6)

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

EL RIO
COMMUNITY HEALTH CENTER

06/18/2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood.

You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study. This would be very helpful for us, as our population in Arizona is predominantly Hispanic, a population that has not been thoroughly studied for gender-affirming care.

I am the (b)(6). Our center provides care for approximately 175 youth ages 4-21 (we also have an adult program that cares for about 300 adult transgender patients). We provide age appropriate primary care as well as puberty blockers and gender-affirming hormone therapy.

Our program would not exist without this research. The high scientific and clinical value of your study cannot be overstated. When we first started our program, we used your research published to date as well as presentations you have done to explain why we needed to provide this service to our patients and to show that what we were doing was not experimental. Your research has shown us that we save lives by intervening early in the care of transgender youth.

Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6)

Sincerely,

(b)(6)

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

El Pueblo Clinic El Rio Health Center
(b)(6)
101 W Irvington Rd
Tucson, AZ 857143050

June 6, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood.

You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study.

In my role as the (b)(6), I provide national leadership and expertise in public education and advocacy efforts on behalf of LGBTQ youth and families. I speak frequently at national and regional conferences and provide training and consultation for child welfare professionals, educators, and healthcare providers. Prior to joining HRC, I (b)(6) (b)(6), and supervisor of a behavioral health program for people with HIV. I am well aware of the urgent need for affirming care for transgender youth; the proposed study is of high scientific and clinical value, and I believe with great conviction that this work saves lives.

Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6).

(b)(6)
Human Rights Campaign Foundation

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD

June 8, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I am happy to write this letter on behalf of The Trevor Project's Research Department in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The data your team is collecting via the Trans Youth Care (TYC) Study examining physiological and psychosocial outcomes of gender-affirming medical intervention among transgender and non-binary adolescents is critical for improving our understanding of these innovative and life-saving treatments. Your ability to extend observation of this sample beyond a 24-month period will vastly improve the field's understanding of longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they continue to mature into young adulthood.

Additionally, your proposal to improve representation of transgender and non-binary youth of color presenting for gender-affirming medical care will be enormously valuable. At The Trevor Project, we value culturally relevant evidence-based care in mental health and medicine. We also recognize that intersectional identities such as race, ethnicity, gender identity, and sexual orientation may be differently impacted by changes experienced as a result of gender-affirming medical care.

Based on my expertise in implementation of evidence-based care for youth and specifically for LGBTQ youth at elevated risk for suicide, I view this research as crucial to improving our understanding of youth's experience of this care.

I look forward to the opportunity to continue learning from the valuable work of your research team to maximize safe and effective delivery of medical intervention for transgender and non-binary youth with gender dysphoria. Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6).

Sincerely,

(b)(6)

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

gender spectrum

June 12, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I enthusiastically write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood.

Your proposal to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study is also very important. We know from first-hand experience with thousands of youth and their families that race, ethnicity and regional sense of place all factor into the determination of effective care for youth.

Your research is desperately needed. Every day in our work at Gender Spectrum we see the challenges families and clinicians have as they struggle to effectively meet the health care needs of transgender and other gender non-conforming youth. The lack of data, especially longitudinal data, leaves many providers without clear guidance regarding how to best meet the needs of those in their care. Your study has both high research and clinical significance and will allow youth across the country to receive more effective treatment.

Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me by phone at (b)(6), or by email at (b)(6).

Sincerely,

(b)(6)

Gender Spectrum

gender spectrum

1271 Washington Ave.
San Leandro, CA 94577

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD

Boston Children's Hospital
Until every child is well™

HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

6/14/19

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood.

You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study.

As an (b)(6), my research focuses on health disparities and inequities in transgender and gender non-binary communities. I am an (b)(6) at Boston Children's Hospital / Harvard Medical School, and (b)(6) at Harvard T.H. Chan School of Public Health I am also (b)(6) (b)(6), a local Boston-area community health center serving more than 3,500 transgender patients. I offer my full support of this proposal with high scientific and clinical value.

Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6).

Sincerely,

(b)(6)

Division of General Pediatrics, Boston Children's Hospital

(b)(6)

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD

Boston Children's Hospital
Until every child is well™

Division of Adolescent/Young Adult Medicine
300 Longwood Avenue
Boston, Massachusetts 02115
Phone (b)(6)
Fax (b)(6)

June 7, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the ongoing Trans Youth Care (TYC) Study to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study. Your ability to extend observation of this sample over time and expand your sample to increase racial/ethnic diversity will yield greater information on the longer-term safety and side effects of gender-affirming medical care with a diverse group of understudied youth as they develop over adolescence and into young adulthood.

I am a researcher with over 10 years of experience working with the transgender community. One of my primary areas of research is psychosocial functioning of transgender youth and their families. I recently finished data collection for a NIH-funded community-based longitudinal mixed methods study of transgender teens and their families to understand how the family environment is related to transgender and non-binary teens' health and well-being across two years. The field of transgender youths' health has been limited in the lack of research on the longitudinal effects of gender-affirming medical care. Findings from the proposed research will significantly contribute to both knowledge about and clinical care with transgender youth. Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to transgender/gender-nonconforming youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6) or (b)(6).

Sincerely,

(b)(6)

(b)(6)

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

Mind the Gap

trans youth mental health consortium
Child and Adolescent Gender Center
(b)(6)

Oakland, California 94610

June 15, 2019

Stephen Rosenthal, MD
Pediatric Endocrinology
Child and Adolescent Gender Center
Division of Pediatrics
University of California San Francisco
San Francisco, CA 94118

Dear Dr. Rosenthal:

We write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender, gender creative, and gender-nonconforming adolescents beyond a 24-month period. Your opportunity to extend observation of this sample over time will yield greater information on the long term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood. The field of transgender healthcare needs this data to inform best practices with youth.

You and your colleagues also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study. We applaud this expansion.

Your study is ground breaking and critically needed to advance the science and develop the standards of practice for clinical work with transgender, gender creative, and gender-nonconfroming youth. The 300+ youth serving health professionals represented by our group **Mind the Gap** are practicing state of the art evaluation and treatment for the youth being studied. Our group represents the majority of mental health clinicians involved in the community with the patients of the Child and Adolescent Gender Clinic at UCSF. Many of our members are nationally known contributors to the care for these youth and we are devoted to excellence and evidence based practice. Through the various organizations in which we collectively are involved we are deeply involved in building capacity in caring for these special young people and their families.

Mind the gap support page 2

Should you be awarded NIH funding, we are hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep us posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6) and (b)(6)

(b)(6)

Mind the Gap

Cc: Robert Garofalo MD, Johanna Olson-Kennedy, MD, Yee-Ming Chan MD, Asa Radix MD

Parents of Transgender Individuals
Support Group

PFLAG

June 20, 2019

Johanna Olson-Kennedy, MD
Division of Adolescent and Young Adult Medicine
Children's Hospital Los Angeles
4650 Sunset Blvd., MS#2
Los Angeles, CA 90027

Dear Dr. Olson-Kennedy,

I write this letter in support of your research proposal submission to the National Institutes of Health entitled "The Impact of Early Medical Treatment in Transgender Youth." The funding for this proposed research will allow you and your collaborators to extend the observational period of the Trans Youth Care (TYC) Study (currently underway) to examine physiological and psychosocial outcomes of gender-affirming medical intervention among transgender/gender-nonconforming adolescents beyond a 24-month period. Your ability to extend observation of this sample over time will yield greater information on the longer-term safety and side effects of gender-affirming medical care with this understudied group of youth as they develop over adolescence and into young adulthood.

You also propose to expand your current sample to better represent the growing ethnic/racial diversity of adolescents presenting for gender-affirming medical care across each of the four sites of your study.

As an organization that cares about young TGNC people and their families we at PTI Chicago value the importance of this proposed study that will be of high scientific and clinical significance and will add to the knowledge base of those professionals that care for our children.

Should you be awarded NIH funding, I am hopeful that your research team will continue to disseminate necessary scientific findings that improve the safe and effective delivery of medical intervention to TGNC youth with gender dysphoria.

Please keep me posted on how I can be of assistance in your important work on this topic. You may contact me at (b)(6)

Sincerely,

(b)(6)

Parents of Transgender Individuals Chicago

Cc: Robert Garofalo MD, Stephen Rosenthal MD, Yee-Ming Chan MD, Asa Radix MD

DATA SHARING PLAN

The proposed research will include data from 316 transgender youth in the gender-affirming hormone (GAH) cohort and 95 in the puberty blocker (GnRHa) cohort that will include survey data and lab data for bone densitometry, hormone levels, and other physiologic and anthropometric parameters collected from four participating sites at baseline through up to seven years. It will also include data from the 95 parents/caregivers of the GnRHa participants seeking puberty suppression. New enrollees (n=202) from selected demographics will have data from baseline through up to four years following initiation of either a GnRHa or GAH. The final datasets will include self-reported demographic and behavioral data from surveys with the participants and laboratory data from specimens provided for routine care of transgender youth. The dataset for the GnRHa cohort will also include demographic and behavioral and mental health data about the youth provided by the parent/caregiver.

We wish to make our results available to the transgender community, mental and medical health providers, public health practitioners, and scientists interested in studying the provision of competent mental and medical healthcare for transgender youth and young adults. Thus, we will submit the data to the NICHD Data and Specimen Hub (DASH) as rapidly as possible. Our plan also includes sharing study findings through multiple presentations at meetings of both community audiences (such as the World Professional Association of Transgender Health, GLMA, Gender Odyssey, Gender Spectrum, Gender Infinity) and national pediatric and transgender health conferences (such as American Academy of Pediatrics, Society for Adolescent Health and Medicine, U.S. Professional Association of Transgender Health, Pediatric Academic Societies).

PI: **Olson, Johanna**	Title: The Impact of Early Medical Treatment in Transgender Youth	
Received: 11/05/2014	Opportunity: PA-12-111	Council: 05/2015
Competition ID: FORMS-C	FOA Title: RESEARCH ON THE HEALTH OF LGBTI POPULATIONS [R01]	
1R01HD082554-01A1	Dual: MH	Accession Number: 3760705
IPF: 1520001	Organization: CHILDREN'S HOSPITAL OF LOS ANGELES	
Former Number:	Department: Pediatrics	
IRG/SRG: CHHD-M	AIDS: N	Expedited: N
Subtotal Direct Costs (excludes consortium F&A) Year 1: (b)(4) Year 2: (b)(4) Year 3: (b)(4) Year 4: (b)(4) Year 5: (b)(4)	Animals: N Humans: Y Clinical Trial: N Current HS Code: (b)(4) HESC: N	New Investigator: N Early Stage Investigator: N

Senior/Key Personnel:	*Organization:*	*Role Category:*
Johanna Olson M.D.	Children's Hospital Los Angeles	PD/PI
Marvin Belzer M.D.	Children's Hospital Los Angeles	Co-Investigator
(b)(6)	(b)(6)	Co-Investigator
Sheree Schrager Ph.D	Children's Hospital Los Angeles	Co-Investigator
Norman Spack M.D.	Boston Children's Hospital	MPI
Daniel Shumer M.D.	Boston Children's Hospital	Co-Investigator
(b)(6)	(b)(6)	Co-Investigator
Robert Garofalo M.D.	Lurie Children's Hospital of Chicago	MPI
Lisa Simons M.D.	Lurie Children's Hospital of Chicago	Co-Investigator
Marco Hidalgo Ph.D	Lurie Children's Hospital of Chicago	Co-Investigator
Scott Leibowitz M.D.	Lurie Children's Hospital of Chicago	Co-Investigator
Courtney Finlayson M.D.	Lurie Children's Hospital of Chicago	Co-Investigator
Joel Frader M.D.	Lurie Children's Hospital of Chicago	Other (Specify)-Ethicist
Stephen Rosenthal M.D.	University of California at San Francisco	MPI
Diane Ehrensaft Ph.D	University of California at San Francisco	Co-Investigator
David Glidden Ph.D	University of California at San Francisco	Co-Investigator

Appendices

Appx b consent permission assent forms,Appx c early pubertal cohort tg specific measures,Appx d late pubertal cohort tg specific measures,Appx a wpath and endocrine society letters

OMB Number: 4040-0001
Expiration Date: 06/30/2016

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE	State Application Identifier

1. TYPE OF SUBMISSION*

❍ Pre-application ❍ Application ● Changed/Corrected Application

4.a. Federal Identifier
HD082554

b. Agency Routing Number

2. DATE SUBMITTED | **Application Identifier**

c. Previous Grants.gov Tracking Number
Grant11778312

5. APPLICANT INFORMATION **Organizational DUNS*:** 052277936

Legal Name*: Children's Hospital Los Angeles
Department: Sponsored Projects Office
Division: The Saban Research Institute
Street1*: 4650 Sunset Blvd., MS #97
Street2:
City*: Los Angeles
County: Los Angeles
State*: CA: California
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 90027-6062

Person to be contacted on matters involving this application
Prefix: (b)(6) First Name*: (b)(6) Middle Name: (b)(6) Last Name*: (b)(6) Suffix:
Position/Title: (b)(6)
Street1*: 4650 Sunset Boulevard, Mailstop #97
Street2:
City*: Los Angeles
County:
State*: CA: California
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 90027-6062
Phone Number*: (b)(6) Fax Number: 323-361-8054 Email: chlaawards@chla.usc.edu

6. EMPLOYER IDENTIFICATION NUMBER *(EIN) or (TIN)** 95-1690977

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

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

8. TYPE OF APPLICATION*

❍ New ● Resubmission
❍ Renewal ❍ Continuation ❍ Revision

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

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

9. NAME OF FEDERAL AGENCY*
National Institutes of Health

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER
TITLE:

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

12. PROPOSED PROJECT
Start Date* 07/01/2015
Ending Date* 06/30/2020

13. CONGRESSIONAL DISTRICTS OF APPLICANT
CA-028

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: Dr. First Name*: Johanna Middle Name: Last Name*: Olson Suffix: M.D.
Position/Title: Assistant Professor
Organization Name*: Children's Hospital Los Angeles
Department: Pediatrics
Division: Adolescent Medicine
Street1*: 4650 Sunset Blvd., MS#2
Street2:
City*: Los Angeles
County: Los Angeles
State*: CA: California
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 90027-6062
Phone Number*: (b)(6) Fax Number: 323-913-3614 Email*: jolson@chla.usc.edu

15. ESTIMATED PROJECT FUNDING

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

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

a. YES ○ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:
DATE:
b. NO ● PROGRAM IS NOT COVERED BY E.O. 12372; OR
○ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

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

● I agree*

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

18. SFLLL or OTHER EXPLANATORY DOCUMENTATION File Name:

19. AUTHORIZED REPRESENTATIVE

Prefix: (b)(6) First Name*: (b)(6) Middle Name: (b)(6) Last Name*: (b)(6) Suffix:
Position/Title*: (b)(6)
Organization Name*: Children's Hospital Los Angeles
Department: Sponsored Projects Office
Division: The Saban Research Institute
Street1*: 4650 Sunset Blvd., MS #97
Street2:
City*: Los Angeles
County: Los Angeles
State*: CA: California
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 90027-6062
Phone Number*: (b)(6) Fax Number: 323-361-8054 Email*: chlaawards@chla.usc.edu

Signature of Authorized Representative*
(b)(6)

Date Signed*
11/05/2014

20. PRE-APPLICATION File Name:

21. COVER LETTER ATTACHMENT File Name:1235-Cover Letter.pdf

424 R&R and PHS-398 Specific Table Of Contents

Number of Attachments in Appendix: 4

OMB Number: 4040-0010
Expiration Date: 06/30/2016

Project/Performance Site Location(s)

Project/Performance Site Primary Location

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

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

Project/Performance Site Location 1

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

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

Project/Performance Site Location 2

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

Organization Name:	Lurie Children's Hospital of Chicago
DUNS Number:	0744387550000
Street1*:	225 East Chicago Avenue
Street2:	
City*:	Chicago
County:	Cook County
State*:	IL: Illinois
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	60614-3393
Project/Performance Site Congressional District*:	IL-005

Funding Opportunity Number: PA-12-111. Received Date: 2014-11-05T18:44:21.000-05:00

Project/Performance Site Location 3

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

Organization Name:	University of California at San Francisco
DUNS Number:	0948783370000
Street1*:	400 Parnassus Ave, Second Floor
Street2:	
City*:	San Francisco
County:	San Francisco
State*:	CA: California
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	94143-0296
Project/Performance Site Congressional District*:	CA-012

File Name

Additional Location(s)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Other Project Information

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

1.a. If YES to Human Subjects

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

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

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

IRB Approval Date:

Human Subject Assurance Number 00001914

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

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ○ Yes ○ No

IACUC Approval Date:

Animal Welfare Assurance Number

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

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

4.b. If yes, please explain:

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

4.d. If yes, please explain:

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

5.a. If yes, please explain:

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

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	1236-Project Summary Abstract.pdf
8. Project Narrative*	1237-Project Narrative.pdf
9. Bibliography & References Cited	1238-References.pdf
10.Facilities & Other Resources	1239-Facilities and Resources.pdf
11.Equipment	
12. Other Attachments	1240-LargeGrantWaiverApproval.pdf

Funding Opportunity Number: PA-12-111. Received Date: 2014-11-05T18:44:21.000-05:00

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 transgender youth who are gender dysphoric (persistently distressed about gender incongruence) are at increased risk for negative mental and medical health outcomes including anxiety, depression, HIV acquisition, suicide, and substance use compared to their peers**.** Therefore, medical intervention is aimed at alleviating gender dysphoria and ameliorating potential negative outcomes. Existing strategies for treating transgender youth depend on the developmental stage at which these youth present for care. For those transgender youth that present for care in the early stages of pubertal development, treatment is aimed at suppressing their endogenous puberty in order to avoid the development of undesired secondary sexual characteristics that intensify the distress associated with gender incongruence. For those youth in later stages of puberty, the goal of treatment is to use cross-sex hormones in order to induce the development of desired secondary sexual characteristics that bring the body into closer alignment with the youth's internal sense of gender. In 2011, the Institute of Medicine emphasized a clear need for the development of evidence-based and rigorous research aimed at understanding the health implications of hormone use in transgender individuals. The proposed study networks four academic sites around the country (Children's Hospital Los Angeles/University of Southern California, Boston Children's Hospital, Lurie Children's Hospital of Chicago/Northwestern University, and University of California San Francisco) with dedicated transgender youth clinics to conduct a multi-site observational study examining the physiological and psychosocial outcomes of existing medical treatment protocols for transgender youth with gender dysphoria. The study will include two groups of gender dysphoric youth: one in the earliest stages of pubertal development to assess the impact of puberty suppression, and one in later stages of pubertal development to assess the impact of cross-sex hormones for gender transition. Specifically, in the earlier pubertal cohort (Tanner stages 2-3; n=80) the study will evaluate the impact on mental health, psychological well-being, physiologic parameters and bone health as well as document safety of GnRH agonists administered for puberty suppression. In the later pubertal cohort (Tanner stages 4-5; n=200) the study will evaluate the impact on mental health, psychological well-being, and metabolic/physiologic parameters, as well as document the safety of cross-sex hormones administered for gender transition. This multi-center study will be the first in the U.S. to evaluate longitudinal outcomes of medical treatment for transgender youth and will provide essential evidence-based data on the physiological and psychosocial effects and safety of treatments currently used for transgender youth.

PROJECT NARRATIVE

The Institute of Medicine's 2011 report "The Health of Lesbian, Gay, Bisexual, and Transgender (LGBT) People," calls for the development of evidence-based and rigorous research aimed at understanding the health implications of hormone use in transgender individuals. The goal of the proposed research is to conduct a multi-site observational study examining the physiological and psychosocial outcomes of existing medical treatment protocols for gender dysphoria in two cohorts: early pubertal and late pubertal transgender youth.

FACILITIES AND RESOURCES

Children's Hospital Los Angeles

Children's Hospital Los Angeles (CHLA)
Located at 4650 Sunset Boulevard in the Hollywood/Wilshire Health District of Service Planning Area 4 of Los Angeles County, Children's Hospital Los Angeles (CHLA) is the largest pediatric facility in the western United States and is the principal pediatric center in Southern California. Founded in 1901, CHLA has been dedicated to serving the needs of critically and chronically ill children with compassion, dedication, and excellence. As a community-based medical center with an international impact, CHLA provides specialized, multi-disciplinary treatment and prevention services for more than 104,000 children and youth each year. Guided by a century of medical care, its mission is "to create hope and build healthier futures." In 1932, CHLA and the University of Southern California (USC) signed an affiliation agreement that made CHLA the principal pediatric teaching facility for the Keck School of Medicine. Full time physicians (176) at CHLA have appointments in the Departments of Pediatrics, Surgery, Pathology, Neurology, and Radiology at the Keck School of Medicine, while the full time basic science faculty (36) holds appointments in the Departments of Biochemistry, Cell Biology, Microbiology, and Physiology.

CHLA is unique because few pediatric hospitals in the world combine a freestanding clinical center with an on-campus research facility – the CHLA Saban Research Institute, one of the largest and most productive pediatric research facilities in the United States. This link offers the ability within a single institution to rapidly move discoveries from the research laboratories to the bedside of children suffering from complex and life-threatening disease. Dedicated to advancing the limits of knowledge, the researchers at CHLA seek solutions for childhood cancer, infections, genetic disease, development disabilities, and healthcare success.

Saban Research Institute at CHLA
Established in 1992, the Saban Research Institute is the umbrella under which research is conducted at CHLA. Its mission is to foster an environment of scientific excellence where research will lead to discoveries involving the molecular and clinical understanding of childhood development and implementation of procedures to diagnose, treat, and prevent pediatric diseases and promote child health. The Saban Research Institute ranks fifth among 26 major pediatric research institutions across the country, and principal investigators utilize more than 150,000-square-feet of research space in the Saban Research Building, the Smith Research Tower, within the hospital, and in the community. Researchers are involved in more than 200 active studies and projects, many of which are funded by NIH. The Research Institute and faculty are affiliated with USC, and at any given time, more than 120 graduate students and post-doctoral fellows are in training.

The Clinical Investigation Center and the Clinical Trials Unit support clinical research while the Office of Research Advancement and Administration provides centralized support for all aspects of research. The Department of Research Administration provides a centralized administrative system that ensures that research is maintained at the highest quality and safety levels. It includes sponsored-research award administration, the Office of Technology Transfer, the Office of Operation and Facilities, and satellite offices for Human Resources, Accounts Payable, Purchasing, and Marketing Communications.

Extramural funding for research totaled $37,412,898 at the end of FY 2009, including $23,345,012 in NIH funding. These research activities reflect a very significant expansion of the Saban Research Institute over the past years. Extramural funding has increased from $20.5 MM (total costs) in 1998 to $37.4 MM in 2009, while NIH funding increased from $10.3 MM in 1998 to $26 MM in 2009. At the same time, institutional intramural funding for research has increased by 1.8 fold, research restricted endowments by 2.5 fold, and research space by 1.6 fold with the completion of the Saban Research Building in June of 2003, reflecting the strong commitment of CHLA to research. As a result, the Research Institute has been able to actively recruit new research faculty members, increasing the pool of extramurally funded investigators from 69 in 1998 to 100 in 2009. A total of 186 extramurally funded research projects existed in 2009.

Research education is an integral part of the mission of CHLA and a top priority of the Saban Research Institute. The Research Institute has developed a comprehensive approach to training and contributing to the development of the research careers of individuals at various levels of their education. The Saban Research

Institute established in 1997 a High School Outreach Program with Marlborough High School supporting four or five students per year to perform research projects under the guidance of individual principal investigators at the Research Institute. The Saban Research Institute funds graduate students who are enrolled in a USC-based graduate program and are working in the laboratory of a principal investigator located at CHLA. An intramural Research Career Development Fellowship (CHLA-RCDF) was established in 1995 that supports the research and promotes the careers of postdoctoral fellows. The Saban Research Institute also established a mentored Research Career Development Award (RCDA) modeled after the NIH RCDA program that supports the academic careers of junior faculty at CHLA. A total of $2.1 MM has been allocated to support these research education efforts since 1995.

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

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

The DAYAM has an accredited adolescent medicine fellowship program, one of only two in California, and an American Psychological Association accredited pre-doctoral internship and post-doctoral fellowship program. In fiscal year 2013-14, the DAYAM's total operating budget exceeded 13.9 million dollars of which 3.3 million dollars were dedicated to a wide range of research activities, including research associated with the national Adolescent Trials Network; the development and evaluation of an evidence-based HIV/AIDS prevention intervention that is being adapted for application with youth from middle and high schools and with emerging adults; epidemiologic and intervention research related to substance use and misuse; service needs assessment of homeless and runaway youth; and evaluation research related to DAYAM programs.

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

- **The Center for Transyouth Health and Development –** The Center for Transyouth Health and Development promotes healthy futures for transyouth by providing services, research, training, and capacity building that are developmentally informed, affirmative, compassionate, and holistic for gender non-conforming children and transyouth. The principal investigator (Dr. Olson) is the Medical Director for the Center. The Center includes the nation's largest pediatric clinic for transgender youth and gender non-conforming children. The Center also houses the DAYAM's mental health, health education, research, and capacity building assistance focused on transgender youth and children.
- **The Research and Evaluation Program** – The Research and Evaluation Program conducts mixed and single-method epidemiologic and evaluation research related to issues affecting the health and well-being of adolescents and young adults. Past and current research foci include, but are not limited to, substance use and misuse, HIV/AIDS, reproductive health, relationship violence, transition of youth with chronic illness and special needs to adult care, and service needs of disenfranchised or marginalized youth. The Research and Evaluation Program also develops and conducts research for each DAYAM service program to support the development and document the impact of our prevention and intervention programs and increase our understanding of the youth utilizing DAYAM services.

Additional programs include:

- **The Teenage and Young Adult Health Center** – health care for youth with complex medical and psychosocial problems. In addition to the health care services offered through the health center, we provide health care at the Los Angeles and Long Beach Job Corps and in community clinics;
- **The Risk Reduction Program** – specialty health care, mental health counseling, case management, and support for HIV positive youth and HIV prevention services for transgender youth and young gay men. The DAYAM has a harm reduction program for transgender youth offering hormone treatment, case management, mental health services, and youth leadership opportunities. The Risk Reduction Program participates in a multicenter research network funded by the NIH to explore promising behavioral and therapeutic interventions for HIV-infected and at-risk adolescents;
- **The Behavioral Health Program** – mental health services for youth 12-21 including assessment; individual, family, and group counseling; and case management services funded by Medi-Cal and under the auspice of the Department of Mental Health;
- **The High Risk Youth Program** – health care, mental health counseling, case management and support for homeless youth. The project is a member of the six agency Hollywood Homeless Youth Partnership and the countywide LA Coalition to End Youth Homelessness.
- **Adolescent Transition Clinic** – in collaboration with CHLA sub-specialty clinics, the Adolescent Transition Team caters to teens and young adults with special health issues and their families to facilitate transition into adulthood and adult healthcare. Provides comprehensive, individualized mental, physical, and social evaluation and planning that emphasizes empowering each young adult to take control of his/her own health issues to ensure successful transition. Tools include health passports, interactive web programs, financial counseling, individual therapy, and peer support.
- **The Gang Reduction/Youth Development Program** – violence prevention services for youth 10-15 years old and their families in the Cypress Park/Glassell Park areas, focused on keeping youth away from gangs, supporting families, and building healthy communities;
- **Project NATEEN** – case management and support for pregnant and parenting teens and young adults with an on-site school, a special employment and life skills program for young parents, and specialized services for young fathers; and
- **The Substance Abuse Prevention and Treatment** – no-cost outpatient services for youth ages 10-25. Services include walk-in screenings and short and long-term individual, family, and group sessions.

Division Director Marvin Belzer, MD, serves as the Principal Investigator of all Los Angeles-based research related to the Adolescent Trials Network (ATN), an NIH-supported national consortium of 14 academic institutions throughout the US. The ATN has put forth a broad research agenda calling for “interventional studies, conducted collaboratively and independently when needed, aimed at the primary, secondary, and tertiary prevention of HIV infection in pre-adolescents, adolescents, and young adults at the trial units in the network.” CHLA, the only ATN site on the West Coast, has been engaged in dozens of ATN studies over the past 15 years as a primary or collaborative research site.

While the Division Director oversees all divisional activities, the DAYAM operates with a 20-member Management Team that includes the managers of each of the community based programs, medical directors, the Director of Behavioral Health, the Director of Research, the Fiscal Administrator, the Associate Director, and the Division Director. A seven person senior management team provides oversight for clinical, research, and training activities, as well as finance and administration, and includes the Director, Associate Director, Fiscal Administrator, Director of Research, and Director of Behavioral Health Services.

Community, Health Outcomes, and Intervention Research (CHOIR) Program

Many of the DAYAM’s faculty are part of the institution-wide Community, Health Outcomes, and Intervention Research (CHOIR) Program of the Saban Research Institute, an assembly of faculty and other CHLA investigators conducting health services/outcomes, social, behavioral, and community-focused research to promote the health and wellbeing of children, adolescents, and families. In an urban, densely populated area such as Los Angeles, there are numerous opportunities to reduce health disparities and address barriers to healthy living for children and adolescents. Our researchers seek to prevent illness, injury and reduce barriers to health care by conducting innovative research, implementing effective interventions, and working to ensure that all children and adolescents receive the high-quality healthcare that they need. Research plays a critical

role in understanding why some children are at greater risk for poorer health than others and how best to intervene to improve health and health outcomes. CHOIR members conduct research that is interdisciplinary, collaborative, cumulative, applied, and closely linked to policy and practice. Moreover, CHOIR's work emphasizes the importance of adopting a developmental framework that focuses attention on the differing needs, circumstances, and key transitions that children, adolescents, and young adults experience as they grow and develop. Whenever possible, CHOIR works closely with faculty and staff across the various Departments and Divisions at CHLA and USC to ensure that there are clear and tangible linkages among research, clinical care, and program development. Finally, considerable effort is made to disseminate the research findings widely and strategically to key stakeholder groups (e.g., federal, state, and local policy makers, health providers, advocacy groups, the media, and parents).

Members of the CHOIR program also participate in a range of formal and informal staff support, research, and technical training meetings convened on a regular basis. These include weekly staff meetings, regular and ongoing seminars convened by researchers who are conducting children's health services and behavioral and social science research as part of several funded research projects, and ongoing technical support and training meetings. Qualitative and quantitative researchers meet regularly to discuss their work, analytic approaches used for various types of research, and mathematical models that can be used and applied to advance our work.

Clinic
The clinical space for outpatient medical services is 3,314 square feet. Clinical space includes eight exam rooms, two laboratories for collection of lab specimens and a utility room containing storage for immunizations and lab collection materials. Access to radiologic services is located at the main campus of CHLA approximately one-half mile from the DAYAM.

Lab
The Department of Pathology and Laboratory Medicine at Children's Hospital Los Angeles provides a full array of laboratory services that draw on both established and state-of-the-art diagnostic techniques. The department, one of the most comprehensive pediatric pathology programs nationwide, is staffed by board-certified pediatric pathologists including several pathologists with sub-specialty expertise. The department directs the operations of the main Clinical Laboratory, Surgical Pathology, and Autopsy Service, as well as phlebotomy services, point-of-care testing, and a laboratory outreach program. In addition, the department is responsible for the Blood Bank, Blood Donor Programs, and Transfusion Medicine. The department's service functions are complemented by an active educational program, with a certified pediatric pathology residency program and a State of California certified education program for Clinical Laboratory Scientists, plus various learning opportunities for hospital and community physicians. The full-service Clinical Laboratory at Children's Hospital Los Angeles provides a broad spectrum of clinical chemistry analyses, including routine chemistry, therapeutic drug monitoring, thyroid testing, transplant immunosuppressive drug monitoring, qualitative drugs-of-abuse screening and blood gas analysis. The hematology laboratory has extensive experience in the diagnosis of a variety of hematological disorders and coagulationopathies. The histocompatibility laboratory supports the extensive programs in bone marrow and solid organ transplantation. Microbiology services are oriented to common pediatric infectious diseases as well as infections in immunocompromised patients. The Special Chemistry laboratory aids in the diagnosis and treatment of metabolic disorders. Many of these services are available around the clock, every day of the year. Special services to meet the needs of the hospital's pediatric population include a comprehensive cytogenetics laboratory (COG certified); catecholamine (vanillymendelic acid and homovanillic acid) testing; and blood lead testing. Appropriate pediatric reference values are included with each laboratory report. The CHLA Laboratories are CLIA Certified, State of California Department of Public Health Licensed, College of American Pathologists Accredited, and hold other relevant certifications and accreditations. Our experienced staff is comprised of American Society for Clinical Pathology-certified technologists who are licensed by the State of California as Clinical Laboratory Scientists.

Computer
CHLA research investigators have access to research computing facilities at their workstations in their offices and at PC work stations in the Biostatistics lab located at CHLA. A computer lab is designated for data entry, management, and statistical support staff. The DAYAM and CHOIR provide statistical database, spreadsheet, word-processing, desktop publishing, accounting, and a variety of utility software programs to all platforms. E-mail and internet access is provided to all staff. In addition, the USC University Computing Services provides a

comprehensive computing environment to support instructional and research goals of the University and its affiliated campuses, including CHLA. Facilities and services include campus-wide networking, a variety of central host systems, public user rooms, and support for distributed systems, hardware maintenance, and user support services. It provides support for and access to departmental and shared campus computing resources, library information systems, and regional, national, and international information resources. USC utilizes the most up-to-date hardware equipment and supports a variety of communication and scientific hardware and software systems. CHLA is connected to USC's health sciences network. Every research faculty and staff member has a computer on his or her desk for database and statistical analysis, simulation, spreadsheet work, and text processing and has the capability to communicate electronically.

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

Other
The Children's Hospital Health Sciences Library provides resources and services to CHLA staff. In addition to its collection of 3,500 print books and 170+ current print journal subscriptions, the library supplies access to over 200 electronic books and 2,000 electronic journals. Online access is available anywhere in the hospital or from remote computers that connect to the USC network. In addition to books and journals, the library also provides local and remote access to journal article databases including: Ovid MEDLINE, Ovid CINAHL, PubMed, PsycINFO, Science Citation Index, and Journal Citation Reports. The library's book and journal catalog, as well as that of the USC Norris Medical Library with whom the CHLA library has reciprocal borrowing agreements, is searchable online as well. Library services include mediated literature searching (searches conducted by a librarian), interlibrary loan borrowing (for obtaining materials that the CHLA library does not own), Ovid AutoAlerts (a current awareness service that delivers weekly citations that match a researcher's predefined topic), and HouseCalls (one-one-one, time-of-need meetings where the librarian can instruct users on a variety of topics including database searching, PowerPoint, or EndNote).

Ann & Robert H. Lurie Children's Hospital of Chicago

Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's; formerly known as Children's Memorial Hospital)
Located at new state of the art facilities at 225 E. Chicago Avenue in Chicago, is a 288 bed pediatric facility with over 1,100 pediatric/adolescent specialists focusing on 70 medical specialties. Lurie Children's provides care to more young people than any other Chicago-area hospital or medical center with more than 330,000 outpatient visits each year and more than 9,000 inpatient visits. Lurie is accredited by the Joint Commission on Accreditation of Healthcare Organization (JCAHO) and has a fully equipped ambulatory adolescent and HIV clinic located at its Clark/Deming building designed to be culturally appropriate for adolescents and young adults specifically. This adolescent specific space has four exam rooms, team meeting space, provider office space and touchdown areas for nursing and social work.

Laboratory
The clinical mass spectrometry lab is located in the Deming Building, room 3043 at Ann & Robert H. Lurie Children's Hospital of Chicago Outpatient Center. The clinical LC-MS/MS laboratory at Lurie Children's Hospital Outpatient Center is an 1100 ft^2 laboratory and is comprised of 5 rooms and is under the direct supervision of Shannon Haymond, Ph.D., a clinical and analytical chemist. The laboratory is CLIA-certified by the College of American Pathologists and performs testing for clinical and research purposes. The processes and procedures used for research samples during the pre-analytical, analytical, and post-analytical phases of

testing are aligned and compliant with CLIA quality regulations for clinical testing. It is staffed by a manager and four technologists/scientists with dedicated training in HPLC and tandem mass spectrometry, in addition to general clinical laboratory functions (e.g., specimen processing, lab information system function, electronic medical record function). The main lab area contains two HPLC, two UPLC, three tandem mass spectrometers (LC-MS/MS) and one graphite furnace atomic absorption spectrometer as well as an automated pipetting system, fume hoods, refrigerator, freezers, evaporators, flammable and acid/base storage cabinets, reverse osmosis water filtration system, sinks, lab benches, storage units, and five technologist PC workstations. Therefore, this room is used for glassware washing, sample preparation, analysis, and documentation. The second room is specifically separated from the main area of the lab to prevent contamination from carryover during analysis as it is used to precisely and accurately weigh the standard compounds used to prepare the calibrators, quality control materials, and other concentrated stock solutions required for the various assays. This room contains a lab bench, sink, freezer, a fume hood, flammable storage cabinet, and analytical balance with balance enclosure situated atop a marble table. The third room contains a nitrogen generator system that supplies high purity nitrogen gas required for operation of the mass spectrometers. It comprises an air compressor, storage tank, dryer unit, and nitrogen generator. Nitrogen cylinders that are connected to an automatic switch over system serve as backup in case of nitrogen generator system failure. The fourth room is the tank room containing 4 high purity argon cylinders to supply gas to the mass spectrometers and the atomic absorption spectrometer. Reagents and stock solutions are stored in -20º C freezers and/or refrigerator located throughout the lab rooms. Specimens are stored at -70° C until ready for analysis. Two dedicated -70° C freezers are located in the final room. Freezer and refrigerator temperatures are monitored and recorded by an automated building alarm system.

