DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health
Eunice Kennedy Shriver National Institute of Child Health and Human Development
Bethesda, Maryland 20892

July 22, 2020

The Honorable Michael S. Lee
United States Senate
Washington, DC 20510

Dear Senator Lee:

Thank you for writing to Alex M. Azar II, Secretary of Health and Human Services (HHS) regarding a study that was funded by the National Institutes of Health (NIH), R01 HD082554: *The Impact of Early Medical Treatment in Transgender Youth*. As the Director of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), the Institute within the NIH that supported this study, I have been asked to respond to your letter.

Congress has charged NIH with encouraging, as appropriate, efforts to improve research related to the health of sexual and gender minority populations. 42 U.S.C. § 283p. An important component of NICHD's scientific mission is to understand human development and enhance the health of children and adolescents. In recent years, the medical community and patient advocacy groups have identified significant gaps in the scientific evidence needed to inform medical decisions regarding the treatment of patients with gender dysphoria. NICHD issued Funding Opportunity Announcement (PA12-111) entitled, "Research on the Health of LGBTI Populations" to gather the scientific evidence necessary to address the health needs of these populations, and the study you reference was submitted in response to that announcement.

R01 HD082554 is an observational study. Observational studies are those in which researchers study the effects of an exposure or intervention but are not involved in the decision to have the intervention—those decisions are made by individuals with their health care providers. The main purpose of this observational study is to gather evidence on potential risks and benefits of hormonal treatment of transgender youth, in order to inform the treatment guidelines for such individuals. In this study, patients had already been referred to specialized clinics in endocrinology, often by their primary care physicians, to seek treatment for gender dysphoria. NIH funded this observational study, the first of its kind in the United States, to evaluate, through survey questionnaires, the long-term outcomes of medical treatments for transgender youth. Physicians at these academic centers follow guidelines that are considered the current standard-of-care for the therapy of transgender youth.[1] Independent of the administration of hormonal therapy, in which the NIH-sponsored research has no role, each transgender child and their parent/guardian are asked if they are willing to participate in the NIH-sponsored observational study and have study personnel follow their progress. If they agree, they are required to sign an assent/consent (child) and a consent/permission form (parent) that allows

[1] Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline J Clin Endocrinol Metab 2017 Nov 1;102(11):3869-3903. doi: 10.1210/jc.2017-01658.

study personnel to administer the survey questionnaires over a period of time. Participants each signed a consent (or assent), and their parents signed a consent (or permission) form, according to the enclosed Institutional Review Board- (IRB) approved protocol consent procedures.
It is important to note that all NIH-funded research is subject to rigorous review. Prior to award, this application received a highly meritorious score in the study section, which indicated that the scientific community considered that the proposed work would have a high impact on medicine and health. The application was also reviewed by NICHD's National Advisory Council. My predecessor at NICHD, Dr. Alan Guttmacher, made the final funding decision. To ensure that appropriate progress is being made and appropriate patient protections are in place, NICHD scientific staff have rigorously reviewed the progress on the grant each year. This grant ended on June 30, 2020. While NIH grantees are permitted to spend any remaining funds past the official end date, an automatic administrative procedure, the grantees have received no new grant award at present.

In response to your specific questions:

1. Please provide us with a citation for the statutory authority the NIH used to create and fund this study, as well as the NIH's justification for using these statute(s).

   Response: NIH's support for R01 HD082554 was provided under its general authority to conduct biomedical research, 42 U.S.C. § 284(b). In addition, NICHD is specifically charged with supporting research and training in child health under 42 U.S.C. § 285g. NIH is charged with encouraging efforts to improve research related to the health of sexual and gender minority populations under 42 U.S.C. § 283q.

2. Please provide us with a list of the taxpayer funding received by each of the four clinics, the specific projects they have been approved to conduct using the funds, the dollar amount each clinic as awarded for each project, and the timeframe over which the funding is available for each clinic to use.

   Response: This award includes funds awarded for consortium activity with the Boston Children's Hospital in the amount of $142,544 ($80,647 direct costs + $61,897 facilities and administrative costs).

   This award includes funds awarded for consortium activity with the Regents of the University of California at San Francisco in the amount of $198,119 ($124,996 direct costs + $73,123 facilities and administrative costs).

