

CONCERNED
WOMEN *for* **AMERICA**
LEGISLATIVE ACTION COMMITTEE

**NIH Research Grants Studying Gender Transition Interventions
Fail to Protect Vulnerable Children from Irreversible Medical Harm**

Background

Since 2015, National Institutes for Health (NIH) extramural grants have been awarded to conduct gender-transition studies on children and youth starting as young as 8-years-old. This is the first grant of its kind giving puberty blockers and opposite-sex hormones to minors. It has opened a Pandora’s box to additional NIH research studies that are now underway. Instead of focusing on the risks or safety of the experimental use of these drugs on children, this project presumes their necessity and examines if earlier medical intervention might decrease other mental health issues within a 2-year timetable. As of 2021, this study has been renewed to evaluate and monitor the longer-term effects of puberty blockers and opposite-sex hormones on participants for up to four more years.

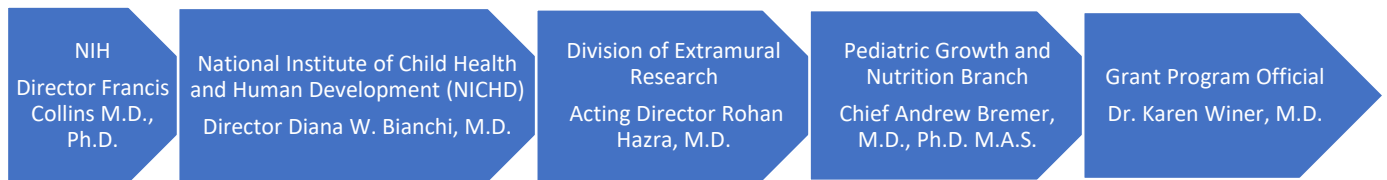
The NIH-funded project administers potent drugs to children in an off-label manner, including untested use of puberty blockers and dangerously high levels of opposite-sex hormones, causing severe and often permanent changes to their bodies. These impacts include irreversible physical and physiological changes, arrested bone and brain development, impaired sexual function, and even sterilization.

Studies show around 80%¹ of gender dysphoric children no longer wish to change genders after puberty; some studies put that number as high as 90%.^{2 3}

Instead of waiting to see if children outgrow gender dysphoria with appropriate compassion and perhaps psychological treatment, this agenda-driven project seeks to lower the age at which radical, irreversible medical interventions are implemented.

Children who receive puberty-blocking hormones followed by opposite-sex hormones are likely to be sterilized permanently.⁴

The Breakdown



Who: Under authority of the National Institutes of Health and above parties. Grantees led by Johanna Olson-Kennedy, M.D., Medical Director of The Center for Transyouth Health and Development; Keck School of Medicine of the University of Southern California (USC).

What: Project titled “[The Impact of Early Medical Treatment in Transgender Youth](#)”

Five-year extramural research grant totaling \$5.7 million. *Extended in 2021.*

NOTE: Additional NICHD active grants through 2019 totaled over \$1.5 million for the same four pediatric transgender clinics.

There are at least five more grants dealing with hormone protocols for gender dysphoric youth totaling an additional \$2.2 million in NIH funding and likely more in a six-page list of related NIH studies.^{5 6}

2021 Renewal: [2R01HD082554-06A1](#) Total additional funding for fiscal year 2021 was \$1,059,628, with most of the funding coming from NICHD and just over \$82,479 from NIMH. This funding is to aid in a renewal study that will evaluate the impacts these medical treatments have on participants for up to four additional years.

Where: Grants awarded to four pediatric transgender clinics at major research universities:

- Children’s Hospital Los Angeles and the Keck School of Medicine of the University of Southern California, Johanna Olson, MD- Principal Investigator/Project Lead⁷
- University of California San Francisco Benioff Children’s Hospital San Francisco, Stephen Rosenthal, MD⁸
- Ann & Robert H. Lurie Children’s Hospital of Chicago and Northwestern University Feinberg School of Medicine, Robert Garofalo, M.D., MPH⁹
- Boston Children’s Hospital and Harvard Medical School, Yee-Ming Chan, MD, PhD¹⁰

When: August 1, 2015 – June 30, 2020

Enrollment of youth participants from July 2016-September 2018

2021 Renewal: Project end date extended to January 31, 2026.

Why: “Ultimately we aim to understand if early medical intervention reduces the health disparities well known to disproportionately affect transgender individuals across their lifespan.”