The clinical chemistry laboratory is located on the 8th floor of the Ann & Robert H. Lurie Children's Hospital of Chicago. It is included within the 'core' laboratory and is under the direct supervision of Shannon Haymond, Ph.D., a clinical and analytical chemist. This laboratory is CLIA-certified by the College of American Pathologists and performs testing for clinical and research purposes. The processes and procedures used for research samples during the pre-analytical, analytical, and post-analytical phases of testing are aligned and compliant with CLIA quality regulations for clinical testing. It is staffed by a manager, three coordinators and over 30 technologists/scientists to maintain the 24/7 operation necessary to support inpatient and outpatient activity in a tertiary care pediatric facility. Policies, procedures, training, and competency documents detailing research services are maintained by the laboratory management and a dedicated coordinator. All laboratory personnel responsible for shipping samples are IATA certified to package and ship biohazardous goods.

All entry points to the laboratory are secure and require badge access. The laboratory receipt and processing area has a window opening to the hallway where specimens are dropped off and picked up by couriers and hospital staff. Next to the window is the tube system where specimens are sent from inpatient units and onsite outpatient centers. The specimen processing areas equipped with all items (e.g. centrifuge, racks, decant tubes, label printer, workstation) necessary to prepare the specimen for testing, storage and shipment. The automated testing area includes Chemistry, Hematology, Coagulation, and Urinalysis. After necessary processing, samples are manually delivered to the performing instrument or laboratory. Specimens are tracked throughout the process using a barcoded specimen management system.

Hematology has three Advia 2120 analyzers. Coagulation has two BCS XP Coagulation analyzers. Urinalysis has two Clinitek Advantus analyzers. Chemistry has two Cobas 6000 analyzers and one Immulite 2000 analyzer and one Nova 8 analyzer. There is a manual testing bench for testing of specialty markers. The laboratory research services utilize two -70° C freezers, 4° C refrigerator, and room temperature storage space. Freezer and refrigerator temperatures are monitored and recorded by an automated building alarm system. Monthly reports are reviewed and approved by the manager of the laboratory receiving and processing area. In the event of failure, samples will be moved to a back-up -70° C freezer that is also monitored and maintained by the Department of Pathology and Laboratory Medicine. A departmental policy contains the details of the temperature monitoring, freezer maintenance, and backup plan.

Computer

Lurie Children's maintains excellent computer support staff for general faculty services (i.e. internet access, purchasing, hardware support) and provides staff with full access to the computer resources. PCs are

connected to secure Intranet, allowing for coordination of data entry and management. The PI will have full access to computers and support staff for technical assistance.

Office
Research personnel have adequate office space at Lurie Children's satellite office in the Uptown neighborhood on the north side of Chicago, housed in the Center for Gender, Sexuality and HIV Prevention. The Center has two floors in this location of approximately 4,800 square feet with five private and shared offices, 20 workstations, and six interview rooms on two floors. Each workstation or office is equipped with a computer networked to Lurie Children's main server.

Other
The Stanley Manne Children's Research Institute (CRI) is one of 13 interdisciplinary research centers and institutes of Northwestern University's Feinberg School of Medicine. All principal investigators at the institute are full-time faculty members at Feinberg. The institute is the research arm of Lurie Children's, which is the primary pediatric teaching hospital for the Feinberg School of Medicine. CRI is one of five institutions in the United States dedicated exclusively to pediatric research. The main laboratory of the institute is the Children's Research Center, a 71,000 square-foot facility that opened in 1995. A subdivision of CRI, the Child Health Research Core focuses on population-based research, including multidisciplinary investigations of children in their families and communities. As the research institute affiliated with Lurie Children's, CRI has a long history of successfully managing large federal research projects and is an ideal site for this project because it complements the 3 missions of the hospital: (1) providing culturally relevant child and adolescent health care services; (2) doing research into the prevention, causes and treatment of diseases that affect children and adolescents; and (3) advocacy for the general well-being of all children/adolescents.

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

Boston Children's Hospital

Boston Children's Hospital
Clinical Recruitment: Patients will be recruited from Boston Children's Hospital, a 395-bed comprehensive center for pediatric health care located at 300 Longwood Avenue in Boston, MA. Boston Children's Hospital has approximately 25,000 inpatient admissions per year and 500,000 annual outpatient visits to 240 specialized clinical programs.

Department of Medicine, Endocrine Division – GeMS Program
Boston Children's Hospital's Division of Endocrinology operates one of the nation's most extensive research programs focused on pediatric endocrine disorders with more than 50 basic science and clinical researchers. The research enterprise addresses an array of endocrine disorders that affect the health and quality of life of children.

The Gender Management (GeMS) Service of Boston Children's Hospital
In 2007, with the support of the hospital administration and clinical leadership of the Division of Endocrinology and the Dept of Pediatrics, the Gender Management Service was inaugurated to serve both transgender adolescents and children, and adolescents with Disorders of Sex Development. The Service was co-directed by the Divisions of Endocrinology under Dr. Spack and the Department of Urology under David Diamond, MD. GeMS was the first academic pediatric center in North America to run a program for the evaluation and

medical treatment of transgender youth and to train pediatric trainees, Endocrinology fellows from pediatric and internal medicine departments and Reproductive Endocrinologists-in-training. In the past six years, ten additional centers in the USA and Canada have initiated their own programs for trans youth, in many cases modeled after the GeMS Program and led by former trainees of ours.

In 2012, we reported on the demographics of the first 100 patients seen in GeMS. Similar to the Dutch, we had equal numbers of genotypic males and females, and 10% of our patients were in the autistic spectrum. Our patients were a bit older by almost two years: 14 years for genotypic males and 15 years for females. Despite being brought to us by both parents with a referral from a gender specialist-therapist following at least six months of counseling, 23% of our patients admitted self-harm prior to their first appointment and 9% had attempted suicide. This data was published in the March issue of Pediatrics in the first article ever written on transgender youth in that journal. From July 1, 2007 – October 31, 2014, GeMS clinic has seen 191 new patients, with a marked increase in the number offered GnRHa analogue since 2011, including genotypic males as genitally advanced as Tanner IV but with incomplete virilization of voice, Adam's apple, facial bones, and facial hair. The long-term benefits of the late intervention need to be ascertained. In addition to our testing psychologist and social worker, we have added a research psychologist, and two part-time endocrinologists. With the receipt of a recent hospital award, our social worker has organized seven Saturday conferences on transgenderism over two years for health professionals, parents, and school personnel. Dr. Spack was invited to eight "visiting professorships" and lectureships in North America in 2013 to strategize about the development of new academic clinics or to be involved in launching them.

Office

Dr. Spack has an office at the 333 Longwood Avenue hospital building across the street from the main hospital. Dr. Shumer has office space in 1 Autumn Street a Boston Children's Hospital office building; Dr. Tishelman has an office at 300 Longwood Avenue, the main building. Office space for study staff will be made available. Offices of faculty and staff at Boston Children's Hospital are fully equipped with telephones with conference calling capability, computers, laser printers, fax machines, scanner, and photocopiers. Locked filing cabinets are part of the office space.

Computer

All investigators have a computer with hospital networking and access to an extensive array of communication, word processing, spreadsheet, graphics, and statistical software. The computers are password protected and there are private servers for data storage. Microsoft Office software includes word processing, spreadsheets (Access, Excel), graphics, and PowerPoint. Statistical software such as SAS, STATA, and SPSS are supported by the hospital's research computing department. Children's Hospital's library supports Endnote citation manager and provides access to extensive resource for literature searches.

Other

- Clinical Research Center (CRC) Established in 1998, the Clinical Research Center (CRC) at Boston Children's Hospital is charged with the mission of providing infrastructure for the conduct of clinical research and methodological expertise to the diverse clinical research community. The goal of the CRC is to provide all investigators with access to expertise in clinical research methods, including biostatistics, epidemiology, survey methods, clinical trials methodology, database programming, data management, and quality control. The faculty and staff of the CRC include doctoral level biostatisticians, master's level biostatisticians, survey epidemiologists, project directors/clinical trials managers, informatics professionals, data managers/study coordinators and data entry staff. The network and computing infrastructure of the clinical research enterprise is supported by the Information Systems Department (ISD) and Research Computing facilities.
- The Children's Hospital library has an extensive collection of pediatric journals and books. The librarian, (b)(6), is also available to assist with literature searches and request interlibrary loans.
- The Francis A. Countway Library of Medicine is the largest medial library in the United States with more than 480,000 volumes, 5,000 periodicals, and complete computer searching capabilities.
- The Harvard Catalyst Program allows investigators to perform cutting edge human research and facilitates human interdisciplinary research across the broad spectrum of departments and research areas through

transformation and extension of the prior NIH-funded General Clinical Research Centers. Now referred to as the Clinical and Translational Study Unit, this resource incorporates dedicated inpatient and outpatient clinical research sites, clinical research personnel, and core laboratory services at the following participating Institutions: Beth Israel-Deaconess Medical Center, Brigham and Women's Hospital, Children's Hospital Boston, Massachusetts General Hospital, and Massachusetts Institute of Technology. Each provides resources available to assist investigators within as well as across these Institutions. Selected resources are available in space dedicated to the CTSU and off-site in other areas where patients are located such as the intensive care units, emergency departments, and ambulatory centers.

University of California San Francisco (UCSF) Benioff Children's Hospital

UCSF Benioff Children's Hospital

The University of California, San Francisco (UCSF) is one of the premier medical research institutions in the world. UCSF is consistently ranked as one of the top five medical schools in the US, and received more research funds from the NIH than any other public institution in 2010 (and ranked third among all institutions nationwide). The 107 acre Parnassus campus houses the schools of Medicine, Dentistry, Pharmacy and Nursing, the Graduate Division, the UCSF Medical Center, The UCSF Benioff Children's Hospital and the Langly-Porter Neuropsychiatric Institute. Additional campuses include the Mt. Zion Cancer Center, the Laurel Heights Campus and the new 43 acre Mission Bay Campus, with >1.3 million ft^2 of research space. There are >1200 principal investigators at UCSF, including 4 Nobel laureates, 42 members of the National Academy of Sciences and 75 members of the Institute of Medicine. Research funding for 2010 was ~$950 million/year, including ~$475 million from NIH: our Schools of Dentistry ($20 M), Nursing ($10 M), and Pharmacy ($23 M) each ranked #1 nationally, and the School of Medicine ($422 M) ranked #2 in NIH funding. Thus scientific excellence pervades the campus.

The UCSF Benioff Children's Hospital is presently a 'hospital-within-a-hospital' at UCSF and accounts for about 25% of the total clinical activity at UCSF Medical Center. In its present configuration within the UCSF Medical Center on Parnassus Avenue, the UCSF Benioff Children's Hospital has 183 beds (excluding well baby bassinettes) in the following units: 67 inpatient medical and surgical beds, 16 intensive care beds, 8 cardiac intensive care beds, 7 bone marrow transplant beds, 5 Pediatric Clinical research Center beds, 51 intensive care nursery beds, 29 perinatal beds, and 12 well baby bassinettes. In 2009-10 there were 5,147 (7,289 including OB) admissions to the Children's Hospital. The general pediatric clinics saw 40,590 visits in 2009-10 and the subspecialty clinics saw 19,714 visits; of these, 4,269 were in pediatric endocrinology.

A new 283-bed Children's, Women's and Cancer Hospital is now under construction on a 14.5 acre plot directly adjacent to the 43 acre UCSF Mission Bay Campus, and is scheduled to open in 2015. The Benioff Children's Hospital, assisted by a $100 million gift from Marc and Lynne Benioff, will occupy 189 of these 283 beds. This new Children's Hospital will include state of the art facilities for translational research with faculty fully integrated into the Mission Bay research campus. Plans are also being developed for new ambulatory facilities along with space for faculty offices, which are also intended to accommodate anticipated expansion of laboratory, clinical, and translational research within the Department of Pediatrics. With the administrative offices of the Clinical and Translational Sciences Institute (CTSI) to be located adjacent to Mission Bay, and as UCSF continues with construction of the 43-acre Mission Bay campus, the Benioff Children's Hospital faculty and trainees will be uniquely positioned to take maximum advantage of the UCSF tradition of research collaboration.

The Clinical and Translational Sciences Institute (CTSI)

UCSF was one of the first twelve academic institutions selected to be part of the NIH's national clinical and translational science consortium, resulting in the creation of the Clinical and Translational Sciences Institute (CTSI). The consortium has a charter to transform clinical and translational research to ensure that the best health solutions get to patients as quickly as possible. The UCSF CTSI is a cross-campus institute. The four major goals of the CTSI are to: 1) enhance, support, and integrate existing training programs, thereby increasing the number and quality of programs, and providing trainees from diverse disciplines with the knowledge, skills, and motivation to make significant contributions to clinical and translational research; 2) enhance, support, and integrate existing infrastructure, thereby implementing changes required to foster the

design and conduct of a diverse spectrum of high quality, original clinical investigation and translational research: 3) enhance career development of faculty and trainees involved in clinical investigation and translational research by providing mentoring, providing opportunities to catalyze original research, and changing the academic culture to appropriately reward original, multidisciplinary, collaborative work; and 4) create a "virtual home" for clinical and translational researchers, thereby nurturing communication, encouraging collaboration, fostering original ideas, and catalyzing the successful conduct of clinical investigation and translational research.

The Pediatric Clinical Research Center (PCRC)

The UCSF PCRC, which was continuously funded by the NIH as a free standing Clinical Research Center from 1967 through 2006, is now part of the unified CTSI Clinical Research Centers (CCRC). The UCSF CTSI-PCRC provides resources for investigator initiated and industry-funded clinical research in a 2,000 sq ft facility located in Moffitt Hospital 6th floor. Available research space relevant to our proposed outpatient study includes 2 outpatient exam rooms, additional rooms for psychosocial assessments, and a conference room for discussion and consenting. The facility is in close proximity to Dr. Rosenthal's office in the Pediatric Endocrinology Divisional space. The PCRC currently provides infrastructure for 78 active principal investigators with 125 approved protocols, and in the past fiscal year had 2,159 outpatient visits and 1,510 inpatient days, with 40 resultant publications. All protocols for research conducted in the PCRC are approved both by the Committee on Human Research/UCSF and by the PCRC Advisory Committee. The PCRC is funded by an NIH National Center for Research Resources (NCRR) grant M01 RR01271. It is one of 77 General Clinical Research Centers nationwide and one of only nine discrete Pediatric Clinical Research Centers.

UCSF Child and Adolescent Gender Center (CAGC)

Under the directorship of Dr. Rosenthal, Professor of Pediatrics and Program Director for Pediatric Endocrinology, the UCSF Child and Adolescent Gender Center (CAGC) is one of the leading centers for the multidisciplinary care of transgender youth in the U.S., and serves as the Pediatric/Adolescent clinical arm of the widely recognized UCSF Center of Excellence for Transgender Health. Housed in the Division of Pediatric Endocrinology at the UCSF Benioff Children's Hospital, the CAGC offers patients and their families an integrated and coherent set of services – medical, mental health, educational, legal, and other forms of advocacy – across the span of childhood and young adulthood, empowering families to more effectively plan for the current and future needs of their gender diverse children. Through a unified network of multi-disciplinary professionals, the CAGC serves to develop and provide best clinical practices, create greater acceptance of gender diversity in schools and other institutions, provide advocacy, influence public policy, and conduct research aimed at enhancing the healthy development and wellbeing of transgender children, adolescents, and young adults. In collaboration with Dr. Rosenthal, the UCSF CAGC provides mental health support under the direction of Diane Ehrensaft, PhD, internationally known child psychologist/gender specialist and widely recognized author, and advocacy support by Gender Spectrum, one of the leading national advocacy groups for transgender youth. The CAGC also provides nursing, social work, and legal support. The CAGC is the only such multi-disciplinary gender program in northern California, attracting patients not only from California, but from as far away as Alaska, Florida, and Egypt. A steady increase in referrals (8-10/month) has led to a quadrupling of services in the last two years. Dr. Rosenthal is a nationally and internationally recognized expert in the care of transgender youth, having been appointed as the official representative of the Pediatric Endocrine Society (PES) to the Endocrine Society (ES)'s Clinical Practice Guidelines Revision Task Force for the Care of Transgender Individuals, and was appointed to the World Professional Association for Transgender Health (WPATH) Consensus committee for revisions of the International Classification of Disease (ICD)-11 pertaining to transgender youth and adults. He has authored 7 manuscripts on transgender youth, including a recently in-press "State-of-the-Art" invited review in *Pediatrics* and an in-press invited review in the "Approach to the patient" series in the *Journal of Clinical Endocrinology & Metabolism*. He has been an invited speaker on transgender youth at annual meetings of PES and ES, as well as at the most recent international meeting of WPATH, and has lectured on this subject at academic centers throughout the U.S. Dr. Rosenthal is also the recipient of the 2013 UCSF Chancellor Award for LGBT Leadership in recognition of his work with transgender youth. As a reflection of its national and international impact, the UCSF CAGC is being featured in an upcoming documentary on transgender youth produced by the British Broadcasting Corporation (BBC).

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

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

Laboratory
The Sample Processing Lab/Pediatric Clinical Research Center is a BSL 1 certified lab, occupying 600sqft in the UCSF Benioff Children's Hospital, 6th floor. It is staffed by 2 FTE providing services to UCSF investigators in routine sample processing, shipping and short-term storage for up to 3 months. The PCRC is equipped with two -80 C freezers, centrifuge, liquid nitrogen storage, CO_2 incubator, and bio-safety cabinets. The PCRC currently supports 55 active investigators with routine processing of blood, urine and other body fluids. On average, the PCRC receives up to 25 specimens per day for routine and specialized processing. Routine processing consists of labeling and identification, processing, shipping, and short-term storage. As a short term storage facility the PCRC lab offers specimen labeling with bar-coded freezer labels and tracking in a sample database. Each freezer is alarmed and monitored by the UC police department who notify PCRC staff of temperature fluctuations. The daily freezer temperature range is monitored twice daily and recorded. In the event of freezer malfunction, samples are transferred to PCRC back up freezers on the Adult CRC sample processing lab for investigator retrieval until the non-functioning freezer is repaired.

Office
Dr. Rosenthal has a 150 square foot office in close proximity to his clinical space. His office has a new PC computer and laser printer. His research staff occupies space nearby, and all are within a very short walk of the clinical space. The Department of Pediatrics at UCSF provides general office machines, faxes, photocopying, and office supplies.

Computer
Dr. Rosenthal's computer has word-processing capability, data analysis, and graphics software, and is connected to the Internet through a campus-wide server. Additional Macintosh and PC computers are available in the Division of Pediatric Endocrinology for use by faculty and staff. Computer support personnel are available through the Information Technology Department of UCSF.

Other
The UCSF library, built in 1990, is both a traditional library, containing extensive collections of scientific books and journals relevant to the study of endocrinology, and is also a teaching and database management facility with The Interactive Learning Center and Center for Knowledge Management. The UCSF Digital Library (GALEN II) offers easy access to a broad collection of databases, reference resources, electronic journals and catalogues of local materials. Through the newly created California Digital Library, students, trainees, and faculty are able to view and request materials from the 10 UC campus libraries. The UCSF library has 900,000 volumes including 2,600 current subscriptions. In addition to the journals and books in the library, the

Interactive Learning Centers maintain facilities for computing with PC and Macintosh computers, printers, software, documentation, consulting support, and connections to the internet, and electronic classrooms. The Multimedia Development Lab provides hardware, software, and consulting support for development of curriculum-integrated, educational materials. Education and Consulting Services offers curriculum-integrated instruction and seminars that assist students, fellows, and faculty in the use of databases, internet, and personal file management software. The Center for Knowledge Management develops knowledge bases and on-line tools for the health sciences, pursues applied research projects, and serves as a laboratory for graduate students interested in using new technologies to solve important health sciences information problems.

ARA acceptance: The Impact of Early Medical Treatment in Transgender Youth

Gorham, Vanessa (NIH/NICHD) [E] [gorhamva@mail.nih.gov]

Sent: Tuesday, February 04, 2014 12:26 PM
To: Olson, Jo
Cc: Freund, Lisa (NIH/NICHD) [E] [freundl@mail.nih.gov]; Hayunga, Eugene G. (NIH/NICHD) [E] [ehayunga@mail.nih.gov]; Dupere, Sherry (NIH/NICHD) [E] [duperes@mail.nih.gov]; Ledu, Melani (NIH/NICHD) [E] [LeduM@niaid.nih.gov]; Nguyen, Hien (NIH/NICHD) [C] [nguyenhi@mail.nih.gov]; Underwood, Brenda (NIH/NICHD) [E] [underwob@mail.nih.gov]; Gorham, Vanessa (NIH/NICHD) [E] [gorhamva@mail.nih.gov]

Dear Dr. Olson:

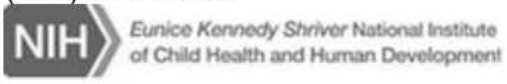
I am pleased to inform you that the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) has approved your request for a waiver of policy and will accept your large grant application for review. We have notified the NIH Center for Scientific Review (CSR) of this decision.

When you submit your application to CSR, please remember to indicate in a cover letter that you have contacted NICHD and that we have agreed to accept this application for review. You may include this letter as an attachment if you wish. Please also remember that all applications requesting $500,000 or more in any budget year are required to include plans for addressing the NIH Policy on Data Sharing (see http://grants.nih.gov/grants/policy/data_sharing/

Acceptance of your application for review does not guarantee that NICHD will fund the application or will fund it at the requested levels, regardless of the outcome of peer review.

Sincerely,

Vanessa Gorham
On behalf of
Eugene Hayunga, PhD
Director, OEP
The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)
Office of Extramural Policy
(301) 435-6856



OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

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

Position/Title*:	Assistant Professor
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Phone Number*: (b)(6) Fax Number: 323-913-3614 E-Mail*: jolson@chla.usc.edu

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

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

Degree Type: MD Degree Year: 1997

	File Name
Attach Biographical Sketch*:	1251-Olson Biosketch.pdf
Attach Current & Pending Support:	

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Marvin Middle Name Eric Last Name*: Belzer Suffix: M.D.

Position/Title*:	Professor
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Credential, e.g., agency login: (b)(6)

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

Degree Type: MD Degree Year: 1987

	File Name
Attach Biographical Sketch*:	1252-Belzer Biosketch.pdf
Attach Current & Pending Support:	

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

PROFILE - Senior/Key Person

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

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

File Name

Attach Biographical Sketch*: (b)(6)

Attach Current & Pending Support:

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Sheree Middle Name Michelle Last Name*: Schrager Suffix: Ph.D

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

Degree Type: PhD Degree Year: 2008

File Name

Attach Biographical Sketch*: 1254-Schrager Biosketch.pdf

Attach Current & Pending Support:

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Norman Middle Name P Last Name*: Spack Suffix: M.D.

Position/Title*:	Associate Clinical Professor
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Project Role*: PD/PI Other Project Role Category:

Degree Type: MD Degree Year: 1969

	File Name
Attach Biographical Sketch*:	1255-Spack Biosketch.pdf
Attach Current & Pending Support:	

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Daniel Middle Name Evan Last Name*: Shumer Suffix: M.D.

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

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

Degree Type: MD Degree Year: 2008

	File Name
Attach Biographical Sketch*:	1256-Shumer Biosketch.pdf
Attach Current & Pending Support:	

PROFILE - Senior/Key Person

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

Position/Title*: (b)(6)
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Division: Endocrinology
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County: Suffolk
State*: MA: Massachusetts
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 02115-5724

Phone Number*: (b)(6) Fax Number: (b)(6) E-Mail*: (b)(6)

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

Project Role*: (b)(6) Other Project Role Category:

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

File Name

Attach Biographical Sketch*: (b)(6)

Attach Current & Pending Support:

PROFILE - Senior/Key Person

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

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

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

Degree Type: MD Degree Year: 1992

File Name

Attach Biographical Sketch*: 1258-Garofalo Biosketch.pdf

Attach Current & Pending Support:

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Lisa Middle Name K Last Name*: Simons Suffix: M.D.

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

Degree Type: MD Degree Year: 2007

	File Name
Attach Biographical Sketch*:	1259-Simons Biosketch.pdf
Attach Current & Pending Support:	

PROFILE - Senior/Key Person

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

Position/Title*:	Medical Psychologist
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Credential, e.g., agency login: (b)(6)

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

Degree Type: PhD Degree Year: 2011

	File Name
Attach Biographical Sketch*:	1260-Hidalgo Biosketch.pdf
Attach Current & Pending Support:	

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Scott Middle Name Last Name*: Leibowitz Suffix: M.D.

Position/Title*:	Attending Psychiatrist
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State*:	IL: Illinois
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	60611-2605

Phone Number*: (b)(6) Fax Number: 312-227-9659 E-Mail*: SLeibowitz@luriechildrens.org

Credential, e.g., agency login:

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

Degree Type: MD Degree Year: 2004

	File Name
Attach Biographical Sketch*:	1261-Leibowitz Biosketch.pdf
Attach Current & Pending Support:	

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Courtney Middle Name Anne Last Name*: Finlayson Suffix: M.D.

Position/Title*:	Attending Physician
Organization Name*:	Lurie Children's Hospital of Chicago
Department:	Pediatrics
Division:	Adolescent Medicine
Street1*:	225 East Chicago Avenue, Box 54
Street2:	
City*:	Chicago
County:	Cook
State*:	IL: Illinois
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	60611-2605

Phone Number*: (b)(6) Fax Number: 312-227-9403 E-Mail*: cfinlayson@luriechildrens.org

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

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

Degree Type: MD Degree Year: 2003

	File Name
Attach Biographical Sketch*:	1262-Finlayson Biosketch.pdf
Attach Current & Pending Support:	

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Joel Middle Name E Last Name*: Frader Suffix: M.D.

Position/Title*: Head, General Pediatrics and Primary Care
Organization Name*: Lurie Children's Hospital of Chicago
Department: Pediatrics
Division: Adolescent Medicine
Street1*: 225 East Chicago Avenue, Box 54
Street2:
City*: Chicago
County: Cook
State*: IL: Illinois
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 60611-2605

Phone Number*: (b)(6) Fax Number: 312-227-9403 E-Mail*: jfrader@northwestern.edu

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

Project Role*: Other (Specify) Other Project Role Category: Ethicist

Degree Type: MD Degree Year: 1974

	File Name
Attach Biographical Sketch*:	1263-Frader Biosketch.pdf
Attach Current & Pending Support:	

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: Stephen Middle Name M Last Name*: Rosenthal Suffix: M.D.

Position/Title*: Professor of Pediatrics
Organization Name*: University of California at San Francisco
Department: School of Medicine
Division: Pediatric Endocrinology
Street1*: 513 Parnassus Ave
Street2:
City*: San Francisco
County: San Francisco
State*: CA: California
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 94143-0296

Phone Number*: (b)(6) Fax Number: 415-476-8214 E-Mail*: rosenthals@peds.ucsf.edu

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

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

Degree Type: MD Degree Year: 1976

	File Name
Attach Biographical Sketch*:	1264-Rosenthal Biosketch.pdf
Attach Current & Pending Support:	

PROFILE - Senior/Key Person

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

Position/Title*: Adjunct Associate Professor of Pediatrics
Organization Name*: University of California at San Francisco
Department: School of Medicine
Division: Pediatrics
Street1*: 505 Parnassus Ave, Med Sci Room 696, Box 0110
Street2:
City*: San Francisco
County: San Francisco
State*: CA: California
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 94143-0296

Phone Number*: (b)(6) Fax Number: 510-547-7692 E-Mail*: dehrensaft@earthlink.net

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

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

Degree Type: PhD Degree Year: 1974

File Name

Attach Biographical Sketch*: 1265-Ehrensaft Biosketch.pdf

Attach Current & Pending Support:

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: David Middle Name V Last Name*: Glidden Suffix: Ph.D

Position/Title*: Professor of Biostatistics
Organization Name*: University of California at San Francisco
Department: School of Medicine
Division: Division of Biostatistics
Street1*: 185 Berry Street, Lobby 5, Suite 5700
Street2:
City*: San Francisco
County: San Francisco
State*: CA: California
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 94143-0296

Phone Number*: (b)(6) Fax Number: 415-514-8150 E-Mail*: dave@biostat.ucsf.edu

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

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

Degree Type: PhD Degree Year: 1993

File Name

Attach Biographical Sketch*: 1266-Glidden Biosketch.pdf

Attach Current & Pending Support:

BIOGRAPHICAL SKETCH

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

NAME	POSITION TITLE
Olson, Johanna L MD	PI/Assistant Professor of Clinical Pediatrics
eRA COMMONS USER NAME (credential, e.g., agency login) (b)(6)	

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

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

A. Personal Statement

The goal of the proposed research is to investigate the impact of early medical treatment in transgender children and adolescents presenting for care at four sites across the United States. As a pediatrician and a leading expert in the field of transgender youth care, I am confident that the proposed multi-site study will inform the development of evidence–based practices, thereby leading to improved health outcomes for this understudied and underserved population. I am uniquely suited to actualize the proposed research agenda. As Principal Investigator at the lead site, I will be responsible for overseeing coordination of care services for participants enrolled in the study at the CHLA site, as well as assist in the development of the implementation protocol and contribute to presentations and manuscripts based on study data. While I am early in my career, I am a recognized leader in the development of research and clinical care for transgender and gender non-conforming children and adolescents. I was selected by my colleagues (i.e. R. Garafolo, S. Rosenthal, and N. Spack) to provide leadership on this study in acknowledgement of my overall expertise and experience. I will be provided with mentorship from both my local site mentors (i.e. M. Belzer and L. Clark) as well as the other three site PIs, Drs. Garofalo, Rosenthal and Spack. I have the only active prospective study in the US investigating the impact of treatment of transgender youth. Over the last 4 years, I have developed research protocols, recruited and retained subjects and have initiated data analyses. I have been the recipient of two training grants to pursue research in the gender non-conforming and transgender youth populations; the first, a two year Clinical Research Career Development Award through the Saban Research Institute at CHLA and the second a KL2 translational science award from USC ending in June 2014. I am finishing a Master's Degree in Clinical and Biomedical Investigations at USC, and have two first author papers about transgender youth already published. I am the Medical Director of our Center for Transyouth Health and Development at CHLA. Over the past five years I have expanded the services of the Center to include care and consultative services for gender non-conforming and transgender children and adolescents ages 4 to 24. Over the past five years I have worked tirelessly to successfully quadruple the number of patients served by the Center, with 335 patients actively enrolled in the clinic at this time, making ours the largest transgender youth clinic in the US. Finally, I have made dozens of appearances across the country and on national television over the past 5 years to educate the community, parents and providers about the needs of transgender youth.

B. Positions and Honors

Positions and Employment

2006- USC/ Children's Hospital Los Angeles Assistant Professor of Clinical Pediatrics
2003-2005 University of California Los Angeles – 2003 – 2005

Professional Appointments

2011–present Medical Director of the Center for Transyouth Health and Development
2008-2012 Adolescent Medicine Fellowship Program Director
2003-2006 Pediatric Practice of Zimble/Reinstein
2004–2006 Northeast Valley Health Corporation
2002-2003 Kaiser Permanente, California Sunset

Professional Activity

2014 Medical Expert "A Report on Transgender Children" – CBS The Sunday Morning Show
2013 Medical Expert "Boy to Girl: One Child's Journey" – People Magazine – July 8, 2013
2013 Medical Expert Gender Non-conforming and Transgender Youth – Kids in the House Website
2012 Medical Expert "Trapped in the Wrong Body"– The Ricki Lake Show
2012 Medical Expert "Transgender Childhood" – Dateline
2012 Medical Expert – LA Times
2012 Medical Expert – Bruce Hentsel Show
2012 Medical Expert – Taboo
2012 Medical Expert Transgender Children - Dateline – July 2012
2011 Present Executive Board Member – TransYouth Family Allies
2011 Medical Expert – My Extraordinary Family – Nightline
2011 Medical Expert for the OWN Network – The DOC Club – Rosie O'Donnell/ Transgender Youth
2011 Medical Expert "Adolescents and Bullying"– Dr. Drew show
2009- Executive Board Member – The Champion Fund
2008 Audience Expert for the Dr. Phil Show – "Lost Little Boy"
2007 Medical Expert – "Born in the Wrong Body" – 20/20

Society Memberships

Society for Adolescent Health and Medicine
American Academy of Pediatrics
Los Angeles Pediatric Society
World Professional Association of Transgender Health

Honors

2009 Health Care Advocacy Champion – Democratic Advocates for Disability Issues.
2010 Clinical Research Academic Career Development Award -Saban Research Center TSRI Program: Community Health Outcomes and Intervention
Project: "Treating transgender youth: the impact of a multidisciplinary care team approach".
2012 Extraordinary Service Award – Equality California

C. Selected Peer-Reviewed Publications

Most relevant to the current application

1. **Olson J,** Schrager S M., Clark L F., Dunlap S L., Belzer M. Subcutaneous Testosterone: An Effective Delivery Mechanism for Masculinizing Young Transgender Men, LGBT Health. September 2014, 1(3): 165-167. doi:10.1089/lgbt.2014.0018.
2. **Olson J**, Garofalo R., The peripubertal gender-dysphoric child: puberty suppression and treatment paradigms. Pediatr Ann. 2014 Jun;43(6):e132-7. doi: 10.3928/00904481-20140522-08.
3. Hildago MA, Ehrensaft D, Tishelman AC, Clark LF, Garofalo R, Rosenthal SM, Spack NP, **Olson J.** The gender affirmative model: What we know and what we aim to learn. *Human Development*, 2013, 3: 285-290.
4. Simons L, Schrager S, Clark LF, Belzer M, **Olson J**. Parental support and mental health among transgender adolescents, *J Adol Health,* September 2013 (10.1016/j.jadohealth.2013.07.019).
5. **Olson J**, Clark L, Schrager S, Simons L, Belzer M. Baseline characteristics of transgender youth naïve to cross sex hormone therapy, *J Adol Health,* February 2013 (Vol. 52, Issue 2, Supplement 1, S35-S36.
6. **Olson J**, Forbes C, Belzer M. Management of the transgender adolescent, *Arch Pediatr Adolesc.* 2011;165(2): 171-176.

Additional recent publications of importance to the field (in chronological order)

7. Puccio, JA, Belzer M, **Olson J**, Martinez M, Salata C, Tucker D, Tanaka D. The use of cell phone reminder calls for assisting HIV infected youth to adhere to highly active antiretroviral therapy: A pilot study. *AIDS Patient Care and STDs*. June 1, 2005, 20(6): 438-444. doi:10.1089/apc.2006.20.438.
8. Belzer M, Sanchez K, **Olson J**, Jacobs A, Tucker D. Advance supply of emergency contraception: A Randomized Trial in Adolescent Mothers. *J Ped and Adolesc Gyn*. 2006, 8, 347-354.
9. Belzer ME, **Olson J.** Adherence in adolescents: A review of the literature. Adolescent Medicine: State of the Art Reviews. Evaluation and Management of Adolescent Issues. *Amer Acad of Peds* 2008:1999-117.
10. Belzer M, Naar-King S, **Olson J,** Kohana S, Mussa S, Thornton S, Gaur A, Clark LF. The use of cell phone support for non-adherent HIV-infected youth and young adults: A randomized and controlled intervention trial. *AIDS and Behav* 2013.

D. Research Support

Ongoing Research Support

KL2 Mentored Career Research Development Program of the Center for Education, Training and Career Development under the SC CTSI
The Impact of Hormone Blockers on the Physiologic and Psychosocial Development of Gender Non-Conforming Peri-Pubertal Youth
Role: PI

Treating Transgender Youth Olson (PI)
Examine the impact of a multidisciplinary treatment model on transgender youth starting cross sex hormones.
Role: PI

Descriptive Study of Transgender Patients at Children's Hospital Los Angeles
This study is a retrospective chart review of transgender patients treated for around one year with cross sex hormones to assess safety of treatment.
Role: Co-PI

U01HD040474 Korelitz (PI) 03/01/11-02/28/16
Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN)
The primary mission of the ATN is to conduct research, both independently and in collaboration with existing research networks and individual investigators, in HIV-infected and HIV-at-risk pre-adolescents, adolescents, and young adults up to age 25 years.
Role: Co-Investigator

Completed Research Support

N01-DK-8-0001 Belzer (Site PI) 12/16/07-08/31/14
IMPAACT, P1076: Impact of oral alendronate therapy on bone mineral density in HIV-infected children and adolescents with low bone mineral density.
Role: Co-Investigator

BIOGRAPHICAL SKETCH

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

NAME	POSITION TITLE
Belzer, Marvin E. M.D.	Professor of Pediatrics and Medicine
eRA COMMONS USER NAME (credential, e.g., agency login) (b)(6)	

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of California, Davis	BS	1981	Zoology
University of Southern California	MD	1986	Medicine
University of California Irvine Medical Center	Intern & Residency	1989	Internal Medicine
Children's Hospital Los Angeles	Fellowship	1991	Adolescent Medicine

A. Personal Statement

I am currently the Director of the Division of Adolescent and Young Adult Medicine at Children's Hospital Los Angeles and an Adolescent Medicine specialist since 1991. I began caring for transgender youth in 1991 and helped develop the first and largest youth-focused, transgender clinic in the United States. I have conducted several research studies looking at risks for female transyouth. I co-chaired the NICHD sponsored study of high risk transgender youth for the Adolescent Trials Network, which included mentoring the protocol chair (Erin Wilson, DrPH) while she was working on her DrPH at UC Berkeley. I have been a site PI In the NICHD supported REACH and ATN Networks for the past 20 years and the PACTG/IMPAACT Network for 15 years. I was the chair of the ATN clinical PI's for a total of 7.5 years and now the ATP representative to the Behavioral Leadership Group. I have extensive experience managing clinical trials and will assist Dr. Olson in managing this complex, 4-site, observational trial of transgender youth. I have been Dr. Olson's primary mentor for her transyouth research over the past 4 years (currently on year 2 of her CTSI KL2 award from the University of Southern California) and well positioned to provide her the support required to ensure this project is successful.