   This award includes funds awarded for consortium activity with the Ann and Robert H. Lurie Children's Hospital of Chicago in the amount of $136,781 ($91,187 direct costs + $45,594 facilities and administrative costs).

   R01 HD082554 was a five-year grant; however, funds are dispersed on an annual basis. As noted, the term of the grant ended on June 30, 2020. However, NIH grantees are permitted to spend any remaining funds up to a year past the official end date, and the official reporting of this grant now indicates that the funds associated with it will be expended through June 30, 2021.

3. Please provide us with the informed-consent policies used by each of the clinics that participated in the study, and whether those clinics in fact obtained adequate consent and assent from patients and their parents.

   Response: The informed consent documents used by each of the clinics participating in this study are enclosed. The families who participated in the study completed these forms prior to their participation.

4. Please provide us with evidence that the NIH received advance notification from the Children's Hospital of Los Angeles that it would be using grant funds from grant 1R01HD082554-01A1 to conduct a study that involved surgical operations.

   Response: The NIH-funded study is only an observational study. The performance of surgical procedures is not part of the study protocol and has not been funded by NIH. If, in the course of their care, participants underwent elective surgery, the questionnaires that are used in the NIH-funded study would capture details about their responses to the surgery, including physical and psychological health outcomes.

5. Please share what steps, if any, the NIH is taking to investigate the Children's Hospital of Los Angeles's use of grant funds for its study on Chest Reconstruction and Chest Dysphoria.

   Response: Since the NIH-study is only observational, none of the grant funds were used to provide medical treatments or surgery. Treatments were received, independent of the NIH study, from the participants' health care providers.

6. Please provide us with the total number of children under the age of 13 who participated in these studies at all four of the clinics that received NIH funds.

   Response: The total number of children under the age of 13 who participated in the NIH-funded observational study at all four clinics was 21, including five participants aged 11 years and 16 participants aged 12 years.

7. Please provide all correspondence between the NIH and all clinicians and clinics who have received funding through this grant, including all correspondence that occurred before the grant was awarded.

   Response: Participants each signed a consent (or assent), and their parents signed a consent (or permission) form, according to the enclosed IRB-approved protocol consent procedures. These consent forms are obtained by the research team for this study, distinct from any consent obtained by clinical providers for clinical care. Research participants and their parents sought and obtained the hormonal therapies as a component of their medical treatment, which was independent of the NIH-funded study. NIH does not have access to the correspondence regarding participants' medical treatment.

8. Please provide us with any plans the NIH has regarding Project Number 5R01HD082554-05 pursuant to the SGMRO's request for public comment on December 13, 2019 regarding the development of its strategic plan for Fiscal Years 2021-25.

   Response: Beginning in the summer of 2019, the Sexual and Gender Minority Research Office (SGMRO) engaged in a process to collect input from various stakeholders to inform the forthcoming FY 2021-FY 2025 NIH Strategic Plan to Advance Research on the Health and Well-being of Sexual and Gender Minorities. Overarching considerations in SGM health research also were identified. One of the overarching considerations highlighted in the strategic plan is the need for scientific inquiry into SGM health outcomes in subpopulations for which research is lacking. The need for further research to understand how an individual's innate sense of gender manifests, develops, stabilizes, and/or changes over time is also underscored. Individual research studies are not highlighted or recommended in the strategic plan.

NICHD funded this project only to collect long-term survey data needed to advance our scientific understanding of the risks and benefits of the treatments (hormonal therapy or surgery) that are now considered standard of care; NIH did not fund the treatments. As there are few studies to inform physicians about the care of transgender youth, these data are critical to understand the long-term impacts of such treatments on, and to improve the long-term health outcomes for, these young people. *Nature Reviews Endocrinology* has published a review[2] of this topic.

Thank you again for writing and for your continued interest in the research activities supported by NIH and NICHD. A similar response has been sent to the co-signers of your letter.

Sincerely,

Diana W. Bianchi M.D.

Diana W. Bianchi, M.D.
Director, NICHD

Enclosures

[2] Kreukels BP, Cohen-Kettenis PT. Puberty suppression in gender identity disorder: the Amsterdam experience. Nature Rev Endocrinol. 2011 May 17;7(8):466-72. doi: 10.1038/nrendo.2011.78. Review.