B. Positions and Honors

Positions and Employment

1991- Assistant Professor of Pediatrics and Medicine-University of Southern California
2003- Associate Professor of Pediatrics and Medicine-University of Southern California
2011- Professor of Pediatrics and Medicine-University of Southern California

Professional Appointments

1991- Medical Director, Risk Reduction HIV Program-Division of Adolescent Medicine, CHLA
1995-2006 Medical Director, Teenage Health Center-Division of Adolescent Medicine, CHLA
2006-2008 Associate Director of Research-Division of Adolescent Medicine, CHLA
2008- Director/Division Head-Division of Adolescent Medicine, CHLA

Other Experience and Professional Memberships

1991-2004 Chairman, Adolescent HIV Consortium, County of Los Angeles, California
1992-1993 Member, Adolescent Scientific Committee for AIDS Clinical Trials
1993-1994 Member, Pediatric Primary Therapy Working Group for AIDS Clinical Trials
1994-2001 Principal Investigator from Los Angeles for the Medicine HIV/AIDS Research Network (NIAID/NICHD/HIRSA/NIDA Funded) Clinical Science Group Chair, Steering/Executive Committee Member
1996-1999 Advisory Board Member, Redefining Actions and Decisions. Carbondale, Colorado
2002- Principal Investigator for the Los Angeles Site of the Adolescent Trials Network for HIV/AIDS
2002-2009 Adolescent HIV Trials Network, Chair Clinical PI's, Executive Committee member,

2011-2013	Site Performance Committee
2002-2006	Member Board of Directors, Los Angeles Physicians AIDS Forum
2002-	Journal Review Panel Member for Journal of Adolescent Health, Archives of Pediatric and Adolescent Medicine, Psychology, Public Policy and Law
2003-	American Academy of HIV Medicine Education Committee
2003-2008	AIDS Project Los Angeles IRB Member
2002-2010	American Board of Internal Medicine Representative to Adolescent Medicine Subboard Committee
2009-2010	American Board of Pediatrics Adolescent Medicine Subboard Chair
2014-	American Board of Pediatrics Adolescent Subboard Medical Editor
2005-2007	HRSA Web-based HIV Care, Education Project (Advisory Committee Member)
2005-2007	Member Los Angeles County Office of AIDS Programs and Policy Standards of Care Task Force
2006-	Children's Hospital Los Angeles GCRC/CTSI Local Advisory Committee
2007-	Children's Hospital Los Angeles GCRC/CTSI Local Advisory Committee Chair
2007-2009	Vice-chair of the Adolescent Trials Network Executive Committee

Society Memberships

Society for Adolescent Medicine-Fellow
American College of Physicians-Fellow
American Academy of HIV Medicine-HIV Specialist
World Professional Association for Transgender Health

C. Selected Peer-Reviewed Publications (Selected from 37 peer-reviewed publications)

Most relevant to the current application

1. Johanna Olson, Sheree M. Schrager, Leslie F. Clark, Shannon L Dunlap and **Marvin Belzer*.** Subcutaneous Testosterone: An Effective Delivery Mechanism For Masculinizing Transgender Men." LGBT Health. 2014;1:1-3. DOI:10.1089/LGBT.2014.0018
2. Simons L, Schrager SM, Clark LF, **Belzer M**, Olson J. Parental support and mental Health among transgender adolescents. *Journal of Adolesc Health*. 2013:53:791– 793.
3. Wilson EC, Iverson E, Garofalo R, Belzer M. Parental support and condom use among transgender female youth. J Assoc Nurses AIDS Care. 2012;23(4): 306-17.
4. Brennan J, Kuhns LM, Johnson AK, **Belzer M,** Wilson EC, Garofalo R. Syndemic theory and HIV-related risk among young transgender women: the role of multiple, co-occurring health problems and social marginalization. *American Journal of Public Health*. 2012;102:1751-7.
5. Olson J, Forbes C, **Belzer M**. Management of the transgender adolescent. *Arch Pediatr Adolesc*. 2011;165(2): 171-176.
6. Wilson EC, Garofalo R, Harris DR, **Belzer M**. Sexual risk taking among transgender male-to-female youths with different partner types. *American Journal of Public Health*. 2010:100:1500-1505.
7. Wilson, EC, Garofalo R, Harris RH, Herrick A, Martinez M, **Belzer M**. Transgender female youth and sex work: HIV risk and a comparison of life factors related to engagement in sex work. *AIDS Behavior*, 2009. DOI 10.1007/s10461-008-9508-8.

Additional recent publications of importance to the field (in reverse chronological order)

8. Schrager SM, Olson J, Beharry M, **Belzer M,** Goldsich K, Desai M, Clark LF. Young men and the morning after: a missed opportunity for emergency contraception provision? *J Fam Plann Reprod Health Care.* Jan 24, 2014. [Epub ahead of print].
9. **Belzer ME**, Naar-King S, Olson J, Sarr M, Thornton S, Kahana SY, Gaur A, Clark L. The use of cell phone support for non-adherent HIV-Infected youth and young adults: An initial randomized and controlled intervention trial. *AIDS and Behav*. 2013 DOI 10.1007/s10461-012-0661-3.
10. Garvie P, Flynn P, **Belzer M**, Britto P, Hu C, Grahm B, Neely M, McSherry G, Spector SA, Guar AH. Psychological Factors, beliefs about medication, and adherence of youth with HIV-1 in a multisite directly observed therapy (DOT) Pilot Study. *Journal of Adolescent Health.*2011:48;637-640.

11. Nugent NR, Brown LK, **Belzer M**, Harper GW, Naar-king S, Nachman S. Youth living with HIV and problem substance use: Elevated distress Is associated with nonadherence and sexual risk. *Journal of the International Association of Physicians in AIDS Care*. Online First, Feb 4, 2010 as doi:10.1177/1545109709709357472.
12. **Belzer ME**, Olson J. Adherence in adolescents: A review of the literature. Adolescent Medicine: State of the art reviews. Evaluation and management of adolescent issues. *Amer Acad of Peds.* 2008;1999-117.
13. Puccio JA, **Belzer M,** Olson J, Martinez M, Salata C, Tucker D, Tanaka D. The use of cell phone reminder calls for assisting HIV-Infected adolescents and young adults to adhere to HAART: A Pilot Study. *AIDS Patient Care and STDs.* 2006;20:438-444.
14. **Belzer MB**, Sanchez K, Olson J, Jacobs A, Tucker D. Use of advance supply of emergency contraception: a randomized trial in adolescent mothers. *J Adol Pediatr Adol Gyn*. 2005;18.
15. Murphy DA, **Belzer ME**, Durako SJ, Sarr M, Wilson CM, Muenz LR. Longitudinal antiretroviral adherence among adolescents infected with human immunodeficiency *virus. Arch Pediatr Adolesc Med*. 2005:159:764-770.

D. Research Support

Ongoing Research Support

U01HD040463 (Belzer), NIH/NICHD **04/16/01-02/29/16**
Adolescent Medicine Trials Network for HIV/AIDS Interventions

U01HD040533 **Wilson (PI)** **04/26/01-02/28/16**
NIH/NICHD via University of Alabama at Birmingham
ATN Coordinating Center
Role: Site PI

U01HD040474 **Korelitz (PI)** **04/01-02/28/16**
NIH/NICHD via Westat
Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN)
The primary mission of the ATN is to conduct research, both independently and in collaboration with existing research networks and individual investigators, in HIV-infected and HIV-at-risk pre-adolescents, adolescents, and young adults up to age 25 years.
Role: Site PI

CPIMP141084-01-00 **Martinez (Grantee Project Director)** **09/30/14-08/30/17**
Office of Minority Health
HIV/AIDS Initiative for Minority Men (AIMM)

Completed Research Support

N01-DK-8-0001 **Belzer (Site PI)** **12/16/07-08/31/14**
NICHD International and Domestic Pediatric and Maternal HIV Studies Coordinating Center
The International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network is a global collaboration of investigators, institutions, community representatives and other partners organized for the purpose of evaluating interventions to treat and prevent HIV infection and its consequences in infants, children, adolescents and pregnant/postpartum women through the conduct of high quality clinical trials.
Role: Site PI

BIOGRAPHICAL SKETCH

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

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

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
(b)(6)	(b)(6)	(b)(6)	(b)(6)

A. Personal Statement

(b)(6)

B. Positions and Honors

(b)(6)

(b)(6)

C. Selected Peer-reviewed Publications (b)(6)

(b)(6)

D. Research Support

(b)(6)

(b)(6)

(b)(6)

BIOGRAPHICAL SKETCH

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

NAME	POSITION TITLE
Schrager, Sheree Michelle	Director of Research
eRA COMMONS USER NAME (credential, e.g., agency login) (b)(6)	

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Wellesley College, Wellesley, MA	BA	05/02	Mathematics, Psychology
University of Wisconsin – Madison, Madison, WI	MS	12/03	Psychology
University of Wisconsin – Madison, Madison, WI	MS	12/06	Statistics
University of Wisconsin – Madison, Madison, WI	PhD	05/08	Psychology

A. Personal Statement

As Co-Investigator, I will 1) advise the study core responsible for establishing standard procedures, merging collected data, and managing, analyzing, and reporting on data from all four study sites and 2) collaborate with the project PIs and Co-Is to provide scientific leadership and direction, particularly related to psychological variable measurement and operationalization. Specifically, I will provide direction to the CHLA site study coordinator, data collection staff, data manager, and biostatistician responsible for data management, cleaning, and analysis. I will also assist with survey development and constructing the protocols that will standardize our data collection and merging procedures; oversee the programming of final data collection instruments and pilot testing of ACASI programming logic; and provide advanced statistical consultation to the project, including diagnosing data problems, developing and executing analytical plans, and advising the analytic team on appropriate longitudinal data analysis methods and procedures. I maintain a similar role as Co-Investigator on a current longitudinal study of adolescent and young adult medical marijuana users (R01DA034067-01A1; PI: Lankenau), which is now successfully finishing its first year of data collection. I have several years' experience working productively with members of the CHLA study team (PI Olson, Co-Is Belzer and Clark), most recently on the PI's KL2 Mentored Research Career Development award, and I was a research mentor to a Co-I (Simons) at the Chicago site during her fellowship at CHLA. My history of NIH funding, extensive research and statistical training and experience, and progressive research management experience have prepared me well for the role of Co-Investigator on this study. As the Director of Research for Hospital Medicine at CHLA, my primary work is to develop the research skills of hospital-affiliated faculty and research staff in all aspects of quantitative research methodology, including experimental and non-experimental study design, survey development, study protocols, and data analysis and reporting, with a particular focus on advanced statistical methods. My primary research area has been the health, functioning, and risk behavior of adolescents and young adults, particularly sexual minority and transgender adolescents, which has allowed me to develop considerable expertise in the methods proposed in this R01 application. Specific areas of focus include psychometric analysis, multivariate statistics, and general linear models with corresponding expertise in a variety of analytic software packages. I am also an IRB member and experienced research project manager whose responsibilities include hiring and managing project staff; assisting with IRB protocol development; designing research protocols and instruments; ensuring compliance with IRB and funding source requirements; documenting research processes, including intervention, process, and evaluation data; and leading and participating in project-specific and general management training and meetings. This leadership experience will support me to facilitate the conduct of rigorous, collaborative, and productive research by the project team.

B. Positions and Honors

Positions and Employment

2002-2008 Graduate Research Fellow, University of Wisconsin – Madison, Madison, WI
2008-2009 Biostatistician, Children's Hospital Los Angeles, Los Angeles, CA
2008-2011 Consultant, Agile Mind, San Francisco, CA
2010-2012 Sr. Research Manager, Children's Hospital Los Angeles, Los Angeles, CA

2011-2013	Consultant, Children and Family Futures, Irvine, CA
2012-2013	Behavioral Research Administrator, Children's Hospital Los Angeles, Los Angeles, CA
2012-	Consultant, University of Southern California School of Social Work, Los Angeles, CA
2014-	Director of Research, Children's Hospital Los Angeles, Los Angeles, CA

Honors

2002	Wellesley College: Summa Cum Laude; Lewis Atterbury Stimson Prize in Mathematics; Departmental Honors in Mathematics and Psychology
	University of Wisconsin-Madison: Graduate Research Fellowship
2003-2006	National Science Foundation Graduate Research Fellowship
2006-2008	Interdisciplinary Training Program in Education Sciences Fellowship
2007	University of Wisconsin-Madison: Royalty Research Foundation Collaborative Research Award (also awarded 2005); Hertz Foundation Research Travel Award (also awarded 2005, 2006); Vilas Travel Grant Award
	Society for Personality and Social Psychology Graduate Student Poster Award

C. Selected Peer-Reviewed Publications

Most relevant to the current application:

1. Olson J, **Schrager SM**, Clark LF, Dunlap SL, Belzer M. Subcutaneous testosterone: An effective delivery mechanism for masculinizing young transgender men. *LGBT Health*. 2014;1(3):165-167.

2. Simon LK, **Schrager SM**, Clark LF, Belzer M, Olson J. Parental support and mental health among transgender adolescents. *J Adolesc Health*. 2013;53(6): 791-793.

3. **Schrager SM**, Olson J, Beharry M, Belzer M, Goldsich K, Desai M, Clark LF. Young men and the morning after: A missed opportunity for emergency contraception provision? *J Fam Plann Reprod Health Care*. 2014 Jan 24 [Epub ahead of print].

Additional recent publications of importance to the field:

4. Wu S, Baker C, Lang ME, **Schrager SM,** Liley FF, Papa C, Mira VM, Balkian A, Mason WH. A randomized controlled trial of nebulized hypertonic saline for bronchiolitis. *JAMA Pediatr*. 2014;168(7):657-663.

5. **Schrager SM**, Latkin C, Weiss G, Kubicek K, Kipke MD. High risk sexual activity in the House and Ball community: Influence of social networks. *Am J Public Health*. 2014;104(2):326-331.

6. Goldbach JT, **Schrager SM**, Dunlap SL, Holloway IW. The application of minority stress theory to marijuana use among sexual minority adolescents. *Subst Use Misuse.* In press.

7. Herrick A, Stall RD, Egan JH, **Schrager SM**, Kipke MD. Pathways towards risk: Syndemic conditions mediate the effect of adversity on HIV risk behaviors among young men who have sex with men (YMSM). *J Urban Health.* In press.

8. Holloway IW, **Schrager SM**, Wong CF, Smith L, Kipke MD. Network correlates of sexual health advice seeking and substance use among members of the Los Angeles House and Ball communities. *Health Educ Res.* 2014;29(2):306-318.

9. Wong CF, **Schrager SM**, Holloway IW, Meyer IH, Kipke MD. Minority stress experiences and psychological well-being: The impact of support from and connection to social networks within the Los Angeles House and Ball communities. *Prev Sci*. 2014;15(1):44-55.

10. Traube DE, **Schrager SM**, Holloway IW, Weiss G, Kipke MD. Environmental risk, social cognition, and drug use among young men who have sex with men: Longitudinal effects of minority status on health processes and outcomes. *Drug Alcohol Depen*. 2013;127(1):1-7.

11. Kecojevic A, Wong CF, **Schrager SM**, Silva K, Jackson Bloom J, Iverson E, Lankenau SE. Initiation into prescription drug misuse: Differences between lesbian, gay, bisexual, transgender (LGBT) and heterosexual high-risk young adults in Los Angeles and New York. *Addict Behav.* 2012;37(11):1289-1293.

12. **Schrager SM**, Do C, Holloway IW, Cheng EM, Chen AY. Profile of insurance coverage in a national inpatient sample. *American Journal of Public Health Research*. 2013;1(1):27-31.

13. Chen AY, **Schrager SM**, Mangione-Smith R. Quality indicators for primary care of complex pediatric patients. *Pediatrics*. 2012;129(3):433-445.

14. Traube DE, Holloway IW, **Schrager SM**, Kipke MD. Utilizing Social Action Theory as a framework to determine correlates of illicit drug use among young men who have sex with men. *Psychol Addict Behav.* 2012;26(1):78-88.

15. **Schrager SM**, Wong CF, Weiss G, Kipke MD. HIV testing and risk behaviors among young men who have sex with men in Los Angeles County. *Am J Health Promot*. 2011;25(4):244-247.

D. Research Support

Ongoing Research Support

R21 HD 082813-01A1 (Goldbach/Schrager), 09/25/14 – 08/31/16
National Institute of Child Health and Human Development (NICHD)
"Measuring Stress Among Diverse Adolescents"
Although sexual minorities consistently report health disparities compared to heterosexuals, the relationship between minority stressors and negative health outcomes remains unclear due to lack of available measures. We will develop an instrument to measure minority stress among racial and ethnically diverse LGBT adolescents. Results will support operationalization of minority stress constructs for adolescents, development of targeted health interventions, and opportunities to measure minority stress in longitudinal designs.
Role: Co-Principal Investigator

R01 DA 034067-01A1 (Lankenau), National Institute on Drug Abuse (NIDA) 07/01/13 – 06/30/18
"Medical Marijuana, Emerging Adults & Community: Connecting Health and Policy"
This five-year study will determine whether: (1) young medical marijuana (MM) patients experience an overall improvement in physical and psychological health; (2) young MM patients experience changes in patterns of misuse of alcohol, prescription, and illicit drugs; and (3) MM dispensaries exert positive or negative effects on emerging adults in their communities. Findings will guide members of the public health community towards devising MM policies that maximize health and minimize negative effects on youth and communities.
Role: Co-Investigator

R01 DA032600-01A1 (Traube), National Institute on Drug Abuse (NIDA) 09/30/12 – 08/31/15
"Isolating Targets with Existing Data to Prevent Teen Drug Use in Child Welfare"
We will conduct analyses of an extant national probability cohort of child welfare involved teens to determine the prevalence and impact of substance use, predictors of substance abuse over the course of adolescent development, and the role that current child welfare services play in ameliorating substance use and abuse.
Role: Co-Investigator

U18 HS020506-01 (Mangione-Smith), 03/01/11 – 02/28/15
Agency for Healthcare Research and Quality (AHRQ)
"Center of Excellence on Quality of Care Measures for Children with Complex Needs"
The quality of care measures to be developed under this award will provide new tools to rigorously and comprehensively evaluate health care for children with complex needs. These measures will be designed for dissemination and use among all Medicaid and Child Health Insurance Programs (CHIP) nationally.
Role: Site Principal Investigator (July 2014-present)

Completed Research Support

KL2 Mentored Research Career Development Program (Olson), 07/01/12 – 06/30/15
Southern California Clinical and Translational Science Institute
"The Physiologic and Psychosocial Development of Gender Non-Conforming Youth"
The purpose of this study was to collect preliminary data on puberty suppression with GnRH analogues, measuring bone mineral density, hormone levels and anthropometric measures including Tanner staging, linear growth, weight and BMI in transgender peri-pubertal youth. Additionally, this study examined the impact of GnRH analogues on depression, anxiety, quality of life, body esteem and suicidal ideation.
Role: Research mentor and biostatistician

R01 HL088503-01A2 (Mangione-Smith; Chen), 03/01/09 – 02/28/14
National Heart, Lung, and Blood Institute (NHLBI)
"Developing Quality Measures to Assess Pediatric Inpatient Respiratory Care"

We developed a rigorously designed quality of care assessment tool to examine the degree to which hospitals caring for children adhere to recommended standards of care for respiratory illness and to determine the feasibility and validity of using administrative data to make these assessments. We used the tool to assess inpatient management for children treated for asthma, bronchiolitis, croup, pneumonia, and cystic fibrosis.
Role: Project manager and biostatistician

K02 HS018087-01 (Chen), Agency for Healthcare Research and Quality (AHRQ) 07/01/09 – 06/30/12
"Measuring Quality of Primary Care in Complex Pediatric Patients"
Children with complex medical conditions (i.e., a developmental condition or two or more chronic conditions) are often managed by multiple providers, but the chronic and complex nature of these conditions, coupled with fragmented interaction and communication, can lead to inconsistent and poorly managed care. Our main objective was to develop a set of rigorously designed medical-record-based quality of care measures using the medical home concept to assess primary care of complex pediatric patients.
Role: Project manager

R01 DA-022968-01 (Kipke), National Institute on Drug Abuse (NIDA) 04/01/08 – 03/31/12
"African American Young Men's Study"
The purpose of this study was to understand and characterize the structural, social, and cultural characteristics of the Ball and House communities in Los Angeles; Ball and House members' use of illicit drugs, involvement in HIV risk and protective behaviors, and their social and sexual networks; and the role that rejection, discrimination and internalized homophobia play with respect to encouraging drug use and HIV risk.
Role: Biostatistician

R01-DA-021299-04 (Lankenau), National Institute on Drug Abuse (NIDA) 09/01/07 – 08/31/11
"Non-Medical Prescription Drug Use Among High-Risk Youth"
This was a comparative study of high-risk youth aged 16 to 25 in New York City and Los Angeles who were homeless, polydrug users, and/or injection drug users. We sought to describe why high-risk youth initiate non-medical prescription drug use, describe variability in the forms of prescription drugs available and behavioral practices employed in their administration, chart the social trajectory of the transition from prescription drug use into other types of controlled substances, and assess the consequences of chronic use of prescription drugs on increased risk for onset of behaviors associated with exposure to HIV and STIs.
Role: Biostatistician

R03-DA-024976-02 (Traube), National Institute on Drug Abuse (NIDA) 09/01/08 – 05/31/11
"Drugs, Sexual Impulsivity, HIV: Psychosocial and Cognitive Risk Factors of YMSM"
This study aimed to empirically validate the chain of relationships depicted in Social Action Theory (SAT) to determine if the theory addresses the interaction of individual, contextual, and social correlates of sexual and drug risk taking behaviors as they relate to YMSM. We further validated SAT by testing and incorporating competing relationships depicted in other behavioral models to develop a comprehensive theory of the social, psychosocial and cognitive risk factors for drug use, sexual impulsivity, and HIV among YMSM.
Role: Biostatistician

R21-DA-024588-01 (Kipke), National Institute on Drug Abuse (NIDA) 02/15/08 – 01/31/10
"HIV Prevention for High Risk African American Young Men"
This study adapted an existing, evidence-based HIV prevention intervention, *Project AIM* (Adult Identity Mentoring), for use with 18-24 year old African American young men who have sex with men (AAYMSM). This study adapted *Project AIM* to be developmentally appropriate and culturally relevant for use with AAYMSM in Los Angeles and pilot tested the feasibility and acceptability of the adapted intervention.
Role: Biostatistician

5-R01-DA-15638-03 (Kipke), National Institute on Drug Abuse (NIDA) 09/01/03 – 06/30/09
"Drug Use, Sexual Risk and Health Promoting Behaviors Among At-Risk Youth"
This study involved community-based, theory-driven longitudinal research with an ethnically diverse cohort of at-risk young men to examine individual, familial, social, and interpersonal risk and protective factors associated with drug use and HIV risk behaviors.
Role: Biostatistician

BIOGRAPHICAL SKETCH

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

NAME	POSITION TITLE
Spack, Norman MD	Associate Clinical Professor in Endocrinology
eRACOMMONS USER NAME (credential, e.g., agency login) (b)(6)	

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Williams College, MA	BA	06/65	Biology
University of Rochester School of Medicine and Dentistry, NY	MD	06/69	Medicine
Boston City Hospital, MA	Intern and Resident	06/72	Pediatrics
Children's Hospital Boston, MA	Fellow	06/75	Adolescent Medicine
Children's Hospital Boston, MA	Fellow	06/77	Diabetes
Children's Hospital Boston, MA	Fellow	06/93	Pediatric Endocrinology

A. Personal Statement

Norman Spack, M.D., is a Senior Associate in the Endocrine Division at Children's Hospital, Boston, and Associate Clinical Professor of Pediatrics at Harvard Medical School. A 1965 graduate of Williams College, he received his MD from University of Rochester School of Medicine and Dentistry in 1969. He completed a Pediatric Residency at Boston City and Children's Hospitals and fellowships in Adolescent Medicine and Endocrinology at Children's, where he was on the team that first used the A1c test in a pediatric population. In 1978, Dr. Spack co-founded the first community-based private practice of Adolescent Medicine in New England. In 1998, he was appointed Clinical Director of the Endocrine Division. He served on the Admissions Committee of Harvard Medical School and is on the Peer Review Committee of Children's Hospital.

He was a member of the 2005 International Consensus Conference on Intersex and on the Endocrine Society's 7-person international task-force that published clinical guidelines for the management of transsexual adolescents and adults in 2009.

Dr. Spack has received awards for his teaching, clinical care, and community service and has mentored dozens of endocrinologists, some now chairing pediatric endocrine deptartments. In 2007, with David Diamond M.D., he co-founded Children's Hospital's GeMS, Gender Management Service, an interdisciplinary clinical program for patients with Disorders of Sex Development (Intersex) or Transgenderism. It is the first such program outside of Europe. He was lead author in a March 2012 Pediatrics article on transgender youth, the first article on that subject in that journal. His review article on transgenderism appeared in JAMA in 2012.

The goal of the proposed research is to investigate early medical treatment in transgender youth. Specifically, we will evaluate the impact of GnRH agonists administered for suppression of puberty on mental health and metabolic parameters and the safety and effect of cross-sex hormones. While these treatments are currently suggested by The Endocrine Society's Clinical Practice Guidelines, they have not been studied extensively in the U.S. population. Dr. Spack, as the co-founder and director of the GeMS program at Boston Children's Hospital, is well suited to lead the institution's participation in this important proposal.

B. Positions and Honors

Positions and Employment

1977-78 Instructor in Pediatrics- Harvard Medical School
1978-96 Clinical Instructor in Pediatrics- Harvard Medical School
1997-12 Assistant Professor of Pediatrics- Harvard Medical School

2013 Associate Clinical Professor of Pediatrics- Harvard Medical School

Appointments at Hospital/Affiliated Institutions

1974-98 Courtesy Staff -Saints Memorial Medical Center, Lowell, MA
1976-80 Assistant in Medicine-Children's Hospital Boston
1978-98 Active Staff-Newton-Wellesley Hospital, Newton, MA
1981- Associate in Medicine-Boston Children's Hospital
1983-95 Medical Staff-N.E. Deaconess Hospital, Boston, MA
1990-95 Medical Staff-Waltham-Weston Hospital, Waltham, MA
1999-01 Active Staff-Lowell General Hospital, Lowell, MA
1999-01 Consulting Staff-St. Elizabeth's Hospital, Boston, MA
1999-10 Consulting Staff-Caritas Norwood Hospital, Norwood, MA

Other Professional Positions

1974-84 Liaison to Children's Hospital- Bridge Over Troubled Waters, Boston, MA
1981-85 Medical Advisory Board- Bridge Over Troubled Waters, Boston, MA
1985-89 Medical Consultant- Multi-Service Center of Newton, MA
1987-92 Coordinator, Prospective Study of Vascular Complications in Adolescent Diabetics- Eye Research Institute Boston and Baylor University School of Medicine
1993-99 Director- Diabetes & Endocrine Youth Program, Saints Memorial Med Center, Lowell, MA
1999-01 Director- Pediatric Endocrine Clinic, Lowell General Hospital, Lowell, MA

Other Experience and Professional Memberships

1975-2002 American Academy of Pediatrics- Member
1975- Society for Adolescent Medicine- Writer, Endocrine Section, First Board Examination
1978- Massachusetts Medical Society- Member
1993- Project Hope Medical Alumni- Member
1996- Harry Benjamin International Gender Dysphoria Association (WPATH)- Member& Abstract Reviewer for Biennial International meeting
1996- Lawson Wilkins Pediatrics Endocrine Society- Member
1997- The Endocrine Society- Member
2005- Standing committee on Disorders of Sex Development, Pediatric Endocrine Society- Member
2005- Standing committee on Disorders of Sex Development, Pediatric Endocrine Society- Member
2008-09 Endocrine Society International Task Force on Clinical Management of Transsexual Persons and co-author of the resulting published Guidelines- Member

Honors

1964 Williams College: Lehman Scholar College; Undergraduate service to college.
1985 Anne Woolf Award: Juv. Diabetes Assoc of Greater Boston for Service to Children with Diabetes
1987 Mead Johnson Clinical Scholar: Dept of Medicine; Teaching
1994 Children's Hospital: Service; Employee Recognition Award
1996 Janeway Service Award: Department of Medicine; Service
2012 David Weiner Award to GeMS from Children's Board of Trustees for Leadership Innovation in Child Health
2012 Annual lecture in honor of John F. Crigler, Jr. MD, Dept of Medicine Grand Rounds ,Sponsored by Endocrine Division
2012 Bicentennial Medal from Williams College for Lifetime Achievement in Transgender Care/Advocacy

C. Selected Peer-reviewed Publications

1. Tishelman A, Kaufman R, Edwards-Leeper L, Madel, F, Shumer DE, **Spack, N**. Serving transgender youth: challenges, dilemmas, and clinical examples. Prof Psychol-Res Pr. 2014. In press.
2. **Spack NP.** Clinical Crossroads, Management of Transgenderism. *JAMA*. 2013;209(5):478-484.
3. **Spack NP,** Edwards-Leeper L, Feldman HA, Leibowitz S, Mandel F, Diamond DA, Vance SR. Characteristics of children and adolescents with gender identity disorder referred to a pediatric medical center. *Pediatrics*. 2012;129(3):418-425.

4. Perrin E, Smith N, Davis C, **Spack N,** Stein MT. Gender variant and gender dysphoria in two young children. *J Dev Behav Pediatr.* 2010;31(2):161-4.
5. Goddard DS, Liang MG, Chamlin SL, Svoren BM, **Spack NP**, Mulliken JB. Hypopituitarism in PHACES Association. *Pediatric Dermatology*,2006. Sept-Oct;23(5):476-80.
6. Poussaint TY, Barnes PD, Anthony DC, **Spack NP**, Scott RM, Tarbell NJ. Hemorrhagic pituitary adenomas of adolescence. *American Journal of Neuro-radiology*. 1996;17:1907-12.
7. Feke GT, Buzney SM, Ogasawara H, Fujio N, **Spack NP**, Gabbay KH. Retinal circulatory abnormalities in type 1 diabetes. *Investigative Ophthalmology & Visual Science*. 1994;35: 2968-75.
8. Gabbay KH, **Spack NP**, Loo S.Hirsch HF and Ackil A. Aldose Reductase Inhibition: Studies with Alrestratin. *Metabolism.* 1979;28(4):471–6.

D. Research Support

Dr. Spack is not supported by grants

BIOGRAPHICAL SKETCH

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

NAME	POSITION TITLE
Daniel Shumer, MD	Fellow in Endocrinology
eRACOMMONS USER NAME (credential, e.g., agency login) (b)(6)	

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Northwestern University, Chicago, IL	BA	08/03	Psychology
Northwestern University, Feinberg School of Medicine, Chicago, IL	MD	05/08	Medicine
University of Vermont / Vermont Children's Hospital	Residency	06/11	Pediatrics
University of Vermont / Vermont Children's Hospital	Chief Resident	06/12	Pediatrics
Harvard University / Boston Children's Hospital, MA	Fellow	Current	Pediatric Endocrinology
Harvard School of Public Health, Boston, MA	MPH (expected)	Current	Clinical Effectiveness

A. Personal Statement

The goal of the proposed research is to investigate early medical treatment in transgender youth. Specifically, we will evaluate the impact of GnRH agonists administered for suppression of puberty on mental health and metabolic parameters and the safety and effect of cross-sex hormones. While these treatments are currently suggested by The Endocrine Society's Clinical Practice Guidelines, they have not been studied extensively in the U.S. population. As a fellow at Boston Children's Hospital (BCH), I have dedicated my clinical time and research to the transgender health care. I have participated in the transgender clinic at BCH since the beginning of fellowship and now care for my own patient cohort. My research focuses on measuring mental health parameters in the transgender patient population. I am also receiving a Masters of Public Health at Harvard School of Public Health as a fellow in the Harvard Pediatric Health Services Research Fellowship. This fellowship is training me for a research and clinical career in the transgender field. I plan to continue as faculty at BCH after fellowship in July 2015 with an administrative, clinical, and research role in the transgender program. The clinical and research skills I have been acquiring during my fellowship have prepared me to contribute to this important project as a co-investigator.

B. Positions and Honors

Positions and Employment

2008-2009 Pediatric Internship, Vermont Children's Hospital, Burlington, VT
2009-2011 Pediatric Residency, Vermont Children's Hospital, Burlington, VT
2011-2012 Pediatric Chief Resident, Vermont Children's Hospital, Burlington, VT
2012- Pediatric Endocrinology Fellow, Boston Children's Hospital, Boston, MA
2013- Investigational Review Board Member, The Fenway Institute, Boston, MA
2013- Research Fellow, Harvard Pediatric Health Services Research Fellowship, Boston, MA

Other Experience and Professional Memberships

2012- Pediatric Endocrine Society

C. Selected Peer-reviewed Publications

1. **Shumer DE**, Spack NP. Current management of Gender Identity Disorder in Childhood and Adolescence: Guidelines, Barriers and Areas of Controversy. *CurrOpinEndocrinol Diabetes Obes*. 2013;20(1):69-73
2. Reisner SL, Vetters R, Leclerc M, Zaslow S, Wolfrum S, **Shumer D**, Mimiaga, MJ. Mental health of transgender youth in care at an adolescent urban community health center: a matched retrospective cohort study. Journal of Adolescent Health. 2014. In press.
3. Tishelman A, Kaufman R, Edwards-Leeper L, Madel, F, **Shumer DE**, Spack, N. Serving transgender youth: challenges, dilemmas, and clinical examples. Prof Psychol-Res Pr. In press.
4. **Shumer DE**, Thaker V, Taylor GA, Wassner AJ. Severe hypercalcemia due to subcutaneous fat necrosis: presentation, management and complications. Arch Dis Child Fetal Neonatal Ed. 2014;99(5):F419-21.
5. **Shumer, DE**, Mehringer JE, Braverman LE, Dauber A. Acquired Hypothyroidism in an Infant Related to Excessive Maternal Iodine Intake: Food for Thought. Endocr Pract. 2013;19(4):729-31

D. Research Support

Ongoing Research Support

Dr. Shumer is currently supported by a training grant through June 2015: 1T32HD075727-01

Completed Research Support

No completed research projects for the past three years (Federal or non-Federally-supported).

BIOGRAPHICAL SKETCH

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

NAME	POSITION TITLE
Amy C. Tishelman	Director of Clinical Research, Disorder of Sexual Development-Gender Management Service Director of Psychology, Department of Urology Boston Children's Hospital Director of Research, Child Protection Program Massachusetts General Hospital Assistant Professor, Harvard Medical School
eRA COMMONS USER NAME (credential, e.g., agency login) (b)(6)	

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Clark University, Worcester, MA	B.A.	1977	Psychology
West Virginia University, Morgantown, WV	M.A.	1985	Clinical Psychology
University of Oklahoma Health Sciences Center	Pre-Doctoral Internship	1987	Pediatric Psychology/ Neuropsychology
West Virginia University, Morgantown, WV	Ph.D.	1988	Clinical Psychology
Center for Advanced Study in the Behavioral Sciences, Stanford, CA	Summer Fellow	1990	Human Development and Psychopathology
Children's Hospital Boston/Harvard Medical School	Fellow	1992-94	Clinical Research Fellow on Family Violence
The Bunting Institute, Radcliffe College and Harvard Medical School/Boston Children's Hospital (Joint Fellowship)	Fellow	1993-95	Family Violence

A. Personal Statement

Amy C. Tishelman, Ph.D. is a clinical psychologist and an Assistant Professor at Harvard Medical School. She is currently Director of Clinical Research and a senior staff psychologist for the Disorders of Sexual Development-Gender Management Service (DSD-GeMS) at Boston Children's Hospital (BCH), where she has been asked to develop a clinical research program related to transgender and gender non-conforming youth, and youth with DSD. She also serves as BCH Director of Psychology in the Urology Department. In addition, Dr. Tishelman is Research Director and a senior staff psychologist for the Child Protection Program at Massachusetts General Hospital. Prior to her current appointments, she was the BCH Director of Research and Training for the Child Protection Program and, earlier, BCH Director of Child Protection Clinical Services (CPCS). She has an abiding interest in clinical work with vulnerable children and families, as well as in scholarship designed to enhance clinical care. Dr. Tishelman is on the editorial boards of several journals, including Child Abuse & Neglect, the Journal of Child Sexual Abuse (JCSA), and the Journal of Family Violence and is an Associate Editor of the Journal of Child and Adolescent Trauma (JCAT). She recently co-edited special double issues of both JCSA and JCAT. Additionally, Dr. Tishelman is a sought after expert in the forensic realm and speaks frequently on issues related to her areas of expertise. She is also a part-time faculty member in the Psychology Department of Boston College, where she has been employed since 1993, and is co-teaching a class annually on Child Maltreatment (with Robin Deutsch, Ph.D.) at the Massachusetts School of Professional Psychology in The Center of Excellence for Children, Families and the Law.

B. Positions and Honors

Positions and Employment

1986-1987 Clinical Psychology Intern, University of Oklahoma Health Sciences Center, Oklahoma City, OK
1987-1988 Lecturer, Department of Psychology, State University of New York, Binghamton, NY
1988-1992 Assistant Professor, Department of Psychology, State University of New York, Binghamton, NY

1993-	Part-time Faculty, Department of Psychology, Boston College, Chestnut Hill, MA
1994-2011	Instructor, Harvard Medical School, Boston, MA
1995-1997	Affiliated Clinician, Psychological Services, Inc. Brockton, MA
1995-2002	Senior Psychologist, Child Protection Program, Boston Children's Hospital, Boston, MA
1995-2003	Clinical Psychologist, Private practice, Cambridge, MA
1999-1999	Staff Psychologist, Child Protection Program, Boston Children's Hospital, Boston, MA
2002-2003	Supervising Psychologist, Optimal Weight for Life Clinic, Children's Hospital, Boston, MA
2002-2005	Director, Child Protection Program, Boston Children's Hospital, Boston, MA
2005-2012	Director, Training and Research, Child Protection Program, Children's Hospital Boston, MA
2011-	Assistant Professor, Harvard Medical School
2013-	Director of Clinical Research, Senior Staff Psychologist, Disorders of Sexual Development-Gender Management Service, Boston Children's Hospital, Boston, MA
2013-	Director of Psychology, Department of Urology, Boston
2013-	Director of Research and Senior Psychologist, Child Protection Program, Massachusetts General Hospital, Boston, MA
2113-	Part-time faculty, Massachusetts school of Professional Psychology

Selected Other Experience

2002-2012	Mental Health Consultant: Suffolk County Child Advocacy Center, Boston, MA
2003-2011	Disaster Response Network (DRN) Steering Committee, Massachusetts Psychological Association
2004-2006	Governors Commission on Sexual and Domestic Violence: Child and Adolescent Committee
2006-2011	Advisory Council, Department of Education Safe and Supportive Learning Environment Project
2007-2010	Ethics Advisory Committee, Children's Hospital Boston
2007-2010	Co-Chair, Child/Youth Services Committee, Governor's Council on Sexual and Domestic Violence, Patrick Administration
2008-2012	Co-Chair, Massachusetts, Guardians Ad Litem Task Force
2007-	Governor's Council on Sexual and Domestic Violence, Patrick Administration
2008-2011	Institutional Review Board (IRB), Children's Hospital Boston, Primary Representative, Psychiatry
2011-2014	Institutional Review Board (IRB), Children's Hospital Boston, Alternate Representative, Psychiatry

Editorial Leadership Roles

2007-2010	Editorial Board, Journal of Child and Adolescent Trauma
2010	Guest Co-Editor, Special Double Issue, Journal of Child Sexual Abuse: Tishelman & Geffner (Eds.), 2010. *Forensic, Cultural and Systems Issues in Child Sexual Abuse Cases,* Volume 19, 5 & 6.
2011	Guest Co-Editor, Special Double Issue, Journal of Child and Adolescent Trauma: Tishelman & Geffner (Eds.), 2011. *Child and Adolescent Trauma Across the Spectrum of Experience: Interpersonal and Ecological Factors. Journal of Child and Adolescent Trauma*
2010-	Editorial Board, Child Abuse and Neglect
2011-	Editorial Board, Journal of Child Sexual Abuse
2011-	Associate Editor, Journal of Child and Adolescent Trauma
2012-	Editorial Board, Journal of Family Violence

Selected Professional Memberships

American Psychological Association
World Professional Association on Transgender Health
Society of Pediatric Psychology

C. Selected Peer-reviewed Publications

Most relevant to the current application (in chronological order)

1. Bell-Dolan, D.J., Foster, S.L., **& Tishelman, A.C.** (1989). An alternative to negative nomination sociometric measures. *Journal of Clinical Child Psychology, 18*, 153-157.

2. Hansen, D.J., Smith, G.M., **Tishelman, A.C.,** Conway, L.P. & MacMillan, V.M. (1989). Parental problem-solving skills and child behavior problems: A comparison of physically abusive, neglectful, clinic and community families. *Journal of Family Violence, 4*, 353-368.
3. Hansen, D. J., **Tishelman, A. C.,** Hawkins, R. P., & Doepke, K. (1990). Habits with potential as Disorders: Prevalence, severity and other characteristics among college students. *Behavior Modification, 14*, 66-80.
4. Evans, I.M., Okifugi, A., Engler, L., Bromley, K & Tishelman, A.C. (1993). Home-school communication in the treatment of child behavior problems. *Child and Family Behavior Therapy, 15,* 37-60.
5. DeRoma, V.M., Hansen, D.J.,**Tishelman, A.C**. & D'Amico, P.(1997). Influence of information related to child physical abuse on professional ratings of adjustment and prognosis. Child Abuse and Neglect, 21, 293-308.
6. **Tishelman, A.C.,** Haney, P., Greenwald O'Brien, J & Blaustein, M. (2010). A framework for school-based psychological evaluations: Utilizing a 'trauma lens'. *Journal of Child and Adolescent Trauma*, 3 (4), 279-302.
7. **Tishelman, A.C.,** Meyer, S.K. Haney, P., McLeod, S.K. (2010). Clinical-Forensic dichotomy in sexual abuse evaluations: Moving toward an integrative model. *Journal of Child Sexual Abuse, 19 (*5), 590-608.
8. **Tishelman, A.C.** & Geffner, R. (2010). Forensic, cultural, and systems Issues in child sexual abuse cases: An introduction. *Journal of Child Sexual Abuse*, *19 (5)*, 485-490.
9. **Tishelman, A.C.** & Geffner, R. (2010). Forensic, cultural, and systems issues in child sexual abuse cases - Part 2: Research and practitioner issues. *Journal of Child Sexual Abuse, 19 (6)*, 609- 617.
10. **Tishelman, A.C**. & Geffner, R. (2011). Child and adolescent trauma across the spectrum of experience: Research and clinical interventions. *Journal of Child and Adolescent Trauma, 4,*1-7.
11. Geffner, R. & **Tishelman, A.C**. (2011). Child and adolescent trauma across the spectrum of experience: Underserved populations and psychological abuse. *Journal of Child and Adolescent Trauma, 4 (2)*, 87-89.
12. Williams, J. Nelson-Gardell, D., Faller, K., Cordisco-Steele & **Tishelman, A.C**. (2013). Is there a place for extended assessments for evaluating concerns about child sexual abuse? Perceptions of 1,294 child maltreatment professionals. *Journal of Forensic Social Work,* 88-105.
13. Hidalgo, M.A. , Ehrensaft, D., **Tishelman, A.C**., Clark, L., Garofalo, R., Rosenthal, S., Spack, N.P & Olson, J. (2013). The gender affirmative model: What we know and what we aim to learn. *Human Development,* 56, 285-290.
14. Williams, J. Nelson-Gardell, D., Faller, K.,**Tishelman, A.C.** & Cordisco-Steele, L.(2014). Is there a place for extended assessments in addressing child sexual abuse allegations? How sensitivity and specificity impact professional perspectives. *Journal of Child Sexual Abuse*, 23, 179-197
15. **Tishelman, A.C.,** Mandel, F. H., Kaufman, R., Edwards-Leeper, L. & Spack, N.P. (in press). Serving Transgender Youth: Clinical Practices, Challenges, and Dilemmas. *Professional Psychology: Research and Practice.*

D. Selected Ongoing and Completed Research Support

Funded

2009-2014: Domestic Violence and Child Interview Practices during Guardian Ad Litem Evaluations: A Preliminary Study
Surveys current approaches to the assessment of domestic violence in custody/access disputes by Custody Evaluators within and outside of Massachusetts.
Current Status: Data collection and analysis completed.
Role: PI

2014: Disclosure in Disorders of Sexual Development
This is a qualitative research study designed to better understand factors that impact how three populations of patients with DSD (Kleinfelter's Syndrome, Turner's Syndrome, and Complete Androgen Insensitivity Syndrome) experience disclosure of medical information, how they disclose to others, and factors impacting their quality of life and relationships.
Current Status: Research protocol successfully reviewed by Scientific Review Committee, and BCH IRB. This study is currently being reviewed by Compliance personnel at BCH. Internally funded by the Department of Urology at BCH.
Role: PI

2014: Cultural issues in Child Sexual Abuse Forensic Interviews: A Qualitative Approach
Qualitative project involving semi-structured interviews of staff involved in forensic interviews of children alleging child sexual abuse, in four geographic regions in the United States; examines important and frequent cultural issues perceived by these interviewers; internally funded by the Child Protection Program at MGH.
Current Status: Recently approved by IRB at MGH and at UMass Amherst. Active research will commence shortly.
Role: PI (with Lisa Fontes, Ph.D.)

Unfunded

2010: Psychosocial and Disclosure Information in Children Evaluated for Child Sexual Abuse: A Preliminary Study of Descriptive Information and Data Correspondence
In children referred for sexual abuse evaluations, behavioral and psychological status of the disclosing and non-disclosing child, from archival evaluation records.
Current Status: Data collection (A subset of this data is being used as part of the dissertation of a BCH staff member.)
Role: PI

2010-2014: Professional Perceptions of the Need for Extended Assessments
This is a collaborative study with colleagues at other institutions nationally (Faller, Nelson-Gardell, Cordisco-Steele & Tishelman) surveying professionals to gather information about 1) their perceptions and experience of the need for extended assessments of allegations of child maltreatemnet, 2) existing extended assessment resources in their communities, and 3) respondent expertise in conducting extended assessments.
Current Status: Data collection and analysis completed. Two publications have resulted from this study; we have a final research paper under review at present.
Role: PI

2013: Psychological Characteristics of Gender Dysphoric Adolescents Presenting for Evaluation and Possible Medical Treatment in a Pediatric Medical Center Gender Clinic
This study has created a database of patients seen for gender dysphoria in the Gender Management Service (GeMS) at Boston Children's Hospital. The database is being used to describe the psychological characteristics of adolescents requesting medical intervention in such a clinic.
Current Status: Data analysis
Role: PI (with Laura Edwards-Leeper, Ph.D. and Dan Shumer, M.D.)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Robert Garofalo MD, MPH	Division Head – Adolescent Medicine Professor of Pediatrics – Northwestern U.
eRA COMMONS USER NAME (credential, e.g., agency login) (b)(6)	

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

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

A. Personal Statement

The primary aim of this proposal is to observational and longitudinal outcomes research related to medical interventions in gender non-conforming children and adolescents. As a pediatrician I believe this work to critically needed in the field to help inform evidence –based practices which is currently lacking as we advise and counsel parents and families. I feel my background in both clinical care and research as it relates to transgender health is well-suited to proposed research. My research career has focused on the collection of basic data on marginalized populations and the translation of this data into intervention development. I have extensive experience engaging transgender women and young MSM age 16-24, in longitudinal and STI/HIV prevention research. I have extensive experience running and being the site PI of clinical and translational research projects funded by the NIH. I have been PI or Co-PI on 6 NIH grants (3 specific to HIV risk among MSM), 2 CDC research grants, and Co-Investigator on 3 additional NIH grants. Across these projects I have developed the skills to lead interdisciplinary and multi-site clinical research teams. Specific to this application, I worked extensively over the past year with the other site PI's on this proposal. I am the Director of The Lurie Children's Hospital Center for Gender, Sexuality and HIV Prevention as well as the Co-Director of our Program in Gender and Sex Development. I also serve as the hospital's Division Head of Adolescent Medicine. I have over 10 years' experience doing clinical work with the proposed populations of youth and adolescents. I have led the formation of a multidisciplinary clinical and research team at our institution as they relate to gender non-conforming children and adolescents. I served on the Institute of Medicine Committee on "The Health of Lesbian, Gay, Bisexual and Transgender People" where my expertise in youth, transgender health and HIV were focal points of my involvement. It is the findings from this Committee that in large part motivate the proposed research. I will take primary responsibility for the implementation of the scientific aims of this project at Lurie Children's as well as the dissemination of our findings. I will appropriately mentor junior and Co-Investigators at my site including Dr.'s Hidalgo, Leibowitz, Finlayson and Simons as this is their primary academic and clinical interest but to-date have not had significant experience with NIH funded research. In addition, along with Dr. Belzer from Children's Hospital of Los Angeles, I will help co-mentor the contact PI Joanna Olsen as I have done throughout her young and promising career. While Dr. Olson may be relatively inexperienced with NIH-funded multisite clinical trials, it is my opinion that she is the emerging clinical leader in this field. The proposed network of 4 sites gave very careful consideration in deciding the contact PI for this proposal. I have fuill confidence that with the appropriate guidance and mentoring that Dr. Olson is ideally suited to lead this effort. She has my full support.

B. Positions and Professional Experience

1997-01	Instructor in Pediatrics, Harvard Medical School
1997	Health Policy Fellow: Office of Senator Edward M. Kennedy. Washington, DC.
1997-01	Assistant in Medicine/Attending Physician, Division of General Pediatrics Children's Hospital/Harvard Medical School, Boston, MA
1997-01	Director of Adolescent Medicine. JRI/Sidney Borum Community Health Center. Boston, MA.
2001-	Attending Physician, Division of General Academic Pediatrics/Infectious Diseases Lurie Children's Hospital (formerly Children's Memorial Hospital)/Northwestern University Medical School, Chicago, IL
2001-11	Program Director/Principal Investigator: PATH Youth Network. HRSA/Ryan White Title IV-funded collaboration for Adolescent HIV: Children's Memorial Hospital and Howard Brown Health Center, Chicago, IL.
2001-	Director of Adolescent HIV Services, Lurie Children's Hospital, Chicago, IL
2002-05	Director of Youth Services; Howard Brown Health Center, Chicago, IL
2006-2011	Duty Director/Director of Youth Services; Howard Brown Health Center, Chicago, IL
2008-	Associate Professor of Pediatrics and Preventive Medicine; Northwestern University Feinberg School of Medicine. Chicago, IL

Committee Service

1997-00	Co-coordinator of the HIV/AIDS Stewardship Committee. Harvard Medical School. Boston, MA
1998-00	Government Affairs Committee: National AIDS Policy Center for Children Youth and Families. Washington, DC
2002	Chair of Organizing Committee. International conference sponsored by the National Security Education program. *Pediatric and Adolescent HIV: An International Perspective.* Northwestern University Feinberg School of Medicine
2000-03	Co-Director of Lesbian, Gay, Bisexual and Transgendered Youth Special Interest Group. Society for Adolescent Medicine
2003-	Professional Education Curriculum Review Committee; Department of Preventive Medicine. Northwestern University School of Public Health
2003-	Board of Directors. Gay and Lesbian Medical Association. San Francisco, CA
2004-	Adolescent Research Advisory Committee. NIAID/Pediatric AIDS Clinical Trials Group (PACTG)
2005-	President. Gay and Lesbian Medical Association. San Francisco, CA
2006	NIH Scientific Review Committee. HIV Behavioral Research Group - AARR G(03). July 2006
2009-	National Community Advisory Board. Human Rights Campaign. Healthcare Equality Index
2010-11	National Academy of Sciences/Institute of Medicine Committee. LGBT Research Gaps/Opportunities
2010-15	NIH Scientific Review Committee. Behavioral and Social Consequences of HIV/AIDS
2011	Expert Advisory Panel. The Joint Commission. Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care for LGBT Communities: A Field Guide

Honors.

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

C. Publications – (selected academic articles and book chapters in chronological order – from 35)

Most relevant to the current application:

1. Wilson E, Garofalo R, Harris R, Herrick A, Martinez M, Martinez J, Belzer M. (2009). Transgender Female Youth and Sex Work: HIV Risk and a Comparison of Life Factors Related to Engagement in Sex Work. AIDS and Behavior, 13(5):902-913. PMCID: PMC2756328.

2. Wilson EC, Garofalo R, Harris RD, Martinez J, Belzer M. (2010). Sexual risk-taking among transgender male-to-female youths with different partner types. Am J Public Health, 100(8):1500-5. PMCID: PMC2901273.
3. Mustanski BS, **Garofalo R**, Emerson E. (2010). Mental Health Disorders, Psychological Distress, and Suicidality in a Sample of Lesbian, Gay, Bisexual, and Transgender Youths. *Am J Public Health*, 100(12): 2426-2432. PMCID: PMC2978194.
4. Dowshen N, Forke CM, Johnson AK, Kuhns LM, Rubin D, Garofalo R. (2011). Religiosity As a Protective Factor Against HIV Risk Among Young Transgender Women. J Adolesc Health; 48(4):410-414.
5. Brennan J, Kuhns LM, Johnson AK, Belzer M, Wilson EC, **Garofalo R**. (2012). Syndemic Theory and HIV-Related Risk Among Young Transgender Women: The Role of Multiple, Co-Occurring Health Problems and Social Marginalization. *American Journal of Public Health,* 102(9):1751-1757. PMCID: PMC3416048.
6. Garofalo R, Johnson A, Kuhns L, Cotten C, Joseph H, Margolis A. (2012). Life Skills: Evaluation of a Theory-Driven Behavioral HIV Prevention Intervention for Young Transgender Women. J Urban Health, 89(3):419-431. PMCID: PMC3368050.
7. Wilson EC, Iverson E, **Garofalo R**, Belzer M. (2012). Parental Support and Condom Use Among Transgender Female Youth. *Journal of the Association of Nurses in AIDS Care,* 23(4):306-317. PMCID: PMC3288276.
8. Bird JDP, Kuhns L, **Garofalo R**. (2012). The Impact of Role Models on Health Outcomes for Lesbian, Gay, Bisexual, and Transgender Youth. *Journal of Adolescent Health,* 50(4):353-357. PMCID: PMC3313463.
9. Hotton AL, **Garofalo R**, Kuhns LM, Johnson AK. (2013). Substance Use as a Mediator of the Relationship Between Life Stress and Sexual Risk among Youth Transgender Women, 25(1): 62-71.
10. **Garofalo R.** (2014). Tipping points in caring for the gender nonconforming child and adolescent, 46(6): 227-229.
11. Olson J, **Garofalo R**. (2014). The peripubertal gender-dysphoric child: Puberty suppression and treatment paradigms. Pediatr Annals, 42(6):e132-137.

Additional recent publications of importance to the field:

12. **Garofalo R,** Mustanski BS, McKirnan D, Herrick A, Donenberg GR. (2007). Methamphetamine and young men who have sex with men: Understanding patterns and correlates of use and the association with HIV-related sexual risk. *Archives Pediatr Adolesc Med*, 161:591-596.
13. **Garofalo R**, Herrick A, Mustanski BS, Donenberg GR. (2007). Tip of the iceberg: Young men who have sex with men, the Internet and HIV risk. *Am J Public Health*, 97(6): 1113-1117.
14. **Garofalo R,** Mustanski BS, Donenberg GR. (2008). HIV Prevention with Young Men Who Have Sex with Men: Parents Know and Parents Matter; Is it Time to Develop Family-Based Programs for This Vulnerable Population? *J Adolesc Health*, 43:201-204. PMCID: PMC2601675.
15. **Garofalo R**, Mustanski B, Johnson A, Emerson E. (2010). Exploring Factors That Underlie Racial/Ethnic Disparities in HIV Risk among Young Men Who Have Sex with Men. *J Urban Health,* 87(2):318-323. PMCID: PMC2845827.

D. Research Support

Ongoing Research Support

R01MH094323-01 Garofalo / Mimiaga (PIs) 06/13/2011 – 03/31/2016
NIMH

HIV Prevention Intervention for Young Transgender Women

The purpose of this study is to test the efficacy of a uniquely targeted HIV risk reduction intervention for young transgender women (YTW), ages 16 to 24, at risk for HIV acquisition or transmission.

R01DA025548 Garofalo / Mustanski (PIs) 04/01/2009 – 01/31/2014
NIDA

Syndemic Development and HIV Risk Among Vulnerable Young Men

This project will investigate a syndemic of psychosocial health issues linked to HIV among YMSM ages 16-20. This syndemic includes HIV risk, drug use, internalizing mental health problems, and violence exposure. The overarching goals of this study are twofold: 1) to provide much-needed epidemiological data on the prevalence of HIV and related health issues in order to inform public health priorities; and 2) to collect vital information on risk and protective factors to inform the development of an intervention targeting this vulnerable population.

R34DA031053 Garofalo (PI) 09/30/2010 – 05/31/2014
NIDA
Text Messaging Intervention to improve Adherence Among HIV-positive Youth and Young Adults
This study is a randomized controlled trial which will test the efficacy of a SMS text messaging intervention on antiretroviral adherence rates among non-adherent youth and young adults living with HIV, ages 16-29.

R34MH097622 Schneider 03/01/2012 - 02/28/2015
NIH/NIMH
Network supported care for young black men newly diagnosed with HIV
Description: This goal of this project is to refine and pilot test a flexible Network Supported Engagement in Care (NSEC) intervention that recruits and motivates one or more organic social support network members of recently HIV diagnosed young black men who have sex with men (YBMSM) to improve engagement in HIV primary care.
Role: Co-Investigator

Completed Research Support:
U01 HD052172 Garofalo (PI) 10/01/2006 – 02/28/2013
NICHD
The PATH Youth Program: HIV/AIDS Interventions in Adolescents
This award is for our site to be a member of the Adolescent Medicine Trials Network (ATN). The ATN conducts clinical and behavioral research projects with HIV+ adolescents and youth at risk of acquiring HIV.

UR6 PS000396 Garofalo (PI) 09/01/2006 – 08/31/2008
CDC
Life Skills Intervention: Safety & Coping Among Transgender Youth and Young Adults
This study, funded by the HIV prevention research branch of the CDC, is to develop and pilot test and HIV prevention intervention for at-risk transgender youth age 14-24. The developed multi-dimensional intervention will be based upon Bronfenbrenner's Social-Ecological Model.

R34 MH079714 Mustanski (PI) 06/01/2007 – 05/31/2010
NIMH
Internet-based HIV/STI prevention for young MSM receiving HIV testing
This three year study involves using the Transtheoretical Model of Behavior Change for the phased development and testing of an online HIV prevention program targeting the unique mechanisms of risk of young adult men who have sex with men (MSM) age 18-24 who recently tested negative from HIV.
Role: Co-Investigator

R34 MH079707 Garofalo (PI) 09/01/2007 – 11/31/2010
NIMH
Intervention Development: Reducing HIV Risk in Vulnerable Youth
This three year study supports the development of a group-based intervention for an ethnically-diverse sample of young men who have sex with other men age 14-20. The intervention, based upon the Social-Personal Model of HIV Risk, will target the unique mechanisms of this high-risk adolescent population

R01HD051438 Eyre (PI) 07/01/2007 – 06/30/2012
NICHD
Cultural Predictors of HIV Risk in African-American Adolescents
This award is for a qualitative and ethnographic study seeking to understand the cultural underpinnings of HIV in African-American male and female adolescents. This is a 3 site study: San Francisco, CA; Chicago, IL; and Birmingham, AL.
Role: Co-Investigator

BIOGRAPHICAL SKETCH

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

NAME	POSITION TITLE
Simons, Lisa K.	Attending Physician *Ann and Robert H. Lurie Children's Hospital of Chicago* Instructor of Pediatrics *Northwestern University Feinberg School of Medicine*
eRA COMMONS USER NAME (credential, e.g., agency login) (b)(6)	

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of Pennsylvania	BA	05/01	Biological Basis of Behavior
Sackler School of Medicine, Tel Aviv, Israel	MD	06/07	Medicine
Johns Hopkins Children's Center, Baltimore, MD		06/10	Residency, Pediatrics
Children's Hospital Los Angeles, CA		06/13	Fellowship, Adolescent Medicine

A. Personal Statement

The primary aim of this proposal is to gather observational and longitudinal outcomes related to the impact of medical treatment for transgender children and adolescents in the United States. As an adolescent medicine fellow with career interests in health care for marginalized youth, I spent three years working at Children's Hospital Los Angeles (CHLA) Center for Transyouth Health and Development learning more about the needs of the transgender population and training in specialized health care for transgender adolescent and young adults. Additionally, during fellowship I worked at a homeless shelter (Covenant House), a drop-in center (Jeff Griffith Youth Center), and a community clinic (Saban Free Clinic) providing health care to homeless and underinsured adolescents. Each of these sites served a disproportionately high number of transgender-identified youth, many of whom shared their experiences of rejection by peers and family; physical, verbal and sexual harassment or assault; and chronic homelessness. A number of these youth suffered from depression and suicidal ideation, and many described prior suicide attempts. While some transgender adolescents I encountered reported poor access to health care, other shared negative experiences trying to obtain even routine medical care. In 2013, I came to Ann & Robert H. Lurie Children's Hospital of Chicago specifically to expand my experience and knowledge base in gender care for youth and young adults, and here I am gaining valuable experience under the mentorship of Dr. Robert Garofalo, MD, MPH. My working relationship with Dr. Olson at CHLA, one of my primary mentors during fellowship at CHLA, remains strong.

B. Positions and Honors

Positions and Employment

2010-2013 Clinical Research Fellow, Division of Adolescent Medicine, Children's Hospital Los Angeles, CA
2013- Attending Physician, Lurie Children's Gender Development Clinic, Division of Adolescent Medicine, Ann and Robert H. Lurie Children's Hospital of Chicago, IL
2013- Instructor of Pediatrics, Northwestern University Feinberg School of Medicine, Chicago, IL
2014- Physician (part-time), Heartland Health Community Center, community-based health center offering comprehensive health care to homeless people of all ages, Chicago, IL

Honors and Awards

2012 Young Scholars Award, North American Society of Pediatric and Adolescent Gynecology

C. Selected Peer-reviewed Publications

Journal Articles

1. **Simons L**, Schrager SM, Clark LF, Belzer M, Olson J. Parental support and mental health among transgender adolescents. *Journal of Adolescent Health.* 2013;53(6):791-793.
2. **Simons LK**, Leibowitz SF, Hidalgo MA. Understanding gender variance in children and adolescents. Understanding gender variance in children and adolescents. *Pediatr Ann.* 2014;43(6):e126-31.

Published Abstracts

1. **Simons L**, Olson J, Belzer M, Clark L, Schrager S. The Relationship between Parental Support and Depression and Suicidality in Transgender Adolescents. Journal of Adolescent Health. 2012;50(2):S29.
2. Olson J, Clark L, Schrager S, **Simons L**, Belzer M. Baseline Characteristics of Transgender Youth Naïve to Cross-Sex Hormone Therapy. Journal of Adolescent Health. 2013;52(2):S35-36.

D. Research Support

While I have not yet received research support, as a fellow I was a co-investigator on Dr. Johanna Olson's) longitudinal observational study (funded by an intramural faculty research grant at Children's Hospital Los Angeles) assessing the impact of a multidisciplinary treatment model for transgender youth that includes provision of cross-sex hormone therapy, psychological counseling and case management.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Marco A. Hidalgo, PhD	**Psychologist** – Division of Adol. Medicine **Assistant Professor** of Psychiatry and Behavioral Sciences, Northwestern Univ., Feinberg School of Medicine
eRA COMMONS USER NAME (credential, e.g., agency login) (b)(6)	

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
San Francisco State Univ; San Francisco, CA	BA	05/04	Psychology
DePaul University; Chicago, IL	MA	06/07	Clinical/Community Psychology
DePaul University; Chicago, IL	PhD	06/11	Clinical Psychology
Postdoctoral Training			
Harvard Medical School, Boston, MA	Fellowship	08/11-08/12	Clinical Psychology

A. Personal Statement

This project proposes to conduct an observational study examining the safety of hormonal interventions and the physiological and psychological outcomes associated with these treatments in a sample of peri- and post-pubertal gender-variant youth gathered from 4 subspecialty clinics serving this population across the US. I have devoted my early career to conducting clinical practice and research among lesbian, gay, bisexual, and transgender/gender-variant youth (LGBT) and my work thus far has prepared me well to contribute to the proposed project as a Co-Investigator. At Lurie Children's, where I provide direct clinical care within a multidisciplinary, subspecialty service offering medical and behavioral health care to gender-variant youth, I rely on evidence-based practice to evaluate and treat gender dysphoria as well as mood, anxiety, traumatic stress, and emotional adjustment disorders in gender-nonconforming and transgender youth. In my research, I have applied mixed-methods approaches to develop, implement, and evaluate HIV prevention interventions among sexual minority males at-risk for HIV-exposure. The majority of my publications to date relate to clinical care and HIV prevention in populations including gender-variant youth, young men who have sex with men (MSM) and other gay/bisexual males. My early career research will continue to expand upon these areas, focusing on the examination of psychosocial resilience in gender-variant youth, and HIV prevention as it relates psychosocial health in adolescent and adult transgender women. I am currently a Co-Investigator on an NIH-funded RCT comparing the effects of individual versus couples-level HIV test counseling on antiretroviral initiation and adherence in MSM, and I plan on applying this methodology to examine couple-level factors affecting HIV transmission in partnerships where one partner is a transgender woman. I have directed a NIH-funded research protocol awarded to Dr. Garofalo (R34 MH079707) and my experience in this role has prepared me well for my administrative and supervisory responsibilities on the proposed study. As a Co-Investigator on this project, I will assist Investigators in directly supervising and managing frontline research activities involving project direction and data management. Specifically, I will supervise the Lurie Children's Project Coordinator in their management of day-to-day tasks by coordinating IRB submissions, developing and overseeing effective recruitment strategies and providing ongoing advice regarding confidential data collection/management procedures. I will also participate directly in data collection efforts, conducting the behavioral health portions of study visits. I will also assist the Data Manager in refining assessment instruments, managing study databases, and creating data manuals. Last, I will contribute to the dissemination of our findings in collaboration with the investigative team.

B. Positions and Professional Experience

2004-2006 Project Director, (PIs: GW Harper and MI Fernandez) Adolescent Community Health Research Group, DePaul University, Chicago, IL
2007-2008 Instructor in Psychology, DePaul University
2008-2010 Research Director in Behavioral Research, (PI: Garofalo) Howard Brown Health Center/Lurie Children's, Chicago, IL

2010-2011 Predoctoral Intern in Clinical Psychology, Center for Addiction Medicine, Alexian Bros Behavioral Health Hospital, Hoffman Estates, IL
2011-2012 Clinical Fellow of Psychology in Psychiatry, Harvard Medical School, Boston, MA
2012-2013 Behavioral Research Scientist, Academic General Pediatrics, Lurie Children's Hospital, Chicago, IL
2013-Present Medical Psychologist, Division of Adolescent Medicine, Lurie Children's Hospital, Chicago, IL

Committee Service

2006-2008 National Student Representative, Executive Committee, Division 27 (Society for Community Research and Action), American Psychological Association.
2014-2016 Founding Chair, Gender Variance Special Interest Group, Division 53 (Society of Clinical Child and Adolescent Psychology), American Psychological Association

Honors.

2004 Magna Cum Laude – San Francisco State University. San Francisco, CA
2010 Recipient, Scrivner Memorial Research Grant ($5,000) – American Psychological Foundation
2013 Finalist, Robert H. DuRant Award for Statistical Rigor and Innovation in Adolescent Health Research – Society for Adolescent Health and Medicine 2014, Austin, TX

C. Selected Peer-reviewed Publications

Most relevant to the current application

1. Simons L, Leibowitz S, **Hidalgo MA**. Understanding gender variance in children and adolescents. *Pediatric Annals.* 2014;43(6):e126-e131. PMID: 24972420
2. **Hidalgo MA**, Ehrensaft D, Tishelman AC, Clark, LF, Garofalo, R, Rosenthal, S., Spack, NP, & Olson, J. The gender affirmative model: What we know and what we aim to learn. *Human Development*. 2013;56(5):285-290.

Additional recent publications of importance to the field:

1. **Hidalgo MA**, Kuhns LM, Hotton AL, Johnson AK, Mustanski B, Garofalo R. The MyPEEPS Randomized Controlled Trial: A Pilot of Preliminary Efficacy, Feasibility, and Acceptability of a Group-Level, HIV Risk Reduction Intervention for Young Men Who Have Sex with Men. *Archives of Sexual Behavior.* 2014:1-11 [epub ahead of print] PMID: 25135064.
2. Garofalo R, Kuhns LM, **Hidalgo M**, et al. Impact of Religiosity on the Sexual Risk Behaviors of Young Men Who Have Sex With Men. *J Sex Res.* Jul 29 2014:1-9. PMID: 25072796
3. **Hidalgo MA**, Cotten C, Johnson AK, Kuhns L, Garofalo R. "Yes, I am More Than Just That": Gay/Bisexual Young Men Residing in the US Discuss the Influence of Minority Stress on Their Sexual Risk Behavior Prior to HIV-infection. *Int J Sex Health.*2013; 25(4):291-304.
4. Wilson BM, Harper G, **Hidalgo MA**, Jamil O, Torres R, Isabel Fernandez M. Negotiating Dominant Masculinity Ideology: Strategies Used by Gay, Bisexual and Questioning Male Adolescents. *Amer J Community Psychology.* 2010;45(1-2):169-185. PMID: 20082238
5. Warren J, Fernández MI, Harper GW, **Hidalgo MA**, Jamil OB, Torres RS. Predictors of Unprotected Sex among Young Sexually Active African American, Hispanic, and White MSM: The Importance of Ethnicity and Culture. *AIDS and Behavior.* 2008;12(3):459-468. PMID:17721725
6. Oden, K., Hernández, B., & **Hidalgo, M. A.** (2010). Payoffs of participatory action research: Racial and ethnic minorities with disabilities reflect on their research experiences. *Community Development: Journal of the Community Development Society*, *41*(1), 21-31. PMID: 20668640
7. Hernández, B., Balcazar, F., Keys, C., **Hidalgo, M. A.**, & Rosen, J. (2006). Taking it to the streets: Ethnic minorities seek inclusion. *Community Development: Journal of the Community Development Society*, *37*, 13-25.

D. Research Support

Completed Research Support:

R34 MH079707 R. Garofalo (PI) 9/1/07 – 11/31/10
NIMH
Intervention Development: Reducing HIV Risk in Vulnerable Youth

This three year study supported the development of a group-based intervention for an ethnically-diverse sample of young men who have sex with other men age 14-20. The intervention, based upon the Social-Personal Model of HIV Risk, targeted the unique mechanisms of this high-risk adolescent population
Role: Project Director

Ongoing Research Support:

R01 HD075655-01A1 R. Garofalo/ R. Stephenson/ M. Mimiaga (PIs) 04/10/13 – 03/31/18
NICHD
CVCTPlus: A Couples-Based Approach to Linkage to Care and ARV Adherence
Multisite RCT evaluating, over 24 mos, couples-based HIV testing versus standard of care on antiretroviral initiation and adherence in gay/bisexual male couples.
Role: Co-Investigator

BIOGRAPHICAL SKETCH

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

NAME	POSITION TITLE
Leibowitz, Scott	Attending Physician, *Ann and Robert H. Lurie Children's Hospital of Chicago* Assistant Professor, *Northwestern University Feinberg School of Medicine*
eRA COMMONS USER NAME (credential, e.g., agency login)	

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Cornell University, Ithaca, NY	BS	05/00	Human Development
Sackler School of Medicine, Tel Aviv, Israel	MD	05/04	Medicine
Long Island Jewish Medical Center/Zucker Hillside Hospital, Glen Oaks, NY		06/08	Residency, Psychiatry
Boston Children's Hospital, MA		06/10	Fellowship, Child and Adolescent Psychiatry

A. Personal Statement

This research proposal aims to assess the long-term medical effects of pubertal suppression with GnRH agonists on transgender adolescents across the four main centers in the United States who are offering such intervention. As a psychiatrist who has developed a psychosocial consultative clinic to meet the needs of gender nonconforming and transgender youth across the developmental spectrum, this research is of particular interest to me and is highly needed to determine the safety of this intervention. Puberty, if unsuppressed, leads to irreversible changes that are often devastating to individuals whose affirmed gender is discordant with their anatomy. The acute and long-term psychiatric implications related to untreated internal distress (gender dysphoria) are significant, with much higher rates of depression, suicidal ideation and behavior, anxiety, potential substance use disorders, high risk-taking behaviors, etc. in this population, even among those youth whose parents are considered accepting. Initial research has shown the marked psychiatric benefits of using pubertal suppression as a method to extend the period of exploration during a time that allows an adolescent to not experience the unwanted irreversible effects of puberty. I will participate on the research team at Lurie Children's Hospital of Chicago by participating in project development calls, assessing patients, and providing the psychiatrist's perspective throughout the various time points of the study.

B. Positions and Honors

Positions and Employment

2010-2013 Instructor of Psychiatry, Harvard Medical School, Boston, MA

2010-2013 Attending Child and Adolescent Psychiatrist, Boston Children's Hospital, MA
I worked both within the Department of Psychiatry and the Division of Adolescent and Young Adult Medicine during this period. In the Department of Psychiatry, I established a consultative psychosocial gender identity clinic that provided assessement, consultation, and ongoing behavioral health services to gender nonconforming and dysphoric youth across the developmental spectrum. In the Division of Adolescent and Young Adult Medicine, I served as the primary psychopharmacologist working on a multidisciplinary team in a primary care setting.

2013- Assistant Professor of Psychiatry and Behavioral Sciences, Northwestern University Feinberg School of Medicine, Chicago, IL

2013- Attending Child and Adolescent Psychiatrist, Head Child and Adolescent Psychiatrist for the Gender and Sex Development Program, Ann and Robert H. Lurie Children's Hospital of Chicago, Department of Psychiatry, Chicago, IL

I currently work on the multidisciplinary team to help assess, consult, and treat the behavioral health aspects of gender nonconforming and dysphoric youth across the developmental spectrum. Our team is involved in clinical, research, and advocacy efforts on behalf of this population for youth in the Chicago metropolitan area and beyond. We are the first major academic pediatric medical center in the Midwest to provide the full range of services to these youth, and are the only clinic in the country to be represented by the full range of disciplines. I also work on the Consultation Liaison service and general outpatient service in the Department of Psychiatry.

Other Experience and Professional Memberships

2009- Sexual Orientation and Gender Identity Issues Committee, American Academy of Child and Adolescent Psychiatry
2013- Committee Co-Chair, Sexual Orientation and Gender Identity Issues Committee, American Academy of Child and Adolescent Psychiatry
2012- Trevor Project Advisory Council
2012- American Association of Medical Colleges, Lesbian, Gay, Bisexual, Transgender, and Disorders of Sex Development Affected Individuals Patient Care Project Advisory Committee

Honors

2011 Campaign for American's Kids Junior Scholar Award, American Academy of Child and Adolescent Psychiatry
2012 Prism Award, GLBT and Friends Committee, Boston Children's Hospital

C. Selected Peer-reviewed Publications

1. **Leibowitz S**, Spack N. "The Development of a Gender Identity Psychosocial Clinic: Treatment Issues, Logistical Considerations, Interdisciplinary Cooperation, and Future Initiatives." *Child and Adolescent Psychiatric Clinics of North America*. 2011; 20(4):701-724.
2. Stoddard J, **Leibowitz S**, Ton H, Snowdon S. "Improving Medical Education About Gender-Variant Youth and Transgender Adolescents." *Child and Adolescent Psychiatric Clinics of North America.* 2011;20(4):779-791.
3. **Leibowitz S,** Telingator C. "Assessing Gender Identity Concerns in Children and Adolescents: Evaluation, Treatments, and Outcomes." *Current Psychiatry Reports.* 2012;14(2):111-120.
4. Adelson, S. et al. "Practice Parameter on Gay, Lesbian, or Bisexual Sexual Orientation, Gender Nonconformity, and Gender Discordance in Children and Adolescence." *Journal of American Academy of Child and Adolescent Psychiatry.* 2012;51(9):957-974. (member of the AACAP committee, Sexual Orientation and Gender Identity Issues Committee, cited in the Attribution section)

D. Research Support

No ongoing or completed research projects for the past three years (Federal or non-Federally-supported).

BIOGRAPHICAL SKETCH

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

NAME	POSITION TITLE
Courtney Anne Finlayson	Assistant Professor of Pediatrics
eRA COMMONS USER NAME (b)(6)	

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of Michigan	BS with honors	1995-1999	Biology
Northwestern University, Evanston, IL	MD	1999-2003	
Rush University, Chicago, IL	Residency	2003-2006	Pediatrics
Northwestern University, Children's Memorial Hospital, Chicago, IL	Fellowship	2006-2009	Pediatric Endocrinology

A. Personal Statement

The goal of the proposed research is to study and improve care for youth who are transgender and gender dysphoric. This is an understudied and generally poorly understood population. In the past, few pediatric endocrinologists have had the knowledge and willingness to care for these children. I am the endocrinologist for the Gender & Sex Development Program at the Ann & Robert H. Lurie Children's Hospital of Chicago. I have had a specific interest in these patients which has guided my research and clinical training. My research as an endocrinology fellow was in the laboratory of Dr. J. Larry Jameson studying sex development. As a junior faculty member, I worked with Dr. Norman Spack in the Gender Management Services program at the Children's Hospital Boston. Following my move to Chicago, I have been the primary endocrinologist to assist in developing our program. As a result of this training and my interest in this population, I am prepared to participate in the proposed project.

B. Positions and Honors

Positions and Employment

2003-2006 Pediatric Resident, Rush University
2003 Staff Physician, American Diabetes Association Triangle D Camp, Illinois
2006 Staff Physician, American Diabetes Association Triangle D Camp, Illinois
2007 Staff Physician, American Diabetes Association Triangle D Camp, Illinois
2006-2009 Pediatric Endocrinology Fellow, Children's Memorial Hospital, Northwestern University
2009-2010 Instructor, Department of Pediatrics, Division of Pediatric Endocrinology, Children's Hospital Boston, Harvard Medical School
2010-2014 Instructor, Department of Pediatrics, Division of Pediatric Endocrinology, Ann & Robert H. Lurie Children's Hospital of Chicago, Northwestern University
2014- Assistant Professor, Department of Pediatrics, Division of Pediatric Endocrinology, Ann & Robert H. Lurie Children's Hospital of Chicago, Northwestern University

Other Experience and Professional Memberships

2003-2010 Member, American Academy of Pediatrics
2006- Member, Endocrine Society
2007- Member, Lawson Wilkins Pediatric Endocrine Society

Honors

1999	Phi Beta Kappa, University of Michigan
2008	Lawson Wilkins Pediatric Endocrine Society Fellows Travel Grant
2008	Endocrine Society Endocrine Trainee Day Travel Grant

C. Selected Peer-reviewed Publications

1. Harris RM, Finlayson C, Weiss J, Fisher L, Hurley L, Barret T, Emge D, Bathgate RA, Agoulnik AI, Jameson JL. A missense mutation in LRR8 of RXFP2 is associated with cryptorchidism. Mamm Genome. 2010. 21(442-9).
2. Weiss J, Hurley LA, Harris RM, Finlayson C, Tong M, Fisher LA, Moran JL, Beier DR, Mason C, Jameson JL. ENU mutagenesis in mice identifies candidate genes for hypogonadism. Mamm Genome. 2012. 23(5-6):346-55.

D. Research Support

No ongoing or completed research projects for the past three years (Federal or non-Federally-supported).

BIOGRAPHICAL SKETCH

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

NAME	POSITION TITLE
Joel E. Frader, M.D., M.A.	A Todd Davis Professor of Academic General Pediatrics, Prof. Medical Humanities and Bioethics
eRA COMMONS USER NAME (credential, e.g., agency login) (b)(6)	

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Columbia University, NYC	BA	1970	Sociology
Tufts University School of Medicine, Boston, MA	MD	1974	
University of Pennsylvania, Philadelphia, PA	MA	1980	Sociology

A. Personal Statement

I pursue scholarly work in pediatric palliative care and medical ethics, especially ethics in pediatrics, human subjects research, transplantation, children with disorders of sex development (DSD), gender nonconformity, clinical innovation, and conscientious objection by health care professionals. I do qualitative social science studies collaboratively with Kelly Michelson, MD, a pediatric critical care physician, on families and staff in the pediatric intensive care unit facing decisions to provide or forgo life-sustaining treatment. My main clinical interests are in pediatric palliative and hospice care, multidisciplinary care of children with DSD and gender nonconformity, and parent support for difficult decisions under conditions of uncertainty.

B. Positions and Honors

Positions and Employment

1974-76	Intern and 2nd Year Resident (Pediatrics): Tufts-New England Medical Center
1976-79	3rd Year Resident (Pediatrics) and Robert Wood Johnson Clinical School, Children's Hospital of Philadelphia and University of Pennsylvania
1979-81	Assistant Professor of Pediatrics, University of Pennsylvania School of Medicine
1981-90	Assistant Professor of Pediatrics, Children's Hosp. of Pittsburgh and University of Pittsburgh School
1986-97	Associate Director, Center for Medical Ethics, University of Pittsburgh
1990-97	Associate Professor of Pediatrics, University of Pittsburgh School of Medicine
1997-2000	Associate Professor of Pediatrics, Assoc. Prof. of Medical Ethics and Humanities, Children's Memorial Hospital and Northwestern University
2000-03	Professor of Pediatrics and Professor of Medical Humanities and Bioethics, Northwestern University
2001-03	Interim Chief, Division of General Academic Pediatrics, Children's Memorial Hospital
2003-	Chief, Academic General Pediatrics, Children's Memorial Hospital (now Lurie Children's Hospital)
2013-	Director, Bridges Pediatric Palliative Care Program, Lurie Children's Hospital

Ethics-Related Experience and Professional Memberships

1983-86	Member, Council (Board of Directors), Society for Health and Human Values (Now American Society for Bioethics and Humanities)
1989-96	Member, Board of Directors, Society for Bioethics Consultation
1990-98	Member, Committee on Bioethics, American Academy of Pediatrics
1991-94	President-elect, President, Immediate Past-president, Society for Health and Human Values
1994-98	Chair, Committee on Bioethics, American Academy of Pediatrics
1994-98	Member, Committee on Ethics, American College of Obstetricians and Gynecologists
1997	Member, NIH Special Study Section: Informed Consent in Research Involving Human Participants

1998	Member, NIH Study Section: Ethical, Legal, and Social Implications of the Human Genome Project
1998-2000	Associate Member, Ethics Committee, American Board of Pediatrics
1998-2007	Ethics Reviewer, NIH Study Section: Hyperaccelerated Award—Mechanisms in Immune Disease Trials
1997	Member, Ad hoc NIH Study Section: Research on Ethical Issues in Human Studies
2000-01	Ethics Member, NHLBI Data Safety Monitoring Board: Fetal Tracheal Occlusion for Severe Diaphragmatic Hernia Clinical Trial
2000	Member, NIH Consensus Development Panel: Antenatal Corticosteroids Revisited: Repeat Courses
2000-03	Member, NHLBI Data Safety Monitoring Board: Recombinant CC10 for Prevention of Neonatal BPD
1999-03	Member, Hastings Center Project on Families and Traumatic Brain Injury
2001-03	Member, Hastings Center Project: Surgically Shaping Children
2002-03	Member, Work Group on Ethical Issues in Human Germline Genetic Modification Research (Convened by R. Dresser, Washington University School of Law)
2003-04	Member, University of Virginia Task Force: Regulating Innovative Surgery: Development of Recommendations for National Policy
2004-09	Member, NHLBI DSMB for Randomized Trial of Pulmonary Valve Replacement in Tetralogy of Fallot and Thymic Tolerance Trial in Pediatric Heart Transplant
2007-	Member, NIDCD DSMB for Phase II randomized clinical trial for Recurrent Respiratory Papillomatosis
2007-10	Member, NIAID Study Section: Ancillary Studies in Immunomodulation Clinical Trials

Honors

1976-79	Robert Wood Johnson Clinical Scholar, University of Pennsylvania
1993	Elected Fellow, The Hastings Center
1995	Elected Member, American Pediatrics Society
2009	Named A Todd Davis Professor of Academic General Pediatrics, Feinberg School of Medicine
2112	Named William G. Bartholome Awardee for Ethical Excellence, American Academy of Pediatrics

C. Selected Peer-reviewed Publications

1. Frader J: Difficulties in providing intensive care. Pediatrics 1979;64(1):10-16.
2. Lantos JD, Frader J: Extracorporeal membrane oxygenation and the ethics of clinical research in pediatrics. N Engl J Med 1990;323:409-413.
3. Truog RD, Brett AS, Frader J: The problem with futility. N Engl J Med 1992;326:1560-64.
4. Frader J, Caniano DA: Research and innovation in surgery. In McCullough LB, Jones JW, Brody BA, eds, Surgical Ethics. Oxford University Press, 1998.
5. Flanagan-Klygis E, Friedman Ross L, Lantos J, Frader J, Yogev R: Disclosing the diagnosis of HIV in pediatrics. J Clin Ethics 2000;12(2)150-157.
6. Daaboul J, Frader J: Management of the patient with intersex: a middle way. J Ped Endocrin Metab, 2001;14(9):1575-
7. Dreger A, Chase C, Sousa A, Gruppuso PA, Frader J: Changing the nomenclature/taxonomy for intersex: a scientific and clinical rationale. J Pediatr Endo Metab 2005;18(8): 729-733.
8. Bosk CL, Frader J. It's not easy wearing green: the art of surgical innovation and the science of clinical trials. In Reitsma AM, Moreno JD eds., Ethical Guidelines for Innovative Surgery. University Publishing Group, 2006.
9. Darugar MA, Harris RM, Frader JE. Consent and cultural conflicts: ethical issues in pediatric anesthesiologists' participation in female genital cutting. In, Von Norman, G, Palmer S, Jackson S, Rosenbaum S, and Cahana A, eds., Clinical Ethics in Anesthesiology: A Case-Based Textbook. New York, Cambridge University Press, 2011.
10. RM Harris, Frader J. Ethical issues in the treatment of pediatric patients with disorders of sex development. In, Diekema DS, Mercurio MR, Adam MB, eds, Clinical Ethics in Pediatrics: A Case-Based Textbook, New York, Cambridge University Press, 2011.

11. Frader J, Kodish E, Lantos JD. Symbolic resuscitation, medical futility, and parental rights. Pediatrics 2010; 126(4):769-772.
12. Michelson KN, Emanuel L, Carter A, Brinkman P, Clayman ML, Frader J. Pediatric intensive care unit family conferences: one mode of communication for discussing end-of-life care decisions. Pediatr Crit Care Med 2011;12(6):e336-43).
13. Michelson KN, Blehart K, Hochberg T, James K, Frader J. Bereavement photography for children: program development and healthcare professionals' response. Death Studies E-pub 11 Jan 2013.
14. Michelson KN, Patel R, Haber-Barker N, Emanuel L, Frader J. End-of-life care decisions in the pediatric intensive care unit: roles professionals play. Pediatr Crit Care Med, 2013;14(1):e34-44.
15. Michelson KN, Clayman ML, Haber-Barker N, Ryan C, Rychlik K, Emanuel L, Frader J. The use of family conferences in the pediatric intensive care unit. J Pall Med. 2013;16(12):1595-601.

D. Research Support

Dr. Frader does not have any ongoing or completed research projects for the past three years (Federal or non-Federally-supported).

BIOGRAPHICAL SKETCH

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

NAME	POSITION TITLE
Rosenthal, Stephen M. M.D.	Professor of Pediatrics
eRA COMMONS USER NAME (credential, e.g., agency login) (b)(6)	

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Yale University, CT	B.A.	1968-72	Psychology
Columbia Univ., College of Physicians & Surgeons, NY	M.D.	1972-76	Medicine
Presbyterian Hospital, Columbia University, NY		1976-79	Intern/Resident, Pediatrics
University of California, San Francisco		1979-82	Fellow, Pediatric Endocrinology

A. Personal Statement

In addition to my role as Program Director for our NIH-funded T32 Pediatric Endocrinology Fellowship at UCSF, I also serve as Director of the Pediatric Endocrine Clinics, Co-Director of the Disorders of Sex Development (DSD) Clinic, and founder and Medical Director of the UCSF Child and Adolescent Gender Center (CAGC). The UCSF CAGC serves as the Pediatric/Adolescent clinical arm of the widely recognized UCSF Center of Excellence for Transgender Health. The CAGC provides multi-disciplinary care to gender non-conforming/transgender youth and adolescents, and is the only such multi-disciplinary gender program in northern California, attracting patients not only from California, but from as far away as Alaska, Florida, and Egypt. A steady increase in referrals (8-10/month) has led to a quadrupling of services in the last two years. In recognition of my experience providing care and developing protocols for transgender youth, I have been appointed as the official representative of the Pediatric Endocrine Society (PES) to the Endocrine Society's (ES) Clinical Practice Guidelines Revision Task Force for the Care of Transgender Individuals, and was appointed to the World Professional Association for Transgender Health (WPATH) Consensus committee for revisions of the International Classification of Disease (ICD)-11 pertaining to transgender youth and adults. I have authored 7 manuscripts on transgender youth, including a recent "State-of-the-art" invited review in *Pediatrics* and an invited review in the "Approach to the Patient" series for the *Journal of Clinical Endocrinology and Metabolism*. I have been an invited speaker on transgender youth at annual meetings of PES and ES, as well as at the most recent international meeting of WPATH, and have lectured on this subject at academic centers throughout the U.S. As a reflection of the national and international impact of the UCSF CAGC, our program for transgender youth is being featured in an upcoming documentary produced by the British Broadcasting Corporation (BBC). I am also the recipient of the UCSF Chancellor Award for LGBT leadership in recognition of my work with transgender youth and am the recipient of the UCSF Family Advisory Council Caring Tree Award and the UCSF Haile T. Debas Academy of Medical Educators Excellence in Teaching Award. I have had significant experience conducting multi-center trials, and I am currently serving as site PI for NIH/NICHD Disorders of Sex Development: Platform for Basic and Translational Research (1R01HD068138-01A1).

B. Positions and Honors

Positions and Employment

1982-83 Clinical Instructor in Pediatrics, University of California San Francisco, CA
1983-92 Assistant Professor of Pediatrics, University of California San Francisco, CA
1992-98 Associate Professor of Pediatrics, University of California San Francisco, CA
1998- Professor of Pediatrics, University of California San Francisco, CA
2006- Director, Pediatric Endocrine Clinics, University of California San Francisco, CA

2008-11 Associate Program Director, Pediatric Endocrinology, University of California San Francisco, CA
2011- Program Director, Pediatric Endocrinology, University of California San Francisco, CA
2011- Medical Director, Child and Adolescent Gender Center, University of California San Francisco, CA

Other Experience and Professional Memberships

1991- Elected to Society for Pediatric Research
2000-05 Appointed to Drug and Therapeutics Committee, Lawson Wilkins Pediatric Endocrine Society
2000-05 Appointed to Special Programs Committee, The Endocrine Society
2002-04 Chair, Drug and Therapeutics Committee, Lawson Wilkins Pediatric Endocrine Society
2005-08 Appointed to Meetings and Educational Programs Committee of The Endocrine Society
2007-13 Appointed to Ethics Committee, Pediatric Endocrine Society
2008-11 Appointed to Annual Meeting Steering Committee, The Endocrine Society
2010-13 Elected to Board of Directors, Pediatric Endocrine Society
2012- Appointed to the Clinical Endocrine Education Committee, The Endocrine Society
2013 Appointed to the World Professional Association for Transgender Health Consensus Committee for ICD-11 revisions pertaining to transgender youth and adults
2014 Appointed as the Pediatric Endocrine Society's official representative to the Endocrine Society's Clinical Practice Guidelines Revision Task Force for the Care of Transgender Individuals

Honors

2012 UCSF Family Advisory Council Caring Tree Award
2013 Chancellor Award for Gay, Lesbian, Bisexual, and Transgender Leadership
2014 UCSF Haile T. Debas Academy of Medical Educators Excellence in Teaching Award

C. Selected Peer-reviewed Publications (Selected from 65 peer-reviewed publications)

Most relevant to current application (in reverse chronological order)

1. **Rosenthal SM**. Approach to the Patient: Transgender Youth: Endocrine Considerations. J Clin Endocrinol Metab, 2014 Aug 20:jc20141919. Epub ahead of print.
2. Vance S, Ehrensaft D, **Rosenthal SM**. Psychological and medical care of gender nonconforming youth. Pediatrics, in press 2014.
3. Bonifacio J, **Rosenthal SM**. Gender variance and dysphoria in children and adolescents. Pediatr Clin North Am, in press 2014.
4. Lee PA, Wisniewski A, Baskin L, Vogiatzi MG, Vilain E, **Rosenthal SM**, Houk C. Advances in diagnosis and care of persons with DSD over the last decade. Int J Pediatr Endocrinol, in press 2014.
5. Vance S, Halpern-Felsher B, **Rosenthal SM**. Health care providers' comfort with and barriers to care of transgender youth. J Adolesc Health, in press 2014.
6. Sherer I, Baum J, Ehrensaft D, **Rosenthal SM**. Gender Nonconforming/Gender Expansive and Transgender Children and Teens. Contemporary Pediatrics, under review (invited manuscript), 2014.
7. Hidalgo MA, Ehrensaft D, Tishelman AC, Clark LF, Garofalo R, **Rosenthal SM**, Spack NP, Olson J. The gender affirmative model: What we know and what we aim to learn. Human Development 56:285-290, 2013.
8. Sherer I, **Rosenthal SM**, Ehrensaft D, Baum J: Child and Adolescent Gender Center: A multidisciplinary collaboration to improve the lives of gender nonconforming children and teens. Pediatr Rev 33:273-275, 2012.

Additional recent publications (in reverse chronological order)

9. Herold KC, Gitelman SE, Willi SM, Gottlieb PA, Waldron-Lynch F, Devine L, Sherr J, **Rosenthal SM**, Adi S, Jalaludin MY, Michels AW, Dziura J, Bluestone JA: Teplizumab treatment may improve C-peptide responses in participants with type 1 diabetes after the new onset period: a randomized controlled trial. Diabetologia 56:391-400, 2013.
10. Cheung CC, Cadnapaphornchai MA, Ranadive SA, Gitelman SE, **Rosenthal SM**: Persistent elevation of urine Aquaporin-2 during water loading in a child with Nephrogenic Syndrome of Inappropriate Antidiuresis (NSIAD) caused by a R137L mutation in the V2 Vasopressin receptor. Int J Pediatr Endocrinol 3:1-6, 2012.

11. Aslan IR, Baca EA, Charlton W, **Rosenthal SM**: Respiratory syncytial virus (RSV) infection as a precipitant of thyroid storm in a previously undiagnosed case of Graves disease in a prepubertal girl. Int J Pediatr Endocrinol 2011:138903. Epub 2011 Mar 22.
12. Rochdi MD, Vargas GA, Carpentier E, Oligny-Longpre G, Chen S, Kavoor, A, Gitelman SE, **Rosenthal SM**, von Zastrow M, Bouvier M: Functional characterization of vasopressin type 2 receptor substitutions (R137H/C/L) leading to nephrogenic diabetes insipidus and nephrogenic syndrome of inappropriate antidiuresis: Implications for treatments. Mol Pharmacol 77:836-845, 2010.
13. Meyer GE, Chesler L, Liu D, Youngren J, Goldfine ID, Weiss WA, Matthay KK, **Rosenthal SM**: Nordihydroguaiaretic acid inhibits insulin-like growth factor signaling, growth and survival in human neuroblastoma cells. J Cell Biochem 102:1529-1541, 2007.
14. Feldman BJ*, **Rosenthal SM***, Vargas GA, Fenwick RG, Huang EA, Matsuda-Abedini M, Lustig RH, Mathias RS, Portale AA, Miller WL, Gitelman SE. Nephrogenic syndrome of inappropriate antidiureses. Identification of novel activating mutations in the vasopressin type 2 receptor causing a newly described genetic disease. N Engl J Med. 352:1884-90 2005. ***denotes co-first author**
15. Tiffin N, Adi S, Stokoe D, Wu NY, **Rosenthal SM**: Akt phosphorylation is not sufficient for insulin-like growth factor-stimulated myogenin expression but must be accompanied by down-regulation of mitogen-activated protein kinase/extracellular signal-regulated kinase phosphorylation. Endocrinology 145:4991-4996, 2004.

D. Research Support

Ongoing Research Support

1R01HD068138-01A1 Vilain (PI) 09/26/2011 - 06/30/2016
NIH/ NICHD
Disorders of Sex Development: Platform for Basic and Translational Research
Role: Site PI

Completed Research Support

U01 DK61010 2009-2012
NIDDK/NIH
UCSF Trial Net: UCSF Trial Net: A Phase II Trial of Imantinib in New Onset Type I Diabetes
Role: Co-PI

R01 2006-2011
NIH/NIDDK/Juvenile Diabetes research Foundation
Phase II Trial of hOKT3 γ1 (Ala-Ala) administered from 4 months to 12 months after diagnosis of Type 1 diabetes mellitus
Role: Co-PI

N01-AI 15416 2005-2012
NIH/NIAID/ITN/NIDDK
Phase II trial of hOKT3 γ1 (Ala-Ala) for treatment of new onset Type 1
Diabetes Mellitus
Role: Co-PI

Immune Tolerance Network 2005-2012
NIH/NIAID
Thymoglobulin for treatment of new onset type 1 diabetes mellitus
Role: Co-PI

Basic Research Award Rosenthal (PI) 2009-2011
ImClone Systems, Inc.
The Therapeutic Potential of A12 Anti-IGF-IR Antibody and Radiation in Neuroblastoma
Role: PI

Thrasher Research Fund 2005-2008
Targeted agents that synergize with radiation in high risk neuroblastoma; The goal of this study was to assess inhibitors of insulin-like growth factors (IGF)-1 signaling and other agents that synergize with radiation in high risk neuroblastoma.
Role: Co-PI

Basic Research Award Rosenthal (PI) 2005-2008
John A. Kerner, M.D. Foundation
Small Molecule Inhibitors of the IGF-I Receptor as a Potential Treatment for Neuroblastoma
Role: PI

N01-AI 15416 2005-2010
NIH/NIAID/ITN/NIDDK
Phase II trial of hOKT3 γ1 (Ala-Ala) for treatment of new onset Type1 diabetes mellitus
The goal of this study was to attempt to prolong endogenous insulin secretion in those with new onset type 1 diabetes mellitus utilizing an anti-CD3 monoclonal antibody at 6 month intervals for a total of 3 doses. This study was part of a multi-center trial.
Role: Co-PI

Translational Basic Research Award Rosenthal (PI) 2004-2005
Pfizer, Inc.
IGFs and Skeletal Muscle: Implications for Myotherapy.
This study explored the mechanisms which influence the decision of skeletal myoblasts to proliferate of differentiate in response to IGFs.
Role: PI

R01 2001-2010
NIH/NIDDK/Juvenile Diabetes Research Foundation
Phase II trial of hOKT3 γ1 (Ala-Ala) administered from 4 months to 12 months after diagnosis of Type1 diabetes mellitus
The goal of this study was to attempt to prolong endogenous insulin secretion in those with new onset type 1 diabetes mellitus utilizing a humanized, anti-CD3 monoclonal antibody. This study was part of a multi-center trial.
Role: Co-PI

R01 DK44181-10 Rosenthal (PI) 1998-2003
NIDDK
IGFs and Skeletal Muscle Cell Differentiation.
The major goals of this project were to investigate the molecular mechanisms by which the insulin-like growth factors (IGFs) regulate myogenesis.
Role: PI

BIOGRAPHICAL SKETCH

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

NAME	POSITION TITLE
Ehrensaft, Diane Ph.D.	Clinical Psychologist Adjunct Associate Professor of Pediatrics
eRA COMMONS USER NAME (credential, e.g., agency login) (b)(6)	

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of Michigan	B.A.	1968	Psychology
University of Michigan	Ph.D.	1974	Psychology

A. Personal Statement

In my roles as Director of Mental Health of the Child and Adolescent Gender Center and attending psychologist at the gender clinic in the Department of Pediatrics at Benioff Children's Hospital UCSF, I oversee the psychological assessment and treatment of all gender non-conforming children and youth who come through our program. This work is complemented by the extensive ongoing clinical work I do with gender nonconforming children and their families in my private practice. Since completing my doctoral dissertation at the University of Michigan on the topic of gender socialization in pre-school children, gender has consistently been the focus of my academic and clinical work. My research and writing has involved in-depth clinical studies of gender-nonconforming children and their families. As new medical interventions have been introduced to facilitate the care and treatment of these children and youth, specifically puberty blockers and cross-sex hormones, it has come to my attention that longitudinal research is now needed to demonstrate whether these medical and accompanying psychological interventions are having good effect in providing supports and positive mental health outcomes for gender-nonconforming and transgender children and youth, and look forward to seeing such a study launched with interdisciplinary and multi-site participation.

B. Positions and Honors

Positions and Employment

2011-	Clinical Faculty, Pediatrics, Psychologist, University of California, San Francisco (UCSF) Gender Clinic
2009-	Director of Mental Health, Child and Adolescent Gender Center
1981-	Clinical Psychologist, Private Practice, Oakland, California
1999-	Faculty, Psychoanalytic Institute of Northern California
1992-	Senior Clinician, A Home Within (non-profit organization addressing emotional needs of children/youth in foster care)
1982-	Licensed Clinical Psychologist (California License # PSY 7342)
1995-1999	Clinical Faculty, Mt. Zion Psychiatric Department, University of California, San Francisco
1992-1998	Clinical Faculty, Ann Martin Children's Center, Piedmont, California
1986-1992	Clinical Faculty, Department of Psychiatry, Children's Hospital San Francisco
1986-1990	Clinical Consultant, Children's Hospital Medical Center of Northern California, Oakland
1985-1986	Consulting Psychologist, Health America Rockridge, Oakland, California
1982-1988	Independent Contractor to Child Development Center, Children's Hospital Medical Center of Northern California
1981-2004	Professor, The Wright Institute, Berkeley
1980-1983	Mental Health Consultant, Alameda Headstart, Alameda, CA
1979-1981	Faculty, University of San Francisco
1977-1979	Faculty, Field Studies Program, University of California, Berkeley
1974-1978	Faculty, Interdisciplinary Program on Day Care and Child Development, University of California, Berkeley
1974-1978	Faculty, School of Social Welfare, University of California, Berkeley

1972-1973 Faculty, Sociology Department, Sir George Williams University, Montreal, Quebec

Other Experience and Professional Memberships

1968, 1969, 1970 NIMH Fellowship, University of Michigan
1971 Rackham Pre-doctoral Fellowship, University of Michigan
1972 University of Michigan Dissertation Grant
1982 Election to Board of the Section on Childhood and Adolescence, Division of Psychoanalysis, American Psychological Association
1992 Election to Board of the Section on Women, Gender, and Psychoanalysis, Division of Psychoanalysis, American Psychological Association
2002 Appointment to Board of Directors, Division of Psychoanalysis, American Psychological Association
2004 Election to Board of the Section on Psychoanalysis and Social Justice, Division of Psychoanalysis, American Psychological Association
2011 Appointment as co-chair of the 2015 Division of Psychoanalysis meeting, San Francisco

Honors

2012 Annual Scholarship Award Advancement of Gender Issues in Psychoanalysis APA, Division of Psychoanalysis
2013 Recognition Award for Outstanding Service, Childhood and Adolescence, APA, Division of Psychoanalysis

C. Selected Peer-Reviewed Publications (Selected from 32 peer-reviewed publications)

Most relevant to the current application (in reverse chronological order)

1. Vance S, **Ehrensaft D**, Rosenthal SM. Psychological and medical care of gender nonconforming youth. Pediatrics, 2014, in press.
2. Sherer I, Baum J, **Ehrensaft D**, Rosenthal SM. Gender Nonconforming/Gender Expansive and Transgender Children and Teens. Under review (invited manuscript) at Contemporary Pediatrics, 2014.
3. **Ehrensaft D**. Found in transition: Our littlest transgender people. Contemporary Psychoanalysis, 2014, in press.
4. **Ehrensaft, D.** Learning from Gender-nonconforming Children. The Psychoanalytic Study of the Child, 2014 (in press).
5. **Ehrensaft D**. "Look, Mom, I'm a Boy—Don't Tell Anyone I Was a Girl." Journal of LGBT Youth, 10:1–20, 2013.
6. Hidalgo MA, **Ehrensaft D**, Tishelman AC, Clark LF, Garofalo R, Rosenthal SM, Spack NP, Olson J. The gender affirmative model: What we know and what we aim to learn. Human Development 56:285-290, 2013.
7. Sherer I, Rosenthal SM, **Ehrensaft D**, Baum J: Child and Adolescent Gender Center: A multidisciplinary collaboration to improve the lives of gender nonconforming children and teens. Pediatr Rev 33:273-275, 2012.
8. **Ehrensaft, D**. From gender identity disorder to gender identity creativity: True gender self therapy. Journal of Homosexuality, 59, 337–356, 2012.
9. **Ehrensaft D.** Boys will be girls, girls will be boys: Children affect parents as parents affect children in gender nonconformity. Psychoanalytic Psychologist 28: 528-548, 2011.
10. **Ehrensaft D.** One pill makes you boy, one pill makes you girl. International Journal of Applied Psychoanalytic Studies, 6: 12–24, 2009.
11. **Ehrensaft D.** Raising Girlyboys: A Parent's Perspective. Studies in Gender and Sexuality 8(3): 269-302, 2007.
12. **Ehrensaft D.** The Stork Didn't Bring Me, I Came From a Dish: Psychological Experiences of Children Conceived through Assisted Reproductive Technology. Journal of Infant, Child, and Adolescent Psychotherapy 6(2): 124-140, 2007.

Additional recent publications of importance to the field (in reverse chronological order)

13. **Ehrensaft D.** What's your gender? In C. Bonovitz & A. Harlem (eds.), Developmental Approaches to Therapeutic Action in Child Psychotherapy, New York: Routledge, 2014, in press.

14. **Ehrensaft D.** A terrible thing happened on the way to becoming a girl. In P. Cohen, K. M. Sossin, & R. Ruth (eds.), Healing After Parent Loss in Childhood and Adolescence, New York: Rowman & Littlefield, 2014.
15. **Ehrensaft, D.** Gender born, gender made: Raising healthy gender-nonconforming children. New York: The Experiment, 2011.

D. Research Support

No ongoing and completed research projects for the past three years (Federal or non-Federally-supported).

BIOGRAPHICAL SKETCH

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

NAME	POSITION TITLE
Glidden, David V.	Professor of Biostatistics
eRA COMMONS USER NAME (credential, e.g., agency login) (b)(6)	

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of California, Berkeley, CA	B.A.	1988	Statistics
University of Washington, Seattle, WA	Ph.D.	1993	Biostatistics
Harvard University, Boston, MA	Fellowship	1995	Biostatistics

A. Personal Statement

I will work as a resource for Dr. Schrager and will provide advice and support on analytic approaches. I will contribute expertise on the statistical design of the study, the framing of hypotheses and development of analysis strategies to test those hypotheses with focus on the analysis of the metabolic data. I will be responsible for the design, analysis plan development, and execution of these analyses.

B. Positions and Honors

Positions and Employment

1988-1993 Research Assistant, University of Washington
1993-1995 Research Fellow, Harvard University, Boston MA
1995-1997 Research Associate, Harvard University, Boston, MA
1997-2003 Assistant Adjunct Professor, University of California, San Francisco
2003-2007 Associate Professor in Residence, University of California, San Francisco
2007- Professor in Residence University of California, San Francisco

Honors and Awards

1988 W.W. Stout Fellowship, Graduate School, University of Washington
1988-1990 Graduate Fellowship Award, Graduate School, University of Washington
1990-1993 National Research Service Award, National Heart, Lung and Blood Institute
1993 School of Public Health Outstanding Student Citation for Biostatistics, Univ. of Washington
2007 TICR Award for Excellence in Teaching

C. Selected Peer-reviewed Publications

Most relevant to the current application

1. Anderson PL, Glidden DV, Liu A, Buchbinder S, Lama JR, Guanira JV, McMahan V, Bushman LR, Casapi M, Montoya-Herrera O, Veloso VG, Mayer KH, Chariyalertsak S, Schechter M, Bekker LG, Kallas EG, Grant RM for the iPrEx Study Team. Emtricitabine-Tenofovir concentrations and pre-exposure prophylaxis efficacy in men who have sex with men. *Science Translational Medicine*, 2012.
2. Grant RM, Lama JR, Anderson PL, McMahan V, Liu AY, Vargas L, Goicochea P, Casapía M, Guanira-Carranza JV, Ramirez-Cardich ME, Montoya-Herrera O, Fernandez T, Veloso VG, Buchbinder SP, Chariyalertsak S, Schechter M, Bekker LG, Mayer KH, Kallas EG, Amico KR, Mulligan K, Bushman LR, Hance RJ, Ganoza C, Defechereux P, Postle B, Wang F, McConnell JJ, Zhang JH, Lee J, Rooney JF, Jaffe HS, Martinez AI, Burns DH, Glidden DV for the iPrEx Study Team. Pre-exposure chemoprophylaxis for HIV prevention in men who have sex with men. *New England Journal of Medicine*, 363: 2587-99, 2010.

3. Glidden DV. Design by Trail. *Nature* 490 :350-1. doi: 10.1038/490350a, 2012 (invited commentary on Rolland, et al, doi:10.1038/nature11519).

Additional recent publications of importance to the field (in chronological order)

4. Fleming TR, Prentice RL, Pepe MS, Glidden D. Surrogate and auxiliary endpoints in clinical trials with potential applications in cancer and AIDS research. Statistics in Medicine 13:955-968, 1994.
5. Glidden DV, Self SG. Semiparametric likelihood estimation in the Clayton-Oakes model. Scandinavian Journal of Statistics 26:363-372, 1999.
6. Glidden DV, Wei LJ. Rank estimation of treatment differences based on repeated measurements subject to dependent censoring. Journal of the American Statistical Association 94:888-895, 1999.
7. Glidden, DV. A two-stage estimator of the dependence parameter in the Clayton-Oakes model. Lifetime Data Analysis 6:141-156, 2000.
8. Para MF, Glidden DV, Coombs RW, Collier AC, Condra JH, Craig C, Bassett R, Leavitt R, Snyder S, McAuliffe V, Boucher C and AIDS Clinical Trials Group Protocol 333 Team. Baseline human immunodeficiency virus type 1 phenotype, genotype, and RNA response after switching from long-term hard-capsule saquinavir to indinavir or soft-gel capsule saquinavir in AIDS Clinical Trials Group Protocol 333. Journal of Infectious Diseases 182:733-743, 2000.
9. Glidden DV. Robust inference for event probabilities with non-Markov data. Biometrics 58:361-368, 2002.
10. Glidden DV. Rejoinder to the discussion of P.R. Burton and M.P. Epstein. Gen Epidemiol 23:219-20, 2002.
11. Glidden DV, Liang K-Y, Chiu Y-F, Pulver AE. Multipoint affected sibpair linkage methods for localizing susceptibility genes for complex diseases. Genetic Epidemiology 24:107-177, 2003.
12. Glidden DV, Vittinghoff E. Modelling clustered survival data from multicentre clinical trials. Stat Med 23:369-88, 2004.
13. Vittinghoff E, Glidden DV, Shiboski SC, McCulloch CE. Regression Methods in Biostatistics: Linear, Logistic, Survival and Repeated Measures Models. Springer, New York, 2005.
14. Glidden DV. Pairwise dependence diagnostics for clustered failure time data. Biometrika 94:371-85, 2007.
15. Geng EH, Glidden DV, Bangsberg DR, Bwana MB, Musinguzi N, Nash D, Metcalfe JZ, Yiannoutsos CT, Martin JN, Petersen ML. A causal framework for understanding the effect of losses to follow-up on epidemiologic analyses in clinic-based cohorts: The case of HIV-infected patients on antiretroviral therapy in Africa. American Journal of Epidemiology, doi: 10.1093/aje/kwr444

D. Research Support

Ongoing Research Support

U01AI064002-07 (Grant; UCSF PI Glidden) 1/31/13-11/30/14
NIH
Chemoprophylaxis for HIV Prevention in Men Expansion
Statistics Core for a randomized trial of chemoprophylaxis for HIV, which evaluates the safety and efficacy of daily oral tenofovir. Supplement to NIH-NIAID U01 AI064002 (Grant).
Role: Co-Investigator

U01 AI069911 (Yiannoutsos; Martin PI UCSF subcontract) 8/5/06-7/31/16
NIH/University of Indiana
East Africa IEDEA Regional Consortium
To contribute and analyze data for the International Epidemiologic Databases to Evaluate AIDS (IEDEA) from the Mbarara, Uganda-based ISS and UARTO cohorts.
Role: Co-Investigator

Completed Research Support

R01NS063876 McQuillen 9/1/09-8/30/12
NIH-NINDS
White Matter Injury in Critically Ill Newborns with Congenital Heart Disease

The goal of this study is to use perioperative advanced MR imaging in fetuses and neonates with congenital heart disease to determine if fetal and postnatal delayed brain development is a risk factor for perioperative white matter injury.
Role: Co-Investigator

P01 NS41997 Carlson; Project 3 Prusiner 7/1/07-6/30/12
NIH-NINDS/McLaughlin Research Inst.
Functional Genetics of Susceptibility to Prions
To develop cell culture models based on neurospheres, to understand the cell biology of various prions strains, and to enable rapid assay of of prions from a range of species.
Role: Co-Investigator

UL1 RR024131 Johnston (PI) 9/30/06-6/30/11
NIH-NCRR
Clinical and Translational Science Institute
To enhance training and infrastructure to foster the translation of discoveries in basic science into practices that promote the health of our patients and our community.
Role: Co-Investigator

U01 AI064002 Grant / Shafer (PI) 8/15/05-1/31/09
NIH/NIAID/Gladstone Inst. Effort ended 1/31/08
Chemoprophylaxis for HIV Prevention in Peruvian Men
To evaluate the safety and efficacy of chemoprophylaxis for HIV prevention in a randomized and blinded trial of daily oral tenofovir versus placebo among men in Peru.
Role: Co-investigator

R01 NS046432 Barkovich (PI) 9/15/04-5/31/08
NIH/NINDS Effort ended 5/31/07
MRSI and DTI of Brain Injury in Preterm Neonates
To determine if MR techniques detect metabolic or microstructural abnormalities associated with subsequent cognitive, visual, motor, and auditory deficits more accurately than current clinical parameters.
Role: Co-investigator

R01 HL65411 Glidden (PI) 4/1/01-3/31/06
NIH/NHLBI
Failure Time Methods for Family Disease Studies
The long-term objective of this research is the development of sound methodologies that will facilitate studying the role of both genetic and environmental factors in cardiovascular disease. The short-term goal of the proposal is to develop statistical methods for age at onset data from population-based family studies of disease incidence.
Role: Principal Investigator

U62/CCU922423 Rutherford (PI) 9/30/02-3/31/06
CDC
Univ. Technical Assistance Projects in Support of the Global AIDS Program: Uganda
Project will provide technical assistant in support of the Global AIDS Program to Uganda. Assistance will be provided in the areas of training, research methodology, and evaluation and monitoring.
Role: Co-investigator

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 1

ORGANIZATIONAL DUNS*: 0522779360000

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2015 **End Date*:** 06-30-2016 **Budget Period: 1**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Dr.	Johanna		Olson	M.D.	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2.	Dr.	Marvin		Belzer	MD	Co-Investigator							
3.				(b)(6)									
4.	Dr.	Sheree		Schrager	PhD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
0	Post Doctoral Associates	(b)(4)	0.00	0.00	(b)(4)	(b)(4)	(b)(4)
0	Graduate Students		0.00	0.00			
0	Undergraduate Students		0.00	0.00			
1	Secretarial/Clerical						
1	Study Coordinator						
1	Data Manager						
1	Clinical Research Manager						
1	Psychologist						
5	**Total Number Other Personnel**						

Total Other Personnel (b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 1

ORGANIZATIONAL DUNS*: 0522779360000
Budget Type*: ● Project ○ Subaward/Consortium
Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2015 **End Date*:** 06-30-2016 **Budget Period: 1**

C. Equipment Description	
List items and dollar amount for each item exceeding $5,000	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	
Additional Equipment: File Name:	

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	0.00
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

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

ORGANIZATIONAL DUNS*: 0522779360000

Budget Type*: ● Project ○ Subaward/Consortium

Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2015 **End Date*:** 06-30-2016 **Budget Period:** 1

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	(b)(4)
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Outpatient Care Costs - Labs	
9 . Participant Incentives	
10 . Participant Transportation	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number) DHHS, 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 ($)*
	0.00

K. Budget Justification* File Name: 1234-CHLA Budget Justification.pdf
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 2

ORGANIZATIONAL DUNS*: 0522779360000

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2016 **End Date*:** 06-30-2017 **Budget Period: 2**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Johanna		Olson	M.D.	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Marvin		Belzer	MD	Co-Investigator							
3 .	Dr.	Leslie		Clark	PhD	Co-Investigator							
4 .	Dr.	Sheree		Schrager	PhD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
1	Secretarial/Clerical	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Study Coordinator						
1	Data Manager						
1	Clinical Research Manager						
1	Psychologist						
5	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)
						Total Salary, Wages and Fringe Benefits (A+B)	(b)(4)

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 2

ORGANIZATIONAL DUNS*: 0522779360000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2016 **End Date*:** 06-30-2017 **Budget Period: 2**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 2

ORGANIZATIONAL DUNS*: 0522779360000

Budget Type*: ● Project ○ Subaward/Consortium

Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2016 **End Date*:** 06-30-2017 **Budget Period:** 2

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	(b)(4)
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Outpatient Care Costs - Labs	
9 . Participant Incentives	
10 . Participant Transportation	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, 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. Budget Justification* File Name: 1234-CHLA Budget Justification.pdf
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 3

ORGANIZATIONAL DUNS*: 0522779360000

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2017 **End Date*:** 06-30-2018 **Budget Period: 3**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Johanna		Olson	M.D.	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Marvin		Belzer	MD	Co-Investigator							
3 .	Dr.	Leslie		Clark	PhD	Co-Investigator							
4 .	Dr.	Sheree		Schrager	PhD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
1	Secretarial/Clerical	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Study Coordinator						
1	Data Manager						
1	Clinical Research Manager						
1	Psychologist						
5	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)
						Total Salary, Wages and Fringe Benefits (A+B)	(b)(4)

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 3

ORGANIZATIONAL DUNS*: 0522779360000

Budget Type*: ● Project ❍ Subaward/Consortium

Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2017 **End Date*:** 06-30-2018 **Budget Period: 3**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees	**Total Participant Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

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

ORGANIZATIONAL DUNS*: 0522779360000

Budget Type*: ● Project ○ Subaward/Consortium

Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2017 **End Date*:** 06-30-2018 **Budget Period: 3**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	(b)(4)
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Outpatient Care Costs - Labs	
9 . Participant Incentives	
10 . Participant Transportation	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number) DHHS, 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. Budget Justification* File Name: 1234-CHLA Budget Justification.pdf
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 4

ORGANIZATIONAL DUNS*: 0522779360000

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2018 **End Date*:** 06-30-2019 **Budget Period:** 4

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Johanna		Olson	M.D.	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Marvin		Belzer	MD	Co-Investigator							
3 .	Dr.	Leslie		Clark	PhD	Co-Investigator							
4 .	Dr.	Sheree		Schrager	PhD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
1	Secretarial/Clerical	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Study Coordinator						
1	Data Manager						
1	Data Coordinating Site Statistician						
1	Clinical Research Manager						
1	Psychologist						
6	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)
						Total Salary, Wages and Fringe Benefits (A+B)	(b)(4)

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 4

ORGANIZATIONAL DUNS*: 0522779360000

Budget Type*: ● Project ○ Subaward/Consortium

Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2018 **End Date*:** 06-30-2019 **Budget Period: 4**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees	**Total Participant Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 4

ORGANIZATIONAL DUNS*: 0522779360000
Budget Type*: ● Project ○ Subaward/Consortium
Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2018 **End Date*:** 06-30-2019 **Budget Period:** 4

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	(b)(4)
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Outpatient Care Costs - Labs	
9 . Participant Incentives	
10 . Participant Transportation	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, 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. Budget Justification* File Name: 1234-CHLA Budget Justification.pdf
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 5

ORGANIZATIONAL DUNS*: 0522779360000

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period: 5**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Johanna		Olson	M.D.	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Marvin		Belzer	MD	Co-Investigator							
3 .	Dr.	Leslie		Clark	PhD	Co-Investigator							
4 .	Dr.	Sheree		Schrager	PhD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
1	Post Doctoral Associates	(b)(4)			(b)(4)	(b)(4)	(b)(4)
	Graduate Students						
	Undergraduate Students						
1	Secretarial/Clerical						
1	Study Coordinator						
1	Data Manager						
1	Data Coordinating Site Statistician						
1	Clinical Research Manager						
6	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 5

ORGANIZATIONAL DUNS*: 0522779360000
Budget Type*: ● Project ○ Subaward/Consortium
Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period: 5**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	(b)(4)
2. Foreign Travel Costs	
Total Travel Cost	(b)(4)

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

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

ORGANIZATIONAL DUNS*: 0522779360000

Budget Type*: ● Project ❍ Subaward/Consortium

Organization: Children's Hospital Los Angeles

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period:** 5

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	(b)(4)
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Outpatient Care Costs - Labs	
9 . Participant Incentives	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, 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. Budget Justification* File Name: 1234-CHLA Budget Justification.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATION – CHILDREN'S HOSPITAL LOS ANGELES

On 2/4/14, NICHD approved our request for a waiver of policy and would accept our large grant application for review (please see Attachment). The total direct costs excluding the consortium F&A costs approved were $(b)(4). The total direct costs excluding the consortium F&A costs for this resubmission are $(b)(4).

A. Senior/Key Personnel

Johanna Olson, M.D., Lead/ Principal Investigator ((b)(4) Calendar Months (CM) Y1; (b)(4) CM Y2-Y4; (b)(4) CM Y5)

Qualifications: Dr. Olson's research has primarily focused on transgender youth. She has a strong experience in research on issues of transgender youth including a two-year CHLA new investigator award and is one and a half years into her KL2 translational science award examining the impact of treatment of transgender youth. Dr. Olson is one semester from finishing a Master's Degree in Clinical and Biomedical Investigations at USC, and has two first author papers about transgender youth currently under review. Finally, she has extensive clinical experience treating transgender youth over the past five years. She expanded the Center for Transyouth Health and Development to include care and consultative services for children of all ages, and over the past two years worked to quadruple the number of patients served by the Center.

Role on Project: As principal investigator, Dr. Olson is responsible for overseeing all aspects of the proposed work at the CHLA site and coordinating with the Principal Investigators and Co-Investigators at the other three sites. Dr. Olson will oversee the activities of the Data Coordinating Site and serve as the liaison to the larger group of PI and Co-investigators. Dr. Olson will oversee development and implementation of the protocols for data collection, including physiologic and psychosocial data, at CHLA. As principal investigator she will be primarily responsible for overseeing coordination of care services for participants enrolled in the study at CHLA, assist in the development of the implementation protocol and contribute to presentations and manuscripts based on study data. **Total Salary Requested Y1-Y5: $**(b)(4)

Marvin Belzer, M.D., Co-Investigator ((b)(4) CM Y1; (b)(4) CM Y2-Y4; (b)(4) CM Y5)

Qualifications: Dr. Belzer is the Director of the Division of Adolescent Medicine and has been PI for Los Angeles Adolescent Trials Network site for the past 13 years. He has been primary mentor for Dr. Olson over the past three and a half years. As a longstanding member of the NICHD funded Adolescent Trials Network, he has been involved in research with HIV+ adolescents and transgender adolescents for several years. Dr. Belzer has provided clinical care for transyouth for over 20 years.

Role on Project: As a Co-Investigator, Dr. Belzer will provide mentorship, expertise, and guidance to Dr. Olson in implementing this complex multi-site research endeavor. **Total Salary Requested Y1-Y5: $**(b)(4)

Leslie F. Clark, Ph.D., M.P.H., Co-Investigator ((b)(4) CM Y1 and Y5; (b)(4) CM Y2-Y4)

Qualifications: Dr. Clark is a social health psychologist with training in public health and the Director of Research for the Division of Adolescent Medicine, Department of Pediatrics, at the USC Keck School of Medicine. She has worked on issues of gay and transgender youth for 18 years. Her CDC- and NIH-funded work include development, implementation, and evaluation of behavioral interventions for minority adolescents, young gay men, transgender youth, homeless youth and HIV+ youth. She was a founding member of the Behavioral Leadership Group of the NIH-funded Adolescent Trials Network and has extensive research experience with standardized measures, instrument development, implementation fidelity, and analysis of longitudinal data sets.

Role on Project: Dr. Clark will have a principal role in design of the study, methodological decision making, setting up study protocols, and survey instrument design. Dr. Clark will be responsible for coordinating the psychosocial aspects of the proposed work, including finalization of psychosocial measures with the behavioral health Co-Is, as well as establishing and maintaining a central repository of measures and relevant literature. She will also assist with survey development, data collection protocols, and intervention implementation plans. She will collaborate in cross-site data analysis, preparation of manuscripts, and strategic dissemination of discovery. **Total Salary Requested Y1-Y5: $**(b)(4)

Sheree M. Schrager, Ph.D., M.S., Co-Investigator ((b)(4) CM Y1-Y5)
Qualifications: Dr. Schrager is a social psychologist with extensive knowledge of advanced statistical methods relevant to social and physical sciences and experience collecting and analyzing cross-sectional and longitudinal psychological and health datasets. She is currently the Co-Investigator of a NIDA-funded R01 grant studying substance use among adolescents in the child welfare system and has numerous publications on LGBT adolescents and young adults. As a senior manager at CHLA, she manages federally funded research projects, including design of study protocols and instruments; ensuring compliance with IRB and funding source requirements; documenting research processes, including intervention, process, and evaluation data; generating data analysis plans and supervising researchers responsible for data collection, management, and analysis; leading project-related training and meetings; and developing manuscripts for publication.
Role on Project: Dr. Schrager will advise the study core responsible for establishing standard procedures, merging collected data, and managing, analyzing, and reporting on data from all four study sites and collaborate with the project PIs and Co-Is to provide scientific leadership and direction, particularly related to psychological variable measurement and operationalization. She will provide direction to the CHLA site study coordinator, data collection staff, data manager, and biostatistician responsible for data management, cleaning, and analysis. She will also assist with survey development and constructing the protocols that will standardize the data collection and merging procedures; oversee the programming of final data collection instruments and pilot testing of ACASI programming logic; and provide advanced statistical consultation to the project, including diagnosing data problems, developing and executing analytical plans, and advising the analytic team on appropriate longitudinal data analysis methods and procedures. **Total Salary Requested Y1-Y5: $(b)(4)**

B. Other Personnel

To Be Named, Post-Doc Fellow ((b)(4) CM Y5)
A Post-Doctoral Fellow will be hired in year 5 to assist in the longitudinal modeling and other data analyses associated with the project and develop manuscripts for publication. **Total Salary Requested Y5: $(b)(4)**

(b)(6), Secretarial/Clerical (Research Assistant) ((b)(4) CM Y1-Y5)
(b)(6) will be responsible for ordering supplies, scheduling conference calls, arranging travel for annual meetings, and conference participation of PIs and Co-investigators. (b)(6) will provide general administrative support to core staff and will report to Drs. Schrager and Olson. **Total Salary Requested Y1-Y5: $(b)(4)**

To Be Named, Study Coordinator ((b)(4) CM Y1; (b)(4) CM Y2-4; (b)(4) CM Y5)
She/he will conduct CHLA Institutional Review Board (IRB) activities, create and implement procedures for study visits per the protocol, collect study data, interact with study participants, and provide feedback to the CHLA research team. **Total Salary Requested Y1-5: $(b)(4)**

To Be Named, Data Manager ((b)(4) CM Y1; (b)(4) CM Y2-Y3; (b)(4) CM Y4-5)
This person will have extensive experience in quantitative research, including the development of data collection protocols, the design of data collection instruments, quality control, and the management of large complex data sets. This person will assist in the generation of cross-site protocols for data collection; templates for the Human Subjects IRB Boards at each site; and forms for respondent recruitment, enrollment and tracking, as well as for off-protocol and adverse events documentation. This person will train site-specific data collection staff; generate tracking tools; and enact quality control procedures for monitoring fidelity of protocol implementation, adverse event reporting, and all study forms. The data manager will be responsible for ensuring that site data are safely transferred via secure protocols to CHLA for cleaning and merging. The data manager will generate tracking reports regarding the accrual of respondents at each site as well as specific characteristics of the emerging cross-site data file. In addition, this person manages the overall data set, merging different elements, cleaning, creating composite variables and scales and running descriptive statistics such as characteristics of subjects for the entire sample (male v. female, other demographics, etc.) for the larger study group. She/he will be responsible for the establishing and maintaining a manual of all documents as implemented, IRB protocols, amendments, approvals, adverse event reporting, and correspondence. **Total Salary Requested Y1-Y5: $(b)(4)**

To Be Named, Data Coordinating Site Statistician ((b)(4) CM Y4; (b)(4) CM Y5)

A Data Coordinating Site Statistician is budgeted for small amounts in the last year to support both central analyses to be used by all sites as well as any analyses to support future collaborative funding efforts. **Total Salary Requested Y4-Y5: $**(b)(4)

(b)(6), **Clinical Research Manager (**(b)(4) **CM Y1-Y5)**

(b)(6) has strong skills in managing clinical research trials. (b)(6) experience includes budget management, supervision of research protocol implementation, conducting quality assurance activities, and IRB and regulatory documentation. (b)(6) will supervise the CHLA Study Coordinator, provide support and assistance for study-related activities, and conduct quality assurance activities. **Total Salary Requested Y1-Y5: $**(b)(4)

(b)(6), **Psychologist (**(b)(4) **CM Y1,** (b)(4) **CM Y2-Y4)**

(b)(6) has extensive experience in providing individual, family, and group therapy to transgender youth. (b)(6) will provide psychological evaluation of CHLA study participants, therapeutic services, and urgent assessments related to research participation. **Total Salary Requested Y1-Y4: $**(b)(4)

Fringe Benefits

The fringe benefit rate for USC Faculty (Dr. Olson, Dr. Belzer and Dr. Clark) is 31.1% of Salaries. The fringe benefit rate for Children's Hospital Los Angeles staff (the rest of the personnel) is 25.5%. Total Fringe Benefits are: Year 1 $(b)(4); Year 2 $(b)(4); Year 3 $(b)(4); Year 4 $(b)(4); Year 5 $(b)(4). **Total Fringe Benefits Requested Y1-Y5: $**(b)(4)

C. Equipment

No Equipment in excess of $(b)(4) per item will be purchased.

D. Travel

The Data Coordinating Site requests travel funds to support an annual trip for non-CHLA PI and Co-Investigators to meet in Los Angeles to discuss research agendas, progress, and products. Domestic travel is budgeted at $1,000 per person (including airfare, hotel, and per diem) for two investigators from San Francisco and $1,500 per person (including airfare, hotel, and per diem) for four investigators from the sites outside of California. In addition, the PI or a Co-I at each site will make one domestic trip to a relevant professional conference, grantee meeting, or to consult with other researchers ($1,750 for hotel, airfare, and per diem). A total of $15,000 is requested for travel in Year 1. In Year 2, $10,000 is requested for the annual PI/Co-I meeting and $4,000 for domestic travel for relevant professional conference, grantee meeting, or to consult with other researchers for at total of $14,000. In Year 3, $7,449 is budgeted for the PI/Co-I meeting. In Year 4, $8,000 is requested for the annual PI/Co-I meeting and $2,278 for domestic travel for relevant professional conference, grantee meeting, or to consult with other researchers for at total of $10,278. In Year 5, $8,000 is requested for the annual PI/Co-I meeting and $7,492 for domestic travel for relevant professional conference, grantee meeting, or to consult with other researchers for at total of $15,492. **Total Travel Requested Y1-Y5: $62,219**

E. Participant/Trainee Support Costs

No Participant/Trainee Supports Costs are being requested.

F. Other Direct Costs

Other Direct Costs are as follows:

F1. Materials and Supplies: Computers are budgeted at $(b)(4) each per site and one for the data manager in Year 1. Software for data collection, management, and storage will be purchased for the four site specific laptops and the data manager computer and is requested at $(b)(4) in Year 1. Project specific supplies for use in study activities are proposed at $(b)(4) for Year 1, $(b)(4) for Year 2, $0 for Years 3 through 5 for a Total of $(b)(4). **Total Materials and Supplies Requested Y1-Y5: $** (b)(4)

F2. Publication Costs: No Publication Costs are being requested.

F3. Consultant Services: No Consultant Services are being requested.

F4. ADP/Computer Services: No ADP/Computer Services are being requested.

F5. Subawards/Consortium/Contractual Costs: Consortium costs are as follows:

Boston Children's Hospital:

	Direct	Indirect ((b)(4) %)	TOTAL Per Year
Year 1	$	$	$
Year 2	$	$	$
Year 3	$ (b)(4)	$ (b)(4)	$ (b)(4)
Year 4	$	$	$
Year 5	$	$	$
TOTAL	**$**	**$**	**$**

Lurie Children's Hospital of Chicago: (b)(4)

	Direct	Indirect (%)	TOTAL Per Year
Year 1	$	$	$
Year 2	$	$	$
Year 3	$ (b)(4)	$ (b)(4)	$ (b)(4)
Year 4	$	$	$
Year 5	$	$	$
TOTAL	**$**	**$**	**$**

University of California San Francisco: (b)(4)

	Direct	Indirect (%)	TOTAL Per Year
Year 1	$	$	$
Year 2	$	$	$
Year 3	$ (b)(4)	$ (b)(4)	$ (b)(4)
Year 4	$	$	$
Year 5	$	$	$
TOTAL	**$**	**$**	**$**

Cost sharing: Expertise across the specialties will be available for all of the sites. In this manner, we are able to avoid duplication and increased cost of specialists at each site. Subawards/Consortium/Contractual cost for Year 1 are $(b)(4), Year 2 $(b)(4), Year 3 $(b)(4), Year 4 $(b)(4), Year 5 $(b)(4). **Total Subawards/Consortium/Contractual Costs Requested Y1-Y5: $** (b)(4)**.**

F6. Equipment or Facility Rental /User Fees: No Equipment or Facility Rental/User Fees are being requested.

F7. Alterations and Renovations: No Alterations and Renovations are being requested.

F8. Outpatient Care Costs: While it is our expectation that insurance will cover the labs associated with this proposal for the most part, we acknowledge that there may be instances where obstacles arise and insurance is unable to cover labs required for research windows as proposed. Therefore, we are requesting $(b)(4) to cover an estimated 10-20% of laboratory costs in Year 1, $(b)(4) in Year 2, $(b)(4) in Year 3, $(b)(4) in Year 4, and $(b)(4) in Year 5. The funding request fluctuates over the years to correlate with the flow of patient visits based on the visit timeline. Children's Hospital Los Angeles has a DHHS-negotiated research patient care rate agreement for in-house clinical research labs at 38% of cost; however, many of these labs are sent to off-site laboratories such as Quest, and those charges are at cost. Examples of expected labs and their associated costs are:
-Gonadotropin Assay (Follicle Stimulating Hormone) $(b)(4)
-Free Testosterone Assay $(b)(4)
-Total Testosterone Assay $(b)(4)
-Estradiol Ultra Sensitive Assay $(b)(4)
Total Outpatient Care Costs Requested Y1-Y5: $(b)(4)

F9. Participant Incentives: Compensation of $40 will be provided at each visit to the participants. For the early pubertal cohort, the parent-child dyad will receive only $40 even though they are both considered research subjects. We anticipate the following numbers of visits by year: Year 1: ; Year (b)(4); Year 3: ; Year 4: , Year 5: . Therefore we request $(b)(4) for Year 1, $(b)(4) for Year 2, $(b)(4) in Year 3, $(b)(4) for Year 4, and $ for Year 5.
Total Participant Incentives Requested Y1-Y5: $(b)(4)

F9. Participant Transportation: For the site-specific activities, participant transportation is requested at $70 per site visit for those participants who do not have reliable transportation. We request $(b)(4) (18 visits) for Year 1, $(b)(4) (72.5 visits) for Year 2, $(b)(4) (50 visits) for Year 3, $(b)(4) (25 visits) for Year 4, and $0 for Year 5. **Total Participant Transportation Requested Y1-Y4: $(b)(4)**

G. Total Direct Costs

Total Direct Costs are as follows:

	Direct
Year 1	$
Year 2	$
Year 3	$
Year 4	$
Year 5	$
TOTAL	**$**

(b)(4)

H. Indirect Costs

Indirect costs (Facilities & Administrative Costs) are based on Modified Total Direct Costs and are (b)(4)% as approved by the Department of Health and Human Services on 2/5/14.

	Indirect (%)
Year 1	$
Year 2	$
Year 3	$
Year 4	$
Year 5	$
TOTAL	**$**

(b)(4)

I. Total Direct and Indirect Costs

	Direct	Indirect (b)(4 %)	TOTAL Per Year
Year 1	$	$	$
Year 2	$	$	$
Year 3	$	$	$
Year 4	$	$	$
Year 5	$	$	$
TOTAL	**$**	**$**	**$**

(b)(4)

J. Fee

No Fee is being requested.

Timeline of Project Activities: Funds will be used to implement the research project according to the following Timeline of Project Activities:

Activities	YEAR 1 (SEP '14-AUG '15)				YEAR 2 (SEP '15-AUG '16)				YEAR 3 (SEP '16-AUG '17)				YEAR 4 (SEP '17-AUG '18)				YEAR 5 (SEP '18-AUG '19)			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Start Up and Project Implementation Activities																				
Ongoing cross-site decisional calls	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Protocol development/IRB approval	X	X																		
Hire project data manager	X																			
Pilot test measures and procedures		X																		
Program and test ACASI		X																		
Hire/train project coordinators and staff			X																	
Convene yearly cross site meetings	X				X				X				X				X			
Data Collection: Early Pubertal Cohort																				
Recruit and consent subjects			X	X	X	X	X	X	X	X										
Baseline ACASI/physiologic data			X	X	X	X	X	X	X	X										
6,12, 24-month assessments					X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Data Collection: Late Pubertal Cohort																				
Recruit and consent subjects			X	X	X	X	X	X												
Baseline ACASI/physiologic data			X	X	X	X	X	X	X											
6,12, 24-month assessments					X	X	X	X	X	X	X	X	X	X	X	X	X			
Data Management, Analysis, and Write Up																				
Data management			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Data analysis							X	X	X	X	X	X	X	X	X	X	X	X	X	X
Dissemination and publications								X	X	X	X	X	X	X	X	X	X	X	X	X

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		
Section B, Other Personnel		
Total Number Other Personnel		
Total Salary, Wages and Fringe Benefits (A+B)		
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs	(b)(4)	(b)(4)
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1		
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		
Section H, Indirect Costs		
Section I, Total Direct and Indirect Costs (G + H)		
Section J, Fee		

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 1

ORGANIZATIONAL DUNS*: 0765937220000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: Boston Children's Hospital

Start Date*: 07-01-2015 **End Date*:** 06-30-2016 **Budget Period: 1**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Norman		Spack	MD	PD/PI	(b)(4)				(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Amy		Tishelman	PhD	Co-Investigator							
3 .	Dr.	Daniel		Shumer	MD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Research Nurse	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Project Coordinator						
2	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 1

ORGANIZATIONAL DUNS*: 0765937220000

Budget Type*: ❍ Project ● Subaward/Consortium

Organization: Boston Children's Hospital

Start Date*: 07-01-2015 **End Date*:** 06-30-2016 **Budget Period: 1**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees	**Total Participant Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

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

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

Start Date*: 07-01-2015 **End Date*:** 06-30-2016 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number) DHHS, Joseph Guarnieri, 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. Budget Justification*	File Name: 1241-Boston Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 2

ORGANIZATIONAL DUNS*: 0765937220000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: Boston Children's Hospital

Start Date*: 07-01-2016 **End Date*:** 06-30-2017 **Budget Period: 2**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Dr.	Norman		Spacks	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2.		(b)(6)											
3.	Dr.	Daniel		Shumer	MD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Research Nurse						
1	Project Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Research Assistant						
3	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)
						Total Salary, Wages and Fringe Benefits (A+B)	(b)(4)

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 2

ORGANIZATIONAL DUNS*: 0765937220000

Budget Type*: ❍ Project ● Subaward/Consortium

Organization: Boston Children's Hospital

Start Date*: 07-01-2016 **End Date*:** 06-30-2017 **Budget Period: 2**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees	**Total Participant Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 2

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

Start Date*: 07-01-2016 **End Date*:** 06-30-2017 **Budget Period:** 2

F. Other Direct Costs	Funds Requested ($)*
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Joseph Guarnieri, 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. Budget Justification*	File Name: 1241-Boston Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 3

ORGANIZATIONAL DUNS*: 0765937220000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: Boston Children's Hospital

Start Date*: 07-01-2017 **End Date*:** 06-30-2018 **Budget Period:** 3

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Dr.	Norman		Spack	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2.				(b)(6)									
3.	Dr.	Daniel		Shumer	MD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person **60,546.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Research Nurse	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Project Coordinator						
1	Research Assistant						
3	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)
						Total Salary, Wages and Fringe Benefits (A+B)	(b)(4)

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 3

ORGANIZATIONAL DUNS*: 0765937220000

Budget Type*: ❍ Project ● Subaward/Consortium

Organization: Boston Children's Hospital

Start Date*: 07-01-2017 **End Date*:** 06-30-2018 **Budget Period: 3**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees	**Total Participant Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

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

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

Start Date*: 07-01-2017 **End Date*:** 06-30-2018 **Budget Period: 3**

F. Other Direct Costs	Funds Requested ($)*
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Joseph Guarnieri, 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. Budget Justification*	File Name: 1241-Boston Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 4

ORGANIZATIONAL DUNS*: 0765937220000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: Boston Children's Hospital

Start Date*: 07-01-2018 **End Date*:** 06-30-2019 **Budget Period: 4**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Dr.	Norman		Spack	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2.		(b)(6)											
3.	Dr.	Daniel		Shuman	MD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Research Nurse						
1	Project Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Research Assistant						
3	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 4

ORGANIZATIONAL DUNS*: 0765937220000

Budget Type*: ❍ Project ● Subaward/Consortium

Organization: Boston Children's Hospital

Start Date*: 07-01-2018 **End Date*:** 06-30-2019 **Budget Period: 4**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees	**Total Participant Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 4

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

Start Date*: 07-01-2018 **End Date*:** 06-30-2019 **Budget Period:** 4

F. Other Direct Costs	Funds Requested ($)*
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Joseph Guarnieri, 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. Budget Justification*	File Name: 1241-Boston Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 5

ORGANIZATIONAL DUNS*: 0765937220000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: Boston Children's Hospital

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period:** 5

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1.	Dr.	Norman		Spack	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2.				(b)(6)									
3.	Dr.	Daniel		Shumer		Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Research Nurse						
1	Project Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Research Assistant						
3	**Total Number Other Personnel**						

Total Other Personnel (b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 5

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

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period: 5**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees	**Total Participant Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

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

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

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period: 5**

F. Other Direct Costs	Funds Requested ($)*
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number): DHHS, Joseph Guarnieri, 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. Budget Justification*	File Name: 1241-Boston Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATION – BOSTON CHILDREN'S HOSPITAL

A. Senior/Key Personnel

Norman Spack, M.D., Principal Investigator ((b)(4) Calendar Months (CM) Y1-Y5)
Qualifications: Dr. Spack is a Pediatric Endocrinologist and a principal in Boston Children's Hospital's Gender Management Service (GeMS) which opened in 2007. GeMS was the first pediatric academic program in the western hemisphere to treat early adolescents with gender dysphoria.
Role on Project: He will collaborate with the project Principal Investigators and relevant Co-Investigators to create and finalize a cross-site study implementation protocol, so that each site carries out the project in the same manner. He will take primary responsibility for the implementation of the scientific aims of this project at Boston Children's Hospital as well as collaborate to disseminate findings. **Total Salary Requested Y1-5: $**(b)(4)

Amy Tishelman, Ph.D., Co-Investigator ((b)(4) CM Y1-5)
Qualifications: Dr. Tishelman is a Clinical Psychologist with significant expertise in scholarship and clinical realms. Before joining the GeMS team, she was the Director of Child Protection Clinical Services at Boston Children's Hospital and subsequently Director of Training and Research for that program.
Role on Project: She will share responsibility for the scientific and fiscal integrity of this project, provide support to research participants when needed, and will oversee all research activities at Boston Children's Hospital. She will assist in directly supervising and managing frontline research activities involving project direction and data management. Specifically, Dr. Tishelman, along with Dr, Shumer, will supervise the Project Coordinator in her/his management of day-to-day tasks by coordinating IRB submissions, developing and overseeing effective recruitment strategies, and providing ongoing advice regarding confidential data collection/ management procedures. She will share responsibility for data interpretation and dissemination of findings with Drs. Spack and Shumer. **Total Salary Requested Y1-5: $**(b)(4)

Daniel Shumer, M.D., Co-Investigator ((b)(4) CM Y1-Y5)
Qualifications: Dr. Shumer is a Pediatric Endocrinologist at Boston Children's Hospital.
Role on Project: As a clinical co-investigator Dr. Shumer will support the PIs around all issues of research at the Boston site. These include hiring, study design, setting up study protocols, and survey instrument design. Along with Dr. Tishelman, he will train and supervise the Project Coordinator and Research Assistant, train the Registered Nurse, and help to oversee all aspects of the research activities at Boston Children's Hospital. He will also assist in data collection protocols and intervention implementation plans. He will collaborate in data analysis, preparation of manuscripts, and dissemination activities. He will conduct patient assessments, review laboratory results, prescribe medication, and consult with the study team on all endocrinological issues such as bone development and growth. Dr. Shumer will assist in protocol development and attend project meetings, phone calls, and other study related interactions as needed **Total Salary Requested Y1-5: $**(b)(4)

B. Other Personnel

To Be Named, Research Nurse, R.N. ((b)(4) CM Y1-Y5)
The Research Nurse will be an individual with a Registered Nurse degree or higher and will have substantial research experience with LGBT, YMSM, and/or YGBM populations. He/she will conduct study-related research visits in collaboration with study faculty and engage in activities such as assessments, collection of study related specimens, and regulatory documentation. **Total Salary Requested Y1-5: $**(b)(4)

To Be Named – Project Coordinator ((b)(4) CM Y1; (b)(4) CM Y2-Y4; CM Y5) (b)(4)
The Project Coordinator will be an individual with a clinical master's degree and substantial research experience with LGBT populations. He/she will meet regularly with project investigators and will coordinate project development, participant recruitment, and overall project implementation. He/she will work with the Co-Is to communicate with the site IRB, coordinate recruitment and retention, manage day-to-day operations of the project, and oversee confidential data collection procedures. He/she will also assist in refining assessment instruments, preparation of procedural manuals, and assist in maintaining IRB approval. He/she will coordinate

and attend staff meetings and other study related collaborations as needed. **Total Salary Requested Y1-5: $** (b)(4)

To Be Named – Research Assistant ((b)(4) **CM Y2-5)**
The Research Assistant will provide data collection support. He/she will also participate in all study-related meetings, calls, and collaborations and assist the Project Coordinator as needed. **Total Salary Requested Y2-5: $** (b)(4)

Fringe Benefits

The fringe benefit rate is (b)(4)% of Salaries. Total Fringe Benefits are: Year 1 $ (b)(4); Year 2 $ (b)(4); Year 3 $ (b)(4); Year 4 $ (b)(4); Year 5 $ (b)(4). **Total Fringe Benefits Requested Y1-Y5: $** (b)(4)

C. Equipment

No Equipment in excess of $5,000 per item will be purchased.

D. Travel

No Travel is requested.

E. Participant/Trainee Support Costs

No Participant/Trainee Supports Costs are being requested.

F. Other Direct Costs

No Direct Costs are being requested.

G. Total Direct Costs

Total Direct Costs are as follows:

	Direct
Year 1	$ (b)(4)
Year 2	$
Year 3	$
Year 4	$
Year 5	$
TOTAL	**$**

H. Indirect Costs

Indirect costs (Facilities & Administrative Costs) are based on Modified Total Direct Costs and are (b)(4)% in Year 1 and (b)(4)% in Years 2 - 5 as approved by the Department of Health and Human Services on 10/1/2013.

	Indirect (b)(4)%	Indirect (b)(4)%
Year 1	$ (b)(4)	
Year 2		$ (b)(4)
Year 3		$

Year 4	$ (b)(4)
Year 5	$
TOTAL	**$**

I. Total Direct and Indirect Costs

	TOTAL Per Year
Year 1	$ (b)(4)
Year 2	$
Year 3	$
Year 4	$
Year 5	$
TOTAL	**$**

J. Fee

No Fee is being requested.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		
Section B, Other Personnel		
Total Number Other Personnel	14	
Total Salary, Wages and Fringe Benefits (A+B)		
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		(b)(4)
Section F, Other Direct Costs		
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1		
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		
Section H, Indirect Costs		
Section I, Total Direct and Indirect Costs (G + H)		
Section J, Fee		

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 1

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2015 **End Date*:** 06-30-2016 **Budget Period: 1**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Robert		Garofalo	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Lisa		Simons	MD	Co-Investigator - Pediatrician							
3 .	Dr.	Marco		Hidalgo	PhD	Co-Investigator - Psychologist							
4 .	Dr.	Scott		Leibowitz	MD	Co-Investigator - Psychiatrist							
5 .	Dr.	Courtney		Finlayson	MD	Co-Investigator - Endocrinologist							
6 .	Dr.	Joel		Frader	MD	Ethicist							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Nurse						
2	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 1

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ❍ Project ● Subaward/Consortium

Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2015 **End Date*:** 06-30-2016 **Budget Period: 1**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees	**Total Participant Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

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

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ❍ Project ● Subaward/Consortium

Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2015 **End Date*:** 06-30-2016 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Mmodified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number) DHHS, Denise Shirlee, 214-767-3261

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Budget Justification* File Name: 1242-Lurie Budget Justification.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 2

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2016 **End Date*:** 06-30-2017 **Budget Period: 2**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Robert		Garofalo	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Lisa		Simons	MD	Co-Investigator - Pediatrician							
3 .	Dr.	Marco		Hidalgo	PhD	Co-Investigator - Psychologist							
4 .	Dr.	Scott		Leibowitz	MD	Co-Investigator - Psychiatrist							
5 .	Dr.	Courtney		Finlayson	MD	Co-Investigator - Endocrinologist							
6 .	Dr.	Joel		Frader	MD	Ethicist							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Data Manager						
1	Nurse						
3	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 2

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ❍ Project ● Subaward/Consortium

Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2016 **End Date*:** 06-30-2017 **Budget Period: 2**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees	**Total Participant Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 2

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ❍ Project ● Subaward/Consortium

Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2016 **End Date*:** 06-30-2017 **Budget Period: 2**

F. Other Direct Costs	Funds Requested ($)*
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number) DHHS, Denise Shirlee, 214-767-3261

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Budget Justification*	File Name: 1242-Lurie Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 3

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2017 **End Date*:** 06-30-2018 **Budget Period: 3**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Robert		Garofalo	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Lisa		Simons	MD	Co-Investigator - Pediatrician							
3 .	Dr.	Marco		Hidalgo	PhD	Co-Investigator - Psychologist							
4 .	Dr.	Scott		Leibowitz	MD	Co-Investigator - Psychiatrist							
5 .	Dr.	Courtney		Finlayson	PhD	Co-Investigator - Endocrinologist							
6 .	Dr.	Joel		Frader	MD	Ethicist							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Data Manager						
1	Nurse						
3	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)
						Total Salary, Wages and Fringe Benefits (A+B)	(b)(4)

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 3

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ❍ Project ● Subaward/Consortium

Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2017 **End Date*:** 06-30-2018 **Budget Period: 3**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

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

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ❍ Project ● Subaward/Consortium

Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2017 **End Date*:** 06-30-2018 **Budget Period: 3**

F. Other Direct Costs	Funds Requested ($)*
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number) DHHS, Denise Shirlee, 214-767-3261

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Budget Justification*	File Name: 1242-Lurie Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 4

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2018 **End Date*:** 06-30-2019 **Budget Period: 4**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Robert		Garofalo	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Lisa		Simons	MD	Co-Investigator - Pediatrician							
3 .	Dr.	Marco		Hidalgo	PhD	Co-Investigator - Psychologist							
4 .	Dr.	Scott		Leibowitz	MD	Co-Investigator - Psychiatrist							
5 .	Dr.	Courtney		Finlayson	MD	Co-Investigator - Endocrinologist							
6 .	Dr.	Joel		Frader	MD	Ethicist							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Data Manager						
1	Nurse						
3	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)
						Total Salary, Wages and Fringe Benefits (A+B)	(b)(4)

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 4

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ❍ Project ● Subaward/Consortium

Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2018 **End Date*:** 06-30-2019 **Budget Period: 4**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees	**Total Participant Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

Tracking Number: GRANT11778555 Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 4

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ❍ Project ● Subaward/Consortium

Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2018 **End Date*:** 06-30-2019 **Budget Period: 4**

F. Other Direct Costs	Funds Requested ($)*
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number) DHHS, Denise Shirlee, 214-767-3261

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Budget Justification*	File Name: 1242-Lurie Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 5

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period: 5**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Robert		Garofalo	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Lisa		Simons	MD	Co-Investigator Pediatrician							
3 .	Dr.	Marco		Hidalgo	PhD	Co-Investigator Psychologist							
4 .	Dr.	Scott		leibowitz	MD	Co-Investigator Psychiatrist							
5 .	Dr.	Courtney		Finlayson	MD	Co-Investigator Endocrinologist							
6 .	Dr.	Joel		Frader	MD	Ethicist							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Coordinator						
1	Data Manager	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Nurse						
3	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)
						Total Salary, Wages and Fringe Benefits (A+B)	(b)(4)

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 5

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ❍ Project ● Subaward/Consortium

Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period: 5**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees	**Total Participant Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

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

ORGANIZATIONAL DUNS*: 0744387550000

Budget Type*: ❍ Project ● Subaward/Consortium

Organization: Ann and Robert H. Lurie Children???s Hospital of Chicago

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period: 5**

F. Other Direct Costs	Funds Requested ($)*
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number) DHHS, Denise Shirlee, 214-767-3261

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	(b)(4)

J. Fee	Funds Requested ($)*

K. Budget Justification*	File Name: 1242-Lurie Budget Justification.pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATION – ANN AND ROBERT H. LURIE CHILDREN'S HOSPITAL OF CHICAGO

A. Senior/Key Personnel

Rob Garofalo, M.D., MPH, Principal Investigator ((b)(4) Calendar Months (CM) Y1-Y5)
Qualifications: Dr. Garofalo is Director of Adolescent HIV Services and Director of the Center for Gender, Sexuality and HIV Prevention at Lurie Children's. He is also Associate Professor in the Departments of Pediatrics and Preventive Medicine, Northwest University's Feinberg School of Medicine. Dr. Garofalo has extensive experience in the clinical care of gender non-conforming children and young adults. His research career has focused on the collection of data, both behavioral and clinical biomarkers, in marginalized populations and the translation of this data into intervention development. As a PI on numerous federally funded studies, he has developed the skills to collaborate with and/or lead interdisciplinary and multi-site research teams.
Role on Project: He will take primary responsibility for the implementation of the scientific aims of this project at Lurie Children's as well as collaborate to disseminate findings. **Total Salary Requested Y1-5: $**(b)(4)

Lisa Simons, M.D., Co-Investigator – Pediatrician ((b)(4) CM Y1-5)
Qualifications: Dr. Simons is Instructor of Pediatrics at Northwestern University, Feinberg School of Medicine and Attending Physician, Division of Adolescent Medicine at Ann & Robert H. Lurie Children's Hospital of Chicago.
Role on Project: She will share responsibility for the scientific and fiscal integrity of this project and will oversee all research activities at Lurie Children's. She will share responsibility for data interpretation and dissemination of findings with Dr. Garofalo. **Total Salary Requested Y1-5: $**(b)(4)

Marco A. Hidalgo, Ph.D., Co-Investigator – Psychologist ((b)(4) CM Y1-Y5)
Qualifications: Dr. Hidalgo is a Medical Psychologist in the Division of Adolescent Medicine at Lurie Children's Hospital.
Role on Project: He will assist Investigators in directly supervising and managing frontline research activities involving project direction and data management. Specifically, Dr. Hidalgo will supervise the Project Coordinator in her/his management of day-to-day tasks by coordinating IRB submissions, developing and overseeing effective recruitment strategies, and providing ongoing advice regarding confidential data collection/ management procedures. He will also assist the Data Manager in refining assessment instruments, managing study databases, and creating data manuals. Dr. Hidalgo will attend staff meetings. **Total Salary Requested Y1-5: $**(b)(4)

Scott Leibowitz, M.D., Co-Investigator – Psychiatrist ((b)(4) CM Y1-5)
Qualifications: Dr. Leibowitz is the only Psychiatrist appointed across all study sites. Dr. Leibowitz has extensive experience working with gender nonconforming children and adolescents.
Role on Project: He will assist in protocol development as well as conduct patient assessments at the Lurie site. Dr. Leibowitz will attend project meetings, phone calls, and other study related interactions as needed. **Total Salary Requested Y1-5: $**(b)(4)

Courtney Finlayson, M.D., Co-Investigator – Endocrinologist ((b)(4) CM Y1-Y5)
Qualifications: Dr. Finlayson's work has focused on pediatric endocrinology and diabetes patients with a specific interest in disorders of sex development and puberty.
Role on Project: She will be the lead Endocrinologist at the Lurie site and will conduct patient assessments, review laboratory results, and consult with the study teams on all endocrinological issues such as bone development and growth. Dr. Finlayson will assist in protocol development and attend project meetings, phone calls, and other study related interactions as needed. **Total Salary Requested Y1-5: $**(b)(4)

Joel Frader, M.D., Ethicist ((b)(4) CM Y1-Y5)
Qualifications: Dr. Frader is the Division Head of Academic General Pediatrics at the Lurie site.
Role on Project: He will examine ethical aspects of the implementation of clinical guidelines, including: identifying the age and developmental/maturational characteristics of decision-making capacity of children and adolescents for treatment; describing the ways in which clinicians and parents manage different points of view regarding treatment, particularly when parent perspectives are based on particular religious and philosophical

convictions; and ethical and legal issues surrounding school or voluntary organization exclusion or other discrimination based on gender nonconformity. Dr. Frader will also assist in protocol development and attend project meetings, phone calls, and other study related interactions as needed. **Total Salary Requested Y1-5: $**(b)(4)

B. Other Personnel

(b)(4) (b)(4)

To Be Named, Project Coordinator (CM Y1; CM Y2-Y5)
The Project Coordinator will be an individual with a clinical master's degree and substantial research experience with LGBT populations. He/she will meet regularly with project investigators and will coordinate project development, participant recruitment, and overall project implementation. He/she will work with the Co-Is to coordinate all IRB-related communication, coordinate recruitment and retention, and manage day-to-day operations of the project, including overseeing confidential data collection procedures. He/she will also assist in refining assessment instruments, preparing procedural manuals, and maintaining IRB approval. He/she will coordinate and attend staff meetings and other study related collaborations as needed. **Total Salary Requested Y1-5: $**(b)(4)

(b)(4)

(b)(6) **, Data Manager (CM Y2-5)**
The data manager will program the computerized data collection instrument and provide data management support (including maintenance of research records, preparation of progress reports, and IRB submission). will also participate in all study-related meetings, calls, and collaborations and assist in the preparation of manuscripts and the presentation of study findings at national conferences. **Total Salary Requested Y2-5: $**(b)(4)

(b)(6)

(b)(4) (b)(4)

To Be Named, Research Nurse, R.N. (CM Y1; CM Y2-Y5)
The Research Nurse will be an individual with a Registered Nurse degree or higher and will have substantial research experience with LGBT, YMSM, and/or YGBM populations. He/she will conduct study-related research visits in collaboration with study faculty and engage in activities such as assessments, collection of study related specimens, and regulatory documentation. **Total Salary Requested Y1-5: $**(b)(4)

Fringe Benefits

Fringe Calculations are based on the Anne and Robert H. Lurie Children's Hospital of Chicago FY14-15 rate of % and total **$**(b)(4) **for Y1-5.**

(b)(4)

C. Equipment

No Equipment in excess of $5,000 per item will be purchased.

D. Travel

No Travel is requested.

E. Participant/Trainee Support Costs

No Participant/Trainee Supports Costs are being requested.

F. Other Direct Costs

No Direct Costs are being requested.

G. Total Direct Costs

Total Direct Costs are as follows:

	Direct
Year 1	$ (b)(4)
Year 2	$
Year 3	$
Year 4	$
Year 5	$
TOTAL	**$**

H. Indirect Costs

Indirect costs (Facilities & Administrative Costs) are based on Modified Total Direct Costs and are 50% in Years 1 - 5 as approved by the Department of Health and Human Services.

Year 1	$ (b)(4)
Year 2	$
Year 3	$
Year 4	$
Year 5	$
TOTAL	**$**

I. Total Direct and Indirect Costs

	TOTAL Per Year
Year 1	$ (b)(4)
Year 2	$
Year 3	$
Year 4	$
Year 5	$
TOTAL	**$**

J. Fee

No Fee is being requested.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		
Section B, Other Personnel		
Total Number Other Personnel	14	
Total Salary, Wages and Fringe Benefits (A+B)		
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		(b)(4)
Section F, Other Direct Costs		
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1		
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		
Section H, Indirect Costs		
Section I, Total Direct and Indirect Costs (G + H)		
Section J, Fee		

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 1

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2015 **End Date*:** 06-30-2016 **Budget Period: 1**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Stephen		Rosenthal	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Diane		Ehrensaft	PhD	Co-Investigator							
3 .	Dr.	David		Glidden	PhD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Study Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Clinical Research Nurse						
2	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 1

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ❍ Project ● Subaward/Consortium

Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2015 **End Date*:** 06-30-2016 **Budget Period: 1**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees	**Total Participant Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

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

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ❍ Project ● Subaward/Consortium

Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2015 **End Date*:** 06-30-2016 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Data Network Recharge	(b)(4)
9 . CCDSS	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (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. Budget Justification* File Name: 1243-UCSF Budget Justification.pdf
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 2

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2016 **End Date*:** 06-30-2017 **Budget Period: 2**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Stephen		Rosenthal	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Diane		Ehrensaft	PhD	Co-Investigator							
3 .	Dr.	David		Glidden	PhD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Study Coordinator						
1	Data Manager	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Clinical Research Nurse						
3	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)
						Total Salary, Wages and Fringe Benefits (A+B)	(b)(4)

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 2

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ❍ Project ● Subaward/Consortium

Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2016 **End Date*:** 06-30-2017 **Budget Period: 2**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees	**Total Participant Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

Tracking Number: GRANT11778555 Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 2

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ❍ Project ● Subaward/Consortium

Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2016 **End Date*:** 06-30-2017 **Budget Period: 2**

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Data Network Recharge	(b)(4)
9 . CCDSS	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (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. Budget Justification* File Name: 1243-UCSF Budget Justification.pdf
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 3

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2017 **End Date*:** 06-30-2018 **Budget Period: 3**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Stephen		Rosenthal	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Diane		Ehrensaft	PhD	Co-Investigator							
3 .	Dr.	David		Glidden	PhD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Study Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Data Manager						
1	Clinical Research Nurse						
3	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)
						Total Salary, Wages and Fringe Benefits (A+B)	(b)(4)

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 3

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ❍ Project ● Subaward/Consortium

Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2017 **End Date*:** 06-30-2018 **Budget Period: 3**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees	**Total Participant Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

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

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ❍ Project ● Subaward/Consortium

Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2017 **End Date*:** 06-30-2018 **Budget Period:** 3

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Data Network Recharge	(b)(4)
9 . CCDSS	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (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. Budget Justification* File Name: 1243-UCSF Budget Justification.pdf
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 4

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2018 **End Date*:** 06-30-2019 **Budget Period: 4**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Stephen		Rosenthal	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Diane		Ehrensaft	PhD	Co-Investigator							
3 .	Dr.	David		Glidden	PhD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Study Coordinator						
1	Data Manager	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Clinical Research Nurse						
3	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 4

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ❍ Project ● Subaward/Consortium

Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2018 **End Date*:** 06-30-2019 **Budget Period: 4**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 4

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ❍ Project ● Subaward/Consortium

Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2018 **End Date*:** 06-30-2019 **Budget Period:** 4

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Data Network Recharge	(b)(4)
9 . CCDSS	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (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. Budget Justification* File Name: 1243-UCSF Budget Justification.pdf
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 5

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ❍ Project ● Subaward/Consortium

Enter name of Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period: 5**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Stephen		Rosenthal	MD	PD/PI	(b)(4)	(b)(4)			(b)(4)	(b)(4)	(b)(4)
2 .	Dr.	Diane		Ehrensaft	PhD	Co-Investigator							
3 .	Dr.	David		Glidden	PhD	Co-Investigator							

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person (b)(4)

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Study Coordinator	(b)(4)			(b)(4)	(b)(4)	(b)(4)
1	Data Manager						
1	Clinical Research Nurse						
3	**Total Number Other Personnel**					**Total Other Personnel**	(b)(4)

Total Salary, Wages and Fringe Benefits (A+B) (b)(4)

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 5

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ❍ Project ● Subaward/Consortium

Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period: 5**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs	**Funds Requested ($)***
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees **Total Participant Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

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

ORGANIZATIONAL DUNS*: 0948783370000

Budget Type*: ❍ Project ● Subaward/Consortium

Organization: The Regents of the University of California at San Francisco

Start Date*: 07-01-2019 **End Date*:** 06-30-2020 **Budget Period:** 5

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Data Network Recharge	(b)(4)
9 . CCDSS	
Total Other Direct Costs	(b)(4)

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	(b)(4)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
1 . Modified Total Direct Costs	(b)(4)	(b)(4)	(b)(4)
		Total Indirect Costs	(b)(4)

Cognizant Federal Agency (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. Budget Justification* File Name: 1243-UCSF Budget Justification.pdf
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

BUDGET JUSTIFICATION: UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

Salaries: Pursuant to University of California (UC) policy, salaries in the initial budget period are based on current published UC salary scales and include University mandated range adjustments and merit increases scheduled to occur before the proposed project start date. Pay rate increases in FY02 through FY05 are based on merit review schedules established by UCSF Academic Affairs.

A. Senior/Key Personnel

Stephen M. Rosenthal, M.D., Site Principal Investigator ((b)(4) Calendar Months (CM) Y1-Y5)
Qualifications: Dr. Rosenthal is Professor of Pediatrics at UCSF, Program Director for Pediatric Endocrinology, Co-Director of the Disorders of Sex Development Clinic, and founder and Medical Director of the UCSF Child and Adolescent Gender Center (CAGC). The UCSF CAGC serves as the Pediatric/Adolescent clinical arm of the widely recognized UCSF Center of Excellence for Transgender Health. The CAGC provides multi-disciplinary care to gender non-conforming/transgender youth and adolescents and is the only such multi-disciplinary gender program in Northern California, attracting patients not only from California, but from as far away as Alaska, Florida, and Egypt. Dr. Rosenthal has been appointed as the official representative of the Pediatric Endocrine Society (PES) to the Endocrine Society's (ES) Clinical Practice Guidelines Revision Task Force for the Care of Transgender Individuals and was appointed to the World Professional Association for Transgender Health (WPATH) Consensus committee for revisions of the International Classification of Disease (ICD)-11 pertaining to transgender youth and adults. Dr. Rosenthal has authored seven manuscripts on transgender youth, including a recent "State-of-the-art" invited review in *Pediatrics* and an invited review in the "Approach to the Patient" series for the *Journal of Clinical Endocrinology and Metabolism*. Dr. Rosenthal has been an invited speaker on transgender youth at annual meetings of PES and ES, as well as at the most recent international meeting of WPATH, and has lectured on this subject at academic centers throughout the U.S. Dr. Rosenthal is also the recipient of the UCSF Chancellor Award for LGBT leadership in recognition of his work with transgender youth and is the recipient of the UCSF Family Advisory Council Caring Tree Award and the UCSF Haile T. Debas Academy of Medical Educators Excellence in Teaching Award. Dr. Rosenthal is an established clinical investigator with greater than 30 years' experience in child and adolescent endocrinology and has significant experience conducting multi-center trials. He is currently serving as site PI for NIH/NICHD Disorders of Sex Development: Platform for Basic and Translational Research (1R01HD068138-01A1).
Role on Project: Dr. Rosenthal will have primary responsibility for the implementation of the scientific aims of this project at UCSF. He will collaborate in protocol development (in particular, the endocrine/metabolic parameters), data analysis, and dissemination of findings. **Total Salary Requested Y1-5: $**(b)(4)

Diane Ehrensaft, Ph.D., Co-Investigator and Psychologist ((b)(4) CM Y1- Y5)
Qualifications: Dr. Ehrensaft is Associate Professor of Pediatrics at UCSF and Mental Health Director of the UCSF Child and Adolescent Gender Center. She is a developmental and clinical psychologist and an internationally recognized child and adolescent gender specialist.
Role on Project: Dr. Ehrensaft will have a primary role in the design and implementation of mental health measures and will collaborate in data analysis and dissemination of findings. **Total Salary Requested Y1-5: $**(b)(4)

David V. Glidden, Ph.D., Biostatistician ((b)(4) CM Y1-Y5)
Qualifications: Dr. Glidden is Professor of Biostatistics at UCSF. He received his Ph.D. from the University of Washington in 1993 and spent four years at the Department of Biostatistics at the Harvard School of Public Health before joining the UCSF faculty in 1997. He has experience in developing methods for data analysis, has been an author of an intermediate textbook (Regression Methods in Biostatistics, Spring, 2nd edition, 2011), and has long experience collaborating with investigators in diverse medical specialties. He also has extensive experience in clinical trials, having been the lead statistician for a pivotal study (Grant et al, 2010; for which he was senior author) for chemoprophylaxis for the prevention of HIV acquisition. He is experienced in the analysis of longitudinal data.
Role on Project: Dr. Glidden will work as a resource for Dr. Schrager, Biostatistician at the Core Site, and will provide advice and support on analytic approaches. He will focus the bulk of his activities on the analysis of the

metabolic data. He will be responsible for the design, analysis plan development, and execution of these analyses. **Total Salary Requested Y1-5: $**(b)(4)

B. Other Personnel

To Be Named, Study Coordinator ((b)(4)**CM Y1;**(b)(4)**CM Y2-Y5)**

Role on Project: The Study Coordinator will meet regularly with project investigators and will coordinate project development, participant recruitment, and overall project implementation. He/she will also work with the site PI to coordinate all Institutional Review Board (IRB)-related communications and will manage day-to-day operations of the project. **Total Salary Requested Y1-5: $**(b)(4)

To Be Named, Data Manager ((b)(4)**CM Y2-Y5)**

Role on Project: The Data Manager will program computerized data collection and provide data management support, including maintenance of research records, preparation of progress reports, and assistance with IRB submissions. The Data Manager will also assist in the preparation of manuscripts and conference presentations. **Total Salary Requested Y1-5: $**(b)(4)

To Be Named, Clinical Research Nurse ((b)(4)**CM Y1;**(b)(4)**CM Y2-Y5)**

Role on Project: The Clinical Research Nurse (Registered Nurse degree or more advanced) will conduct study-related research visits in collaboration with study investigators and will assist with collection of study-related specimens and regulatory documentation. **Total Salary Requested Y1-5: $**(b)(4)

Fringe Benefits

Fringe Benefits include health and life insurance, social security, Medicare, dental plan, vision, unemployment insurance, non-industrial disability insurance, worker's compensation insurance, and retirement. Our request is based on actual fringe rates for current employees, which varies according to each person's benefit enrollments. Fringe benefits for TBN employees are 47.8% of salaries for staff personnel, as of July 1, 2015. Fringe benefits for current and TBN employees escalate by 2% each year, based on campus budget projections and consistent with guidance from the University of California, San Francisco (UCSF) Office of Sponsored Research. Total Fringe Benefits are: Year 1 $(b)(4); Year 2 $(b)(4); Year 3 $(b)(4); Year 4 $(b)(4); Year 5 $(b)(4). **Total Fringe Benefits Requested Y1-Y5: $**(b)(4)

C. Equipment

No Equipment in excess of $5,000 per item will be purchased.

D. Travel

No Travel is requested.

E. Participant/Trainee Support Costs

No Participant/Trainee Supports Costs are being requested.

F. Other Direct Costs

UCSF Data Network Recharge: Effective November 1, 2009 the Chancellor's Executive Committee approved a UCSF data network services recharge. The recharge provides funding for critical equipment in support of the campus network. The funding model for data network service includes a UCSF-wide per capita recharge of $/month/FTE. The rate increases in future years, as follows: 7/1/16-6/30/17: $/month/FTE and $/month/FTE from 7/1/17 until amended. As permissible by OMB A-21 and per review and agreement

by our cognizant federal agency, UCSF data network costs are an allowable direct expense. **Total UCSF Data Network Recharge Requested: $** (b)(4)

Computing and Communication Device Support Services (CCDSS): CCDSS provides integral support to campus voice and data technology functions. CCDSS includes software installation/updates, internet security, hardware setup/configuration, and centrally managed patching, storage and backup. The university charges these expenses to all funding sources based on a monthly recharge rate per FTE, consistent with the university's current methodology used for data network services. The recharge rates are provided for under our approved DS-2, will be computed in accordance with applicable OMB requirements, including 2 CFR Part 220 (formerly Circular A-21), and will be reviewed and adjusted annually. **Total Computing and Communication Device Support Services Requested: $** (b)(4)

G. Total Direct Costs

Total Direct Costs are as follows:

	Direct
Year 1	$ (b)(4)
Year 2	$
Year 3	$
Year 4	$
Year 5	$
TOTAL	**$**

H. Indirect Costs

(b)(4)

Indirect costs (Facilities & Administrative Costs) are based on Modified Total Direct Costs and are [ ]% in Years 1 - 5 as approved by the Department of Health and Human Services.

Year 1	$ (b)(4)
Year 2	$
Year 3	$
Year 4	$
Year 5	$
TOTAL	**$**

I. Total Direct and Indirect Costs

	TOTAL Per Year
Year 1	$ (b)(4)
Year 2	$
Year 3	$
Year 4	$
Year 5	$
TOTAL	**$**

J. Fee

No Fee is being requested.

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		
Section B, Other Personnel		
Total Number Other Personnel	14	
Total Salary, Wages and Fringe Benefits (A+B)		
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		(b)(4)
Section F, Other Direct Costs		
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1	(b)(4)	
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		
Section H, Indirect Costs		
Section I, Total Direct and Indirect Costs (G + H)		
Section J, Fee		

Funding Opportunity Number: PA-12-111 . Received Date: 2014-11-05T18:44:21.000-05:00

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

1. Project Director / Principal Investigator (PD/PI)

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

2. Human Subjects

Clinical Trial? ● No ○ Yes
Agency-Defined Phase III Clinical Trial?* ○ No ○ Yes

3. Permission Statement*

If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?

● Yes ○ No

4. Program Income*

Is program income anticipated during the periods for which the grant support is requested? ○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

Budget Period*	Anticipated Amount ($)*	Source(s)*

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5. Human Embryonic Stem Cells

Does the proposed project involve human embryonic stem cells?* ● No ○ Yes

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Cell Line(s): Specific stem cell line cannot be referenced at this time. One from the registry will be used.

6. Inventions and Patents (For renewal applications only)

Inventions and Patents*: ○ Yes ○ No

If the answer is "Yes" then please answer the following:

Previously Reported*: ○ Yes ○ No

7. Change of Investigator / Change of Institution Questions

❑ Change of principal investigator / program director

Name of former principal investigator / program director:

Prefix:

First Name*:

Middle Name:

Last Name*:

Suffix:

❑ Change of Grantee Institution

Name of former institution*:

PHS 398 Research Plan

Please attach applicable sections of the research plan, below.

OMB Number: 0925-0001

1. Introduction to Application (for RESUBMISSION or REVISION only)	1244-Introduction to Application.pdf
2. Specific Aims	1245-Specific Aims.pdf
3. Research Strategy*	1246-Research Strategy.pdf
4. Progress Report Publication List	
Human Subjects Sections	
5. Protection of Human Subjects	1267-Protection of Human Subjects.pdf
6. Inclusion of Women and Minorities	1268-Inclusion of Women and Minorities.pdf
7. Inclusion of Children	1269-Inclusion of Children.pdf
Other Research Plan Sections	
8. Vertebrate Animals	
9. Select Agent Research	
10. Multiple PD/PI Leadership Plan	1270-Multiple PI Leadership Plan.pdf
11. Consortium/Contractual Arrangements	1271-Consortium Contractual Arrangements.pdf
12. Letters of Support	1272-Letters of Support.pdf
13. Resource Sharing Plan(s)	1273-Resource Sharing Plan Data Sharing.pdf
Appendix (if applicable)	
14. Appendix	1247-Appx A WPATH and Endocrine Society Letters.pdf 1248-Appx B Consent Permission Assent Forms.pdf 1249-Appx C Early Pubertal Cohort TG Specific Measures.pdf 1250-Appx D Late Pubertal Cohort TG Specific Measures.pdf

INTRODUCTION TO RESUBMISSION APPLICATION

We would like to thank the committee for a thorough and detailed review of our proposal. We were pleased with a priority score of 26/12th percentile and that the reviewers clearly recognized the significance, importance, and critical need for this research examining health outcomes among transgender children and adolescents. Reviewers noted a great many strengths to the proposal including the overall team across institutions surrounding and supporting Dr. Olson as a new investigator, as well as the innovation of developing a national network of four primary institutions involved in the care of transgender youth. The committee also commented on the considerable impact with regard to public health that this study would have, providing the first U.S. longitudinal data evaluating medical intervention for transgender youth. The few weaknesses noted by the reviewers and individual reviews are addressed below, with corresponding changes italicized in brackets throughout the Research Strategy section.

Lack of a control group for the younger cohort receiving gonadotropin releasing hormone (GnRH) agonists for suppression of endogenous puberty by our estimation was the most significant issue raised by the initial review. We very much appreciate the reviewers' thoughtful comments and have carefully considered options trying to balance the scientific integrity and strength of the data collection with the ethics involved in being responsive to the needs of the target population. The PI's recognize that comparison of a treated vs. an untreated control group could be considered the gold standard for understanding impact of existing recommendations for care of transgender youth. However, the current standards of care from the Endocrine Society and the World Professional Association of Transgender Health (WPATH) were developed from a panel of scientific experts and a consensus-building process based largely upon clinical experience and existing minimal research, and each supports the positive impact of intervention and the negative impact of no intervention. In the context of these guidelines, we strongly believe that a non-intervention control group, or certainly any control group as part of a traditional randomized trial, would be both impractical and unethical (see the Endocrine Society and WPATH letters of support regarding our cohort design in Appendix A). In considering the reviewers' concerns, we are committed to collecting longitudinal outcome data from a group that might be considered a "natural control" – those youth appropriate for GnRH agonist treatment, but who refuse treatment as part of the informed consent process. In a small, but not rare, number of cases at our institutions, parents and/or the children may elect under certain circumstances (e.g., cost, fears given a lack of scientific evidence, etc.) to not initiate pubertal suppression. This outcome data will be collected along the same visit schedule as our treated cohort for comparison. In addition, as part of our original study design we will collect data on age and Tanner staging to be able to examine if early vs. delayed treatment in these young people affects health outcomes. Further discussion of a control group is included in section C3: Study Design.

Reviewers noted that demographic data collection was missing from the proposal. Age, place of birth, current residence, religion, ethnicity, and race will be collected at baseline. These are outlined in section C4b for the younger cohort and highlighted in section C5b for the older cohort of youth. Additionally, we plan to collect transgender experience data including assigned gender at birth, age of discovery of gender incongruence, age of disclosure to parents, and sexual orientation.

In order to address the reviewers concerns about **inclusion of multi-cultural participants**, we will translate ACASI instruments and informed consents into Spanish, so that monolingual Spanish speakers can participate. This has been added to the inclusion criteria for both cohorts. Additionally, the audio version of the ACASI will be available for younger children who may not be proficient in reading.

We appreciate the recommendation and will add a DSMB to oversee all aspects of our network's work. As one reviewer put quite nicely, "While this is technically an observational design, these vulnerable youth will be undergoing longitudinal medical treatment that could potentially have negative side effects."

As recommended by Reviewer 1, scheduled in-person meetings of core personnel at the 4 sites will occur at least bi-annually in person and quarterly via teleconference to improve the cohesiveness of the proposed study, discuss scientific oversight, and identify problems that arise so that they may be addressed in a timely and efficient manner. Monthly calls between the Project Coordinators will be scheduled to discuss and troubleshoot logistical issues that might arise that are site specific or worthy of discussion between the PI's.

One reviewer raised concerns about the inclusion of the UCSF site based upon what was submitted via the "Resources" page of the original grant submission. We apologize for not having adequately detailed that site's strengths but feel very strongly that UCSF is a key and vital component to our network and proposed research. We have included additional information about Dr. Rosenthal and the UCSF team in the Facilities and Resources section and this document now details the strengths this site brings to the proposed study as the pediatric/adolescent clinical arm of the nationally recognized UCSF Center of Excellence for Transgender Health.

SPECIFIC AIMS

Transgender children and adolescents, those who experience incongruence between assigned birth sex and internal gender identity, are a poorly understood and a distinctly understudied population in the United States. The limited available data suggest that transgender youth who are gender dysphoric (persistently distressed about gender incongruence) are at increased risk for **anxiety, depression, suicide, and substance use** compared to their peers**.** The development of undesired secondary sex characteristics during puberty intensifies the distress associated with gender incongruence and increases the risk for these conditions.

Current clinical practice guidelines aim to decrease gender dysphoria and ameliorate potential negative health outcomes. Treatment recommendations vary depending on the age and developmental stage of youth with gender dysphoria. For those youth in the earliest stages of pubertal development (Tanner 2-3), treatment with gonadotropin-releasing hormone (GnRH) agonists is recommended in order to suppress endogenous puberty and avoid the development of undesired secondary sex characteristics. In older adolescents in the later stages of pubertal development (Tanner 4-5), treatment with cross-sex hormones is recommended to induce desired masculine or feminine features. While these guidelines have been used at academic and community centers across the U.S., they are based on very limited data. Furthermore, there are **no available data examining the physiologic and metabolic consequences of cross-sex hormone treatment in youth.** This represents a critical gap in knowledge that has significant implications for clinical practice across the U.S. In 2011, a report of the Institute of Medicine called for the development of rigorous research aimed at understanding the health implications of hormone use and other transgender-specific issues.

The objective of the proposed research is to **provide evidence-based data to inform clinical care for transgender youth.** The study will leverage the partnership between four, university-affiliated, gender clinics across the U.S. to recruit two developmental cohorts and conduct **a multi-site, observational study** examining the safety of hormonal interventions and the physiological and psychosocial outcomes associated with these treatments. The Specific Aims are:

Aim 1: To evaluate the impact of **GnRH agonists** administered for puberty suppression, on **mental health, psychological well-being, physiologic parameters, and bone health** as well as document the safety of GnRH agonists in an **early-pubertal** cohort (Tanner stages 2-3; n=80) of transgender children and adolescents**,** comparing baseline and follow-up assessments at 6 months, 1 year, and 2 years after initiating treatment.

Hypothesis 1a: Patients treated with GnRH agonists will exhibit decreased symptoms of depression, anxiety, trauma symptoms, self-injury, and suicidality and increased body esteem and quality of life over time.
Hypothesis 1b: GnRH agonists will be tolerable and safe for early-pubertal transgender youth, i.e., fasting lipids and glucose, liver enzymes, electrolytes, insulin, and HbA1c will not increase above clinically safe ranges.
Hypothesis 1c: Raw bone density scores will remain stable for early-pubertal transgender youth receiving GnRH agonists; however, age-matched z-scores may decrease.

Aim 2: To evaluate the impact of **cross-sex hormones** administered for gender transition on **mental health, psychological well-being, and metabolic/physiologic parameters** as well as document the safety of cross-sex hormones in a **late-pubertal** cohort (Tanner stages 4-5; n=200) of transgender adolescents**,** comparing baseline and follow up assessments at 6 months, 1 year, and 2 years after initiating treatment.

Hypothesis 2a: Patients treated with cross-sex hormones will exhibit decreased symptoms of gender dysphoria, depression, anxiety, trauma symptoms, self-injury, and suicidality and increased body esteem and quality of life over time.
Hypothesis 2b: Cross-sex hormones will be tolerable and safe to use for late-pubertal transgender youth initiating phenotypic transition, i.e., will not increase fasting lipids and glucose, liver enzymes, electrolytes, and hemoglobin above clinically safe ranges.

Aim 3 (Exploratory): Based on evidence of high rates of substance use and HIV infection in some transgender adolescents (specifically, young transgender women), we will **determine substance use and sexual risk behavior over time**. *A priori* hypotheses regarding the impact of hormone treatment on sexual and substance use behaviors cannot be specified given that these behaviors increase through adolescence.

This multi-center study will be the **first in the U.S.** to evaluate longitudinal outcomes of medical treatment for transgender youth, and it will provide highly needed evidence-based data on the physiological and psychosocial effects and safety of treatments currently used for transgender youth.

A. SIGNIFICANCE

A1. Transgender Youth are an Underserved, Understudied Population

Transgender adolescents and children, those who experience incongruence between assigned birth sex and internal gender identity, are a poorly understood and understudied population in the United States. As detailed in the May 2011 Institute of Medicine (IOM)[1] report, "The Health of Lesbian, Gay, Bisexual, and Transgender People," the existing body of scientific evidence documenting health and well-being of transgender individuals is sparse. The report explicitly calls for NIH-supported research on transgender health needs, including the development of evidence-based data for providing transgender-specific health care to address gender dysphoria and rigorous research aimed at understanding the health implications of hormone use and other transgender-specific issues. In addition, the IOM report calls for longitudinal and cohort studies that incorporate a life course perspective to examine the specific experiences of transgender individuals across different chronological ages.

Research on transgender youth has historically focused on the disproportionate morbidity and mortality among transgender individuals in comparison to the population at large. One study of 55 transgender youth in New York City reported that 45% had seriously thought about suicide, and 26% had attempted suicide at least once, indicating that transgender youth specifically are at increased risk for **anxiety, depression, social isolation, and suicide** compared to non-transgender peers.[2-4] Our recent pilot study with a cohort of 70 multi-ethnic transgender youth at Children's Hospital Los Angeles (CHLA), the lead agency for the proposed study, supports these numbers, with 52% participants reporting thoughts of suicide and 30% reporting having attempted suicide at least once. Without appropriate care, as they age, transgender youth are likely to face economic and societal marginalization, incarceration, and physical abuse leaving them at significantly higher risk for drug abuse, violence, HIV acquisition, other sexual transmitted infections, and homelessness.[2,4-6]

A2. The "Dutch Model"

Over the past 30 years, a team of specialists in the Netherlands at the Amsterdam Center of Expertise on Gender Dysphoria observed that transgender individuals who underwent hormonal gender transition at earlier ages assimilated easier into their "new gender" roles because of improved physical outcomes.[7] Additionally, transgender youth suffering through an undesired endogenous puberty experience distress, and this "wrong puberty" has a strong negative impact on their emotional, academic, and family functioning.[7,8] Based on these clinical observations, Dutch clinician investigators initiated early treatment of transgender youth aimed at suppressing undesired puberty with gonadotropin-releasing hormone agonists (GnRHa's). GnRHa's have previously been used as the primary strategy for the suppression of puberty in children experiencing precocious puberty.[9] Early results from the first 70 gender dysphoric youth undergoing puberty suppression with GnRHa's in the Netherlands showed a decrease in behavioral and emotional problems, as well as a decrease in depressive symptoms. Improved general functioning for these youth was also reported.[10] By blocking the progression of puberty, the distress associated with full development of adult sexual characteristics incongruent with an internal gender identity is prevented.[11] A single study examining the physiologic impact of puberty suppression with GnRHa's reported that the first 21 patients undergoing this treatment had adequate suppression of their pituitary gonadal axis and no progression of their endogenous puberty. While on GnRHa's, height standard deviation scores decreased, and bone density remained in the same range for patients experiencing suppression. Compared to age-matched peers, bone density z-scores went down while patients were being suppressed.[11] In 2006, the "Dutch Model" was introduced, outlining this new approach to the care of transgender youth. Gender dysphoric adolescents 12 years and older are given GnRHa's to prevent (or minimize in those already undergoing puberty) the development of undesired secondary sexual characteristics. For youth on GnRHa's who continue to experience gender dysphoria through adolescence, appropriate cross-sex hormones (estrogen for the development of female characteristics and testosterone for the development of male characteristics) are added to the regimen to feminize or masculinize accordingly. The Dutch model recommends the addition of cross-sex hormones to allow the body to be brought into closer alignment with the identified internal gender when youth reach age 16. *[A recent follow up study from the Dutch team examining the impact of puberty suppression followed by cross sex hormones and gender reassignment surgery in 55 transgender young adults showed alleviation of gender dysphoria and steady improvement of psychological functioning.]*[12]

One important limitation of the Dutch model is the chronological age criterion that requires gender dysphoric children be at least age 12 before initiating suppression of puberty; however, by that age, it is well documented that many children in the United States are already well into their puberty.[13,14] In 2010, Biro et al. reported that across three metropolitan areas of the U.S., 42.1% of girls had Tanner 2 breast development by the age of

eight years.[15] Relying on this chronological age criterion rather than sexual developmental stage decreases early intervention potential and may increase risk for negative mental health outcomes. Additionally, only a few studies describe the physiological[11] and psychosocial impact of this treatment protocol for puberty suppression.[10] Finally, the recommendations from the Dutch model are based on data collected from a homogenous population of white, European youth living in relatively supportive environments and are not necessarily generalizable to multi-ethnic transgender youth in the U.S.

A3. The Endocrine Society Clinical Practice Guidelines

In 2009, using the best available evidence, the Endocrine Society incorporated the Dutch model into the clinical guidelines "Endocrine Treatment of Transsexual Persons," which includes recommendations for treatment of transgender youth.[16] In contrast to the Dutch model, the Endocrine Society recommends starting treatment with GnRHa's for puberty suppression based on sexual development (Tanner staging) rather than chronological age. These guidelines recommend puberty blocking medications for youth with gender dysphoria at the beginning stages of puberty (Tanner stage 2 or 3), followed by appropriate cross-sex hormone therapy at around age 16. Since the introduction of these guidelines, **no data have been collected in the U.S. on the physiologic and mental health impact, safety, or tolerability of pubertal-blocking medical interventions with GnRHa's for transgender youth, particularly in children younger than age 12**, leaving a gap in the evidence for this practice. Furthermore, the impact of GnRHa's on the bone health of transgender children, specifically in those younger than 12 years, remains unknown. **This study will investigate the physiologic and mental health impact of GnRHa administration as well as document the safety of GnRHa's in a large cohort of transgender children and adolescents in the early stages of puberty.**

The Endocrine Society Clinical Practice Guidelines include recommendations to initiate cross-sex hormones for gender dysphoric, late pubertal adolescents at around the age of 16. For those youth who are on GnRHa's, cross-sex hormones are added to the regimen. For those new to clinical care, cross-sex hormones are prescribed without GnRHa's, a protocol commonly used in both adolescents and adults. Studies in adult transgender populations have reported on the physiologic impact of cross-sex hormones,[17-19] but no studies to date have detailed the physiological impact of cross-sex hormone administration in transgender adolescents. **This study will investigate both the physiologic and the mental health impact of cross-sex hormone administration as well as document the safety of cross-sex hormones in transgender adolescents in the later stages of puberty.**

A4. Contribution of the Proposed Work

The lack of data supporting medical interventions for transgender youth combined with a shortage of providers knowledgeable in the complex psychosocial risk factors facing these young people contributes to a health disparity and public health crisis of considerable magnitude. The proposed investigation is highly significant in scope as it is the first longitudinal study collecting data - assessing both physiologic and mental health outcomes - to evaluate commonly used clinical guidelines for transgender youth in the U.S. In addition, we propose to do this work in four geographically distinct sites, in part because of the relative rarity of these conditions and also to increase the generalizability of the work. Results from this study have the potential to significantly impact the medical and mental health services provided to transgender youth in the U.S. by making available rigorous scientific evidence outlining the impact and safety of early treatment based on sexual development stage.

B. INNOVATION: The proposed study is innovative in the following ways:

B1. Creation of a National Network of Gender Centers to Study Treatment Outcomes of the Endocrine Society Clinical Practice Guidelines for Transgender Children and Adolescents

There are providers scattered around the U.S. (and the world) utilizing the Endocrine Society Clinical Practice Guidelines, but there are no formal empirical studies of related clinical outcomes in transgender children and adolescents. This application proposes to create a network of four academic hospitals (i.e., Children's Hospital Los Angeles/University of Southern California, Boston Children's Hospital, Lurie Children's Hospital of Chicago/Northwestern University, and the Benioff Children's Hospital/University of California San Francisco) strategically situated across the country with strong histories of clinical service in this area to investigate the impact of the treatment on multi-ethnic transgender youth. All four sites have dedicated transgender youth clinics, employ a similar model of care that includes medical and mental health professionals, and are considered the national leaders in the care of transgender children and adolescents. The involvement of these four sites provides the experience, expertise, and clinic populations for a research endeavor of this magnitude and importance. In addition to the significant combined clinical experience of these four sites, all of the sites have strong and deep-rooted ties to academic research.

B2. The Clinical Sites Provide Services to Diverse, Multiethnic, Transgender Children and Adolescents Across the Developmental Stages Targeted for this Study

Available data about the impact of the recommended treatment protocols come from a primarily white, European cohort in the Netherlands. This study proposes examining the impact of treatment on diverse, multiethnic, transgender youth more representative of the U.S. population.

B3. This Study Targets an Early Pubertal Cohort, as Recommended by Clinical Practice Guidelines

Avoiding the development of undesired secondary sexual characteristics by starting puberty suppression at the earliest stages of puberty is recommended in the Endocrine Society Clinical Practice Guidelines, but has never been comprehensively studied in the U.S. and has never been studied in children under the age of 12 years. This study proposes to enroll transgender children eight years or older in the earliest stages of puberty to start treatment with GnRH agonists for puberty suppression, which will provide a critically important extension to the base of empirical knowledge about treatment outcomes.

B4. Early Initiation of Cross-sex Hormone Therapy in Transgender Adolescents

Despite the knowledge that transgender identity is stable by the time youth reach adolescence,[7] The Endocrine Society Clinical Practice Guidelines recommend introducing cross-sex hormones "around" the age of 16. This study proposes to evaluate the effects and document the tolerability and safety of cross-sex hormones in youth in Tanner stages 4 and 5, including those younger than 16 years. While it is common for this team of experts to initiate cross-sex hormone therapy in transgender youth younger than age 16, there are no available data on this younger population.

B5. Groundwork for Future Investigation

The development of this four-site network with the capacity to enroll hundreds of transgender children and adolescents in clinical research paves the way for ongoing longitudinal investigation of this unique population as they age into adulthood. Clinical trials investigating best practices on hormone regimens, optimizing growth, predicting persistence of gender incongruence from childhood into adolescence, identifying resiliency factors, and investigating treatment as prevention from HIV acquisition are just a few of the future research endeavors that will be possible with the existence of this new network. *[The investigators acknowledge it is highly likely that cultural values and beliefs impact families' decision-making around seeking treatment for gender dysphoria. Although the specific study of cultural differences that impact decision-making around care are beyond the scope of what is proposed herein, it is the PI's intent to attune to these issues as they arise and develop sub-studies that the four city network is well poised to undertake.]*

B6. Summary of Innovation

This longitudinal, observational study proposes to collect critical data on the existing models of care for transgender youth that have been commonly used in clinical settings for close to a decade, although with very limited empirical research to support them. The gap in existing knowledge about the impact of these practices leaves providers and caretakers uncertain about moving forward with the recommended medical interventions for transgender youth seeking phenotypic transition. The proposed research is a direct response to the IOM report calling for such studies, as well as the needs of clinicians and patients. **The findings from this research have the capacity to substantially expand treatment across the country by providing rigorous evidence to demonstrate the benefits of early treatment and ultimately decrease the health disparity currently existing for transgender youth.**

C. APPROACH

C1. Study Objectives

The primary objective of this observational, longitudinal, multicenter study is to investigate the impact of medical treatments for gender dysphoria in two developmental and multi-ethnic cohorts of transgender youth recruited from across the nation via a network of Gender Centers dedicated to their care (Children's Hospital Los Angeles/University of Southern California, Boston Children's Hospital, Lurie Children's Hospital of Chicago/Northwestern University, and the Benioff Children's Hospital/University of California San Francisco). The proposed project aligns with the objectives outlined by the Institute of Medicine in "The Health of Lesbian, Gay, Bisexual, and Transgender People." Long-term follow-up on this ethnically diverse population is critical for generating the scientific evidence required to maximize treatment protocols and generate standards of care for the U.S. Results for this study are sorely needed to expand the body of evidence-based knowledge surrounding the practice of puberty suppression and cross-sex hormone use in adolescence and constitute the basis for further follow-up of these cohorts.

C2. Study Sites/Preliminary Data

Dr. Johanna Olson (Pediatrics and Adolescent Medicine) is the Medical Director for the Center for Transyouth Health and Development and PI at CHLA/USC. The Center has provided transgender youth care services for over 20 years and currently has 335 transgender youth in active care. Each month, this site enrolls 8-10 new transgender youth in services at the Center. **Dr. Norman Spack** (Pediatric Endocrinology) is the Medical Director of the Gender Management Service (GeMS) and is the PI at Boston Children's Hospital. GeMS was the first pediatric academic program in the Western Hemisphere to treat early adolescents with gender dysphoria. GeMS provides clinical services for 75 transgender youth and enrolls two new patients into care each month. **Dr. Robert Garofalo** (Pediatrics and Adolescent Medicine) is Co-Director of the Gender and Sex Development Program and the PI for Lurie Children's Hospital of Chicago/ Northwestern University. He has considerable experience leading and working on NIH-funded research and has been providing clinical services for transgender youth for more than a decade. The program currently has over 125 gender non-conforming children and transgender adolescents in care and on average enrolls 3-5 new patients each month. **Dr. Stephen M. Rosenthal** (Pediatric Endocrinology) is the Medical Director of the Child and Adolescent Gender Center (CAGC) and the PI at Benioff Children's Hospital/UCSF. He has significant experience conducting multi-center trials and is currently site PI for NIH/NICHD Disorders of Sex Development: Platform for Basic and Translational Research. The UCSF CAGC team has been providing multi-disciplinary care for gender non-conforming/transgender youth and adolescents for the past six years. Currently, the program has 125 youth in clinical services and is enrolling 8-10 new patients into care each month.

A pilot study funded by The Saban Research Institute conducted by Dr. Olson (CHLA) included 70 transgender youth between the ages of 12 and 24 years treated with cross-sex hormones for gender transition. Of the youth approached to participate, 99% agreed to take part in this study. The initial baseline data from this cohort confirmed high rates of suicidal ideation, suicide attempts, and drug use in this population. Fifty-four percent of participants reported thinking about suicide, and 33% had attempted suicide at least once in their lives. These numbers are three and four times higher, respectively, than the rates for general youth reported in the Youth Risk Behavior Survey (YRBS) data in 2011.[20] The majority of participants reported using alcohol, tobacco, and cannabis (78.5%, 68%, and 68% respectively). Six of the youth reported trading sex for money, food, drugs, or a place to live (survival sex). These results underscore that transgender youth remain at high risk for psychosocial morbidity. This initial pilot study, funded via a short term clinical research career development award, does not allow for longitudinal follow-up of the cohort. Additionally, this pilot cohort was primarily Caucasian and Latino/a. In order to better inform current guidelines and clinical care, the proposed project intends to include a more geographically and ethnically diverse sample; will collect expanded information about baseline mental health, comprehensive anthropometrics, and physiologic and metabolic parameters; and report follow-up results and changes over longer periods of time after treatment is initiated.

C3. Study Design

The study has a longitudinal observational design for both the early pubertal and late pubertal cohorts. *[Comparing a treated vs. an untreated control group would be the ideal mechanism to study the impact of existing recommendations for care of transgender youth, including administration of GnRHa's for younger youth and cross sex hormones for older youth. However, the current standards of care from the Endocrine Society and the World Professional Association of Transgender Health (WPATH) were both developed from a panel of scientific experts and a consensus-building process based largely upon clinical experience and the existing minimal, predominantly non-U.S. body of research, and each supports the positive impact of intervention and the negative impact of no intervention. Proceeding through an undesired puberty without treatment causes distress for transgender youth. Thus, an untreated control group does not represent a "neutral" option, but in actuality places transgender youth at risk for negative health outcomes. Inclusion of a non-intervention control group or any control group as part of a traditional randomized trial would be both impractical and unethical. Letters of support regarding our cohort design from both the Endocrine Society and WPATH are included in Appendix A. The study does include collecting longitudinal outcome data from what might be considered a "natural control" – those gender nonconforming youth who meet diagnostic criteria and get offered GnRHa's for suppression but who elect or refuse treatment as part of the informed consent process. In a small, but not rare, number of cases, parents and/or the children may elect under certain circumstances (e.g. cost, fears given a lack of scientific evidence, etc.) to not initiate pubertal suppression. For this cohort, we propose enrolling these patients and collecting and capturing outcome data for comparison along the same visit schedule as our treated cohort. In addition, as part of our original study design we will collect data on age and Tanner staging to be able to examine if early vs. delayed treatment in these young*

people affects health outcomes.] The anthropometric and physiologic parameters in the study are those routinely collected within the constructs of the clinical visit at each site. Audio computer-assisted self-interviewing (ACASI) survey instruments will be used to collect demographic, mental health, psychosocial, and behavioral data from 1) early pubertal cohort youth and their parent/caretaker and 2) late pubertal youth.

Youth participants will be recruited from patients seeking care at any of the four study sites. Because presentation of gender dysphoric youth in Tanner stage 2 or 3 is less common than presentation in later Tanner stages, we will enroll 88 youth in the early pubertal cohort, which allows for 10% anticipated attrition across the follow-up assessments. In the late pubertal cohort, 240 participants will be enrolled, which takes into account an expected 20% attrition across follow-up assessments in order to obtain a sample of 200 participants. While patients between 8 and 21 years old will be eligible for enrollment in one or the other cohorts depending on their Tanner staging, the focus of this investigation is *early treatment.* Therefore, we will not enroll more than 20% of youth age 19 or older in the late pubertal cohort. We will aim to enroll equal numbers of each gender for both cohorts. Clinical observation indicates that equal number of girls and boys seek care for gender dysphoria in the specialty clinics; thus, we do not anticipate overrepresentation of either gender.

C4. Early Pubertal Cohort

C4a. Early Pubertal Cohort - Study Enrollment and Inclusion/Exclusion Criteria

The early pubertal cohort will be recruited from those youth in early stages of puberty presenting for care at any of the four sites along with their parent/primary caretaker. Transgender children and adolescents in the first stages of pubertal development will be screened by the primary medical provider at each site for participation in the study with the following criteria:

Inclusion criteria: 1) gender dysphoria as defined by DSM-V;[21] 2) Tanner stage 2 or 3 of sexual development; 3) desire to undergo puberty suppression; and 4) *[ability to read and understand English or Spanish.]* Parent/Caretaker inclusion criteria includes reading and understanding English or Spanish.

Exclusion criteria: 1) prior utilization of GnRHa's; 2) precocious puberty (natal males younger than 9 years or natal females younger than 8 years); or 3) pre-existing osteoporosis.

Youth who meet inclusion criteria will provide assent, and their parent/caretaker will provide informed consent for participation in the study. (For consent forms, see Appendix B: Consent Forms.)

C4b. Early Pubertal Cohort: Treatment Plan and Data Collection

Medications used in the course of this study are the standard of care for puberty suppression at the four study sites and include the GnRHa's leuprolide acetate and histrelin acetate. The study will not influence prescription patterns among the clinical providers. Decisions about GnRHa dosing will be individually determined based on subjects' adequate and appropriate response to medications, as well as tolerability of side effects. Patients who experience intolerable side effects will have medication adjustments made according to the discretion of the medical provider at the site where they are receiving care.

*[**Demographic data** including age, ethnicity, religion, educational level, relationship to child (biological parent, adoptive parent) and birth city/country];* **anthropometric measures,** including height, weight, BMI, sitting height, and Tanner stage; **physiologic parameters,** including fasting lipids and glucose, blood pressure, liver enzymes, electrolytes, and glycosylated hemoglobin; and **hormone levels** used to assess adequate pubertal suppression, including ultrasensitive luteinizing hormone and estradiol or testosterone based on gender, will be collected at baseline (T0) and at 6 months (T1), 12 months (T2), and 24 months (T3) following initiation of GnRHa treatment. **Measures related to bone health,** including bone mineral density (BMD), bone age, 25-hydroxy vitamin D, calcium, phosphate, and serum bone-specific alkaline phosphatase, will be collected at baseline and at 12 months and 24 months following initiation of GnRHa treatment.

Psychosocial ACASI Assessments

The life course approach highlights the importance of adolescence as a developmental stage in which self-identity formation and validation are crucial tasks that affect the remainder of adulthood.[22] Careful attention was given to choosing age-appropriate standardized measures with strong reliability for each construct. The use of the life course approach to our choice of psychosocial assessments dictates a focus on contextual variables that will strengthen our understanding of risk and resilience within our cohorts. These measures include the experience of life stressors and traumatic events, parental and peer relationships, and quality of life. While we will use the standardized instruments described in Table 1, we will also add events and experiences specific to the age range of our respondents, based on our teams' experiences as physicians and psychologists treating these youth, as well as information from youth and their parents. Table 1 lists the

measures, the intended respondent: Parent (P), Child (C), or both (P/C), the number of items (#), and the Cronbach alpha value. The measures in the ACASI survey fall into four domains: 1) demographic 2) transgender-specific experiences including gender dysphoria, 3) mental health and trauma assessments, and 4) additional psychosocial information including quality of life and relationships with parents and peers. ACASI survey instruments for youth and for parent/caretaker will be administered at the initial visit (T0) and 6 months (T1), 12 months (T2), and 24 months (T3) following initiation of GnRHa treatment (Table 2).

Table 1. ACASI Survey Instruments: Early Pubertal Cohort

Construct	Scale	#	α
Parent/Caretaker Survey			
Demographics	As described above	--	--
Gender Identity	Parent Report Gender Identity Questionnaire[23]	14	--
Social Transitioning	Social Transitioning Scale[24]	8	--
Trauma symptoms	Trauma Symptom Checklist: Young Children[25]	20	.81-.88
Child Anxiety	Screen for Child Anxiety Related Disorders [26]	41	.78-.90
Child's Life events	Life Incidence of Traumatic Events [27]	16	--
Child's Resilience	Strengths & Difficulties[28]	25	.76
Child Survey			
Gender Identity			
Body Esteem	Revised Body Esteem 8-10.5[29]	20	.73-.77
Body Image	Body Image Scale[30]	30	
Anxiety	Screen for Child Anxiety Related Disorders[26]	41	.78-.90
Depression	Beck Depression Inventory[31] Youth (7-12)	20	
Self injury/Suicide	Suicide and self-harm[32]	6	--
Quality of Life	Health-related Quality of Life in Children (KINDL)[33]		
Peer relationships	Harter Social Competence[34]		

Parent/Caretaker ACASI Instrument

Transgender experience will be assessed as child gender identity, child's age of realization of transgender status, child's age of first living in the desired gender role, domains where the child is living in their desired gender role, social transitioning, parental/guardian support, and disclosure of child's transgender status to others. Mental health and trauma assessments include parent reports of child's anxiety, child's experience of trauma and trauma symptoms (including those associated with impending or beginning pubertal development), child's suicide (ideation and attempts), and self-harm. Additional psychosocial measures include child's quality of life and child's strengths and difficulties.

Child ACASI Instrument

Transgender experience includes age of realization of transgender status, social transitioning, gender identity, and gender dysphoria. Additional measures will assess body esteem and body image. Mental health assessments will include anxiety, depression, suicide (ideation and attempts), and self-harm. Additional psychosocial measures include peer relationships. (See Appendix C: Transgender Specific Measures – Early Pubertal Cohort.)

Table 2. Data Collection Schedule – Early Pubertal Cohort

Measure	T0 (Baseline)	T1 (6 mo)	T2 (12 mo)	T3 (24 mo)
Anthropometric Measures - height, weight, BMI, sitting height, and Tanner stage	X	X	X	X
Physiologic Parameters - fasting lipids and glucose, blood pressure, liver enzymes, electrolytes, prolactin level, and glycosylated hemoglobin	X	X	X	X
Hormone Levels - luteinizing hormone via ultrasensitive assay, and estradiol or testosterone via ultrasensitive assay based on gender	X	X	X	X
Measures of Bone Health - Bone mineral density (BMD), bone age, 25-hydroxy vitamin D, calcium, phosphate, and serum bone-specific alkaline phosphatase	X		X	X
Parent/Caretaker and Child Demographic, Transgender Experience, and Psychosocial ACASI - (see Table 1)	X	X	X	X

C5. Late Pubertal Cohort

C5a. Late Pubertal Cohort - Study Enrollment and Inclusion/Exclusion Criteria

Transgender adolescents in later stages of puberty (Tanner stage 4 or 5) seeking medical treatment for the purpose of phenotypic gender transition at any of the four sites will be screened by the primary medical provider at each site for participation in the study with the following criteria:

Inclusion criteria: 1) the presence of gender dysphoria as defined by the DSM-V;[21] 2) Tanner stage 4 or 5 of sexual development; 3) interested in pursuing a phenotypic gender change with cross-sex hormones; and 4) *[ability to read and understand English or Spanish.]*

Exclusion criteria: 1) <13 or >21 years old or 2) prior utilization of cross-sex hormones. Youth who are under the age of 18 will provide assent for participation, and their parents/legal guardian will provide consent. Youth age 18 or older will provide consent for participation. (For consent forms, see Appendix B: Consent Forms.)

C5b. Late Pubertal Cohort: Treatment Plan and Data Collection

Medications used in the course of this study (i.e., feminizing agents for transgender females and masculinizing agents for transgender males) are the standard of care at the four study sites. As the study is observational, it will not influence prescription patterns among the clinical providers. Decisions about medication doses are individually determined based on adequate and appropriate response to medications, as well as tolerability of side effects. Feminizing medications include oral, transdermal, or intramuscular 17B-estradiol. Spironolactone, commonly used to suppress testosterone synthesis and action in natal males, is often used in combination with estradiol to further assist in feminization. Medroxyprogesterone is occasionally used in patients to further breast development. Masculinization medications include injectable or transdermal testosterone esters. Data on specific hormone type and dosing will be collected to evaluate differences as part of the analysis.

*[**Demographic data** including age, ethnicity, race, religion, sexual orientation educational level and birth city/country];* **anthropometric measures** including height, weight, BMI, and Tanner stage and **physiologic parameters** including fasting lipids and glucose, blood pressure, liver enzymes, electrolytes, prolactin level, hemoglobin, glycosylated hemoglobin and hormone levels will be collected at baseline (T0) and 6 months (T1), 12 months (T2), and 24 months (T3) following initiation of treatment with cross-sex hormones.

Psychosocial ACASI Assessments

As mentioned above, the life course approach highlights the importance of adolescence as a developmental stage in which self-identity formation and validation are crucial tasks as well as the importance of social environments.[22] Age-appropriate standardized measures with strong reliability were chosen wherever possible. As with the younger cohort, we will add events and experiences specific to the age range of our respondents, based on our teams' experience as well as information from youth themselves. Table 3 lists the measures chosen for the late pubertal cohort, the number (#) of items, and the Cronbach's alpha value. Our choice of measures to use in the ACASI survey fall into five domains: 1) demographics; 2) transgender-specific experiences including gender dysphoria; 3) mental health and trauma assessments; 4) additional psychosocial information including quality of life and relationships with parents and peers; and 5) behavior risk including alcohol/drug use, sex work and high-risk sexual activities.

Table 3. ACASI Survey Instruments: Late Pubertal Cohort

Construct	Scale	#	α
Transitioning	Transitioning Scale	8	--
Gender Dysphoria	The Gender Identity/Gender Dysphoria Questionnaire for Adolescents and Adults[35]	12	.74-.86
Body Esteem	Body Esteem[36]	30	.81-.94
Body Image	Body Image Scale[30]	30	
Depression	BDI II (Adolescent)[37]	21	.90
Anxiety	Manifest Anxiety Scale[38]	36	.91
Trauma Symptoms	Trauma Symptom Checklist[39]	17	--
Life events	Life Events Checklist[40]	21	--
Self Injury/Suicide	Suicide and Self-Harm[32]	6	--
Quality of Life	Health-related Quality of Life[41]	17	.74-.82
Stress/Connectedness	Gender Minority Stress[42]	55	.71-.93
Social Support	Multi-Dimensional Social Support [43]	12	.92
Drug Use	Alcohol, Smoking, and Substance Involvement Screening Test[44]	48	--
Sexual Risk	Adolescent Sexual Activity Index[45]	13	--

Transgender experience questions will include gender identity (age of realization of transgender status), transitioning (age of first transitioning or "real life experience" in the desired gender role), gender dysphoria, previous hormone use, and length of treatment. Additional measures will assess body esteem, and body image, Mental health and trauma assessments will include depression, anxiety, experience of trauma and trauma symptoms (including those associated with being transgender), suicide (ideation and attempts) and self-harm. Additional psychosocial measures include quality of life, social support from peers and family. In addition, stress will be captured by the Life Events and Gender Minority Stress Scales, including additions specific to transgender experience. (See Appendix D: Transgender Specific Measures - Late Pubertal Cohort). Behavioral risk will include assessment of drug use and sexual activity, including high-risk sexual behavior such as sex work.

Table 4. Data Collection Schedule – Late Pubertal Cohort

Measure	T0 (Baseline)	T1 (6 mo)	T2 (12 mo)	T3 (24 mo)
Anthropometric Measures - height, weight, BMI, and Tanner stage	X	X	X	X
Physiologic Parameters - fasting lipids and glucose, blood pressure, liver enzymes, electrolytes, prolactin level, hemoglobin, glycosylated hemoglobin, estradiol, and free and total testosterone	X	X	X	X
Demographic, Transgender Experience, Psychosocial, and Behavioral Risk ACASI - see Table 3	X	X	X	X

C6. Data Management

The PIs from the four sites will collaborate with relevant Co-Investigators to create and finalize a cross-site study implementation protocol for each site to carry out the project in a consistent manner. The data coordination staff, housed at CHLA, will support all PIs with the generation of a cross-site protocol for data collection and templates for the Institutional Review Boards at each site. The final data collection instruments, vetted by each site PI/Co-I, will be programmed into the ACASI software by core staff. Programming will be overseen and ACASI logic (skip patterns, etc.) will be tested by Dr. Schrager. Once piloted by core staff, computers for each site will be loaded with survey data collection and data housing software. In the event of changes to future surveys, the study core will release updated survey versions and instructions for loading onto site computers to the study coordinator at each site.

Data will be collected systematically at each site using identical operating procedures, including case report forms (CRFs) for abstracting physiological parameters from medical chart data, ACASI programming, and data flow sheets to facilitate the creation of a data repository that is suitable for analysis and available for all four sites to explore. The data will be owned equally by each of the four participating sites. Data will be stored at each site and transferred to CHLA. Study-wide data management procedures, including integration and verification of multi-site data, will take place at CHLA under the direction of Dr. Schrager (CHLA Co-I).

The data manager at the coordinating site will be responsible for ensuring that site data are safely transferred via secure protocols to CHLA for cleaning and merging. The data manager will generate tracking reports regarding the accrual of participants at each site, as well as specific characteristics of the emerging cross-site data file (such as balance of male and female transgender respondents, respondent ages or age categories, etc.). The data manager will work with site staff to facilitate the receipt of data, provide technical assistance as necessary, and meet regularly via telephone with the staff person responsible for site-specific quality assurance. In addition, the data manager will manage the overall dataset, merging elements, cleaning data, creating composite variables and scales, and running descriptive statistics such as characteristics of subjects for the entire sample (male v. female, other demographics, etc.) for the larger study group.

Cleaned and coded data from all four sites, including scored measures and created scales, will be made readily available to all PIs. To meet NIH obligations for data sharing, other investigators not affiliated with the study will also be able to access de-identified study data pursuant to a signed Data Use Agreement. The core staff will be responsible for maintaining Data Use Agreement records and secure transmission of data to outside investigators.

C7. Analytical Plan and Power Analysis

C7a. General Analytical Framework for Aims 1 and 2

The analysis plan of categorical and continuous variables consists of the following: descriptive analyses; psychometric analyses of scales; and use of generalized linear models to evaluate study hypotheses (including, but not limited to multiple linear and logistic regression, path analyses, and structural equation

modeling). SPSS (version 22) and Mplus (version 7.11) will be used for data management and all preliminary and formal hypothesis-testing analyses. Prior to beginning hypothesis testing, we will undertake the following activities with all waves of psychological and physiological data from both cohorts.

C7b. Data Checking, Cleaning, and Management

Procedures to clean and screen the survey data will include univariate analyses (e.g., mean, standard deviation, plausible range and value, skewness, and kurtosis), patterns of correlation and covariance, and checks for multicollinearity and singularity of variables. These procedures will facilitate the identification of multivariate outliers and check assumptions of multivariate normality (e.g., normal distribution, linearity, and homoscedasticity). Transformation of variables (e.g., log transformation) will be conducted as needed to reduce the effects of valid outliers or violations of multivariate normality. Univariate statistics will be used to broadly examine the characteristics of the sample, including demographics, mental health, physiological parameters, substance use, and other risk behaviors (e.g., sexual risk), social support, and parental measures for the early puberty cohort. Bivariate analyses (e.g., correlation analyses) will examine relationships among variables of interest and identify potential covariates for inclusion in later multivariate models. Data reduction techniques such as factor analysis will be used to identify and/or verify scale structure of constructs of interest. Scale scores will be created as means or sums of unweighted composite scores or composite scores weighted by factor loadings, as appropriate. Confirmatory factor analysis will be considered for evaluating the stability of composite scores over time. Psychometric properties (e.g., Cronbach's alpha) of all scale measures will be evaluated at each assessment time point.

Following these preliminary analyses, formal hypothesis testing to address **Specific Aims 1 (early pubertal youth) and 2 (late pubertal youth)** will proceed as follows:

Effects of Hormonal Interventions on Mental Health and Psychological Well-Being

Hypothesis 1a: Patients treated with GnRHa's will exhibit decreased symptoms of gender dysphoria, depression, anxiety, trauma symptoms, self-injury, and suicidality and increased body esteem and quality of life over time.

Hypothesis 2a: Patients treated with cross-sex hormones will exhibit decreased symptoms of anxiety and depression, gender dysphoria, self-injury, trauma symptoms, and suicidality and increased body esteem and quality of life over time.

Hypotheses 1a and 2a will be tested in the early-puberty and late-puberty cohorts, respectively, using repeated measures multivariate analysis of variance (MANOVA) to assess the trajectories of continuous mental health outcomes and psychological well-being over time within each cohort. The MANOVA approach will preserve statistical power to detect significant effects among this set of related continuous outcomes without the inflated Type I error rates associated with a series of individual ANOVA or regression analyses. The MANOVA analyses will investigate the changes over time in gender dysphoria, depression, anxiety, trauma symptoms, self-injury, suicidality, body esteem, and quality of life. The model will incorporate time (i.e., measurement time point: baseline, 6-month, 12-month, or 24-month survey) as a within-subjects factor. Asserted gender, age, ethnicity, and other socio-demographic variables may additionally be entered as possible covariates (i.e., ANCOVA) to improve statistical power to detect significant time effects. However, we do not propose any *a priori* hypotheses about demographic effects on these outcomes, and any demographic variables that do not contribute significantly to the model will be removed from the analysis in order to preserve power and increase model parsimony.

In keeping with conventional practice, analysis will first proceed with a review of Box's test for the equality of covariance matrices. Violations of this assumption would require the use of Pillai's trace, as opposed to Wilks' Lambda, to determine multivariate statistical significance. If, as hypothesized, the within-subjects time variable demonstrates significant multivariate effects, the follow-up univariate results will be inspected as appropriate. The assumption of sphericity via Mauchly's test will be checked for each measured outcome; if sphericity is violated, the Huyhn-Feldt correction for degrees of freedom will be applied to that outcome. Finally, for outcomes showing significant time effects, linear and quadratic contrasts will be checked for significance and marginal means will be computed and plotted to create a visual display of significant trajectories. An *a priori* p-value of 0.05 will be applied as the criterion for statistical significance in all analyses.

Safety of Hormonal Interventions

Hypothesis 1b: GnRH agonists are tolerable and safe for early-pubertal transgender youth, i.e., lipids, glucose, liver enzymes, electrolytes, insulin, and HgbA1c will not increase above clinically safe ranges.

Hypothesis 2b: Cross-sex hormones are tolerable and safe to use with late-pubertal transgender youth initiating phenotypic transition, i.e., will not increase lipids, glucose, liver enzymes, electrolytes, hemoglobin A1c and hemoglobin above clinically safe ranges.

Unlike the mental health and psychological well-being measures, the question of interest for these metabolic and physiological parameters is not whether they show significant fluctuation over time (which may or may not be meaningful), but rather whether development after initiation of hormonal interventions pushes any physiological indicator above the clinically safe range for that indicator, i.e., above predetermined safety cutoff values based on previous literature and clinical guidelines. Safety will be assessed cross-sectionally with one-sided one-sample t-tests comparing cohort mean scores to the cutoff value. We hypothesize that the cohort means will be significantly lower than the cutoff score. We will use the Benjamini-Hochberg procedure[46] to account for inflated family-wise alpha due to multiple comparisons at each time point.

Additionally, ranges of raw scores from all patient labs will be computed at each time point as part of the preliminary data cleaning and descriptive analysis phase. This will provide an immediate assessment whether the indicator value for any individual patient has crossed the safety threshold for that indicator as data are collected at each time point. In the event any patient experiences an individual increase in laboratory values above the threshold, medication adjustments will be made to protect the well-being of the patient according to the discretion of the medical provider at the site where they are receiving care regardless of the whole-cohort significance test results for that time point.

Bone Density in Early Pubertal Youth

Hypothesis 1c: Raw bone density scores will remain stable for early-pubertal transgender youth receiving GnRH agonists; however, age-matched z-scores may decrease.

We will use repeated measures ANOVA to estimate trajectories of raw and age-matched bone density scores over time in early pubertal youth. As before, asserted gender and socio-demographic variables may be entered as possible covariates, linear and quadratic contrasts will be assessed, and marginal means will be computed and plotted to create a visual display of trajectories for both outcomes. We hypothesize that for raw scores, the linear term will *not* differ significantly from zero, indicating net stability in bone density over time. However, for age-matched z-scores, the linear term may be negative as gender non-conforming youth receiving GnRH agonists fail to add bone density at a rate comparable to their age-matched peers.[11]

Risk Behavior in Late Pubertal Youth

Exploratory Aim 3: Based on evidence of high rates of substance use and HIV infection in some transgender adolescents, we will measure substance use and sexual risk behavior over time.

We will conduct an exploratory assessment of sexual risk and substance use behavior in the late pubertal cohort, using repeated measures MANOVA to model trajectories of these risk outcomes over time. As before, asserted gender and socio-demographic variables may be entered as possible covariates. Given that sexual risk and substance use behaviors increase during adolescence in normative samples, we do not specify *a priori* hypotheses regarding the impact of hormone treatment on these risk outcomes in our transgender population. However, linear and quadratic contrasts will be assessed. Significant positive terms (indicating increased risk over time) would be indicative of a typical adolescent risk trajectory, whereas significant negative terms (indicating decreasing engagement in risky behaviors) or non-significant time effects (suggesting no net change in risk) would instead support a "treatment-as-prevention" explanation. Again, Box's test will be reviewed for equality of covariance matrices and multivariate test statistic determined accordingly, and sphericity will be assessed via Mauchly's test with the Huyhn-Feldt correction applied as needed.

C7c. Additional Analytic Considerations: Site Clustering Effects

Although the proposed observational study will take place at four sites nationwide, we do not anticipate substantial site effects. To verify this, a group identifier for each participant will be included in the merged analytic dataset, and the intra-class correlation (ICC) for each outcome will be calculated prior to conducting multivariate analyses. If, as anticipated, no significant variance is carried at the group level, we will reduce the