Stated justification: Based on the Institute of Medicine 2011 study, “The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding,” recommending “a more rigorous research program is needed to understand the health implications of hormone use and other transgender-specific issues.”¹¹

NOTE: Study refers to opposite-sex hormones as “gender-affirming hormones.”

How: Study divided into two groups to examine how aggressive hormone intervention affects “mental health, psychological well-being, and metabolic and physiologic parameters.”¹¹ Both groups received baseline assessments with follow-ups at 6, 12, 18, and 24-months.

First Group: Puberty blockers for 90 pre-pubescent children.

- 51% male, 49% female
- Permitted age range: 8-16 years old

Second Group: Opposite-sex hormones for 301 children and adolescents

- 67% female, 33% male
- Permitted age range: 8-20 years old
- Minimum age was originally 13 but lowered to 8 in 2017 change request^{12*}
- Opposite-sex hormones were given to 7 children under the age of 13

*Argues treatment should be based on the stage of development, not chronological age.

All children recruited for the study were already seeking treatment at one of the grantee pediatric transgender clinics.

2021 Renewal: The main objective stated for the renewal study is to evaluate the longer-term physiological and psychological impact of the existing medical treatments in adolescents with gender dysphoria for up to four more years. A secondary objective is to increase the diversity and size of the cohorts by adding more youth of color (n=89) and males at birth (n=110).

Major Concerns

Fails to address the safety, ethics, and harm of medical intervention

The NIH study does not seek to answer the primary question of the safety of puberty blockers and/or opposite-sex hormones, let alone the long-term impact of their experimental use on minors.

Safety and long-term effects of opposite-sex hormones and puberty blockers are neither known nor examined in this study. The researchers themselves admit there is a “paucity of empirical research” on such treatments.¹³

- Puberty blockers arrest bone growth, decrease bone density, and prevent normal sexual development of the brain. Studies suggest delaying puberty may have a permanent effect on bone density.¹⁴
- High doses of opposite-sex hormones can be carcinogenic,¹⁵ increasing breast cancer in males who have taken estrogen to transition,¹⁶ and increased rates of ovarian cancer in females.¹⁷

This project presumes hormonal interventions are necessary and inevitable, ignoring data demonstrating 80% of children outgrow their gender dysphoria and accept their innate gender after going through normal puberty.¹⁸

Children who receive puberty-blocking hormones followed by opposite-sex hormones risk permanent sterilization.

Children and youth are incapable of understanding and giving informed consent to irreversible physical alterations, including sexual function and sterility, as well as the long-term physiological and mental-health implications of those alterations resulting from opposite-sex hormones and the unknown effects of the “off label” experimental use of puberty blockers.

Fails to meet standards of “rigorous, scientific research”

The NIH grant project claims to meet the 2011 Institute of Medicine study recommendation:

*An evidence base for providing transgender-specific health care to address gender dysphoria should be created. Most such research is based on small, non-probability samples. A more rigorous research program is needed to understand the health implications of hormone use and other transgender-specific issues.*¹⁹

However, the NIH study only uses a small, non-probability sample and fails to meet other standards of rigorous scientific research:

- There is no control group.
- As an observational study, it at most shows potential association. It cannot prove causation.
- There is no randomization in this project's population.

Bias is evident from the start with opposite-sex hormones referred to as “gender-affirming hormones.” Further, pre or co-existing issues, such as anxiety, depression, or autism spectrum disorder, are presumed to be the result of unaddressed gender dysphoria, not something to be otherwise considered.

All children participating were already seeking treatment at one of the four pediatric transgender clinics before being recruited and added to this observational study.

The lack of randomization alone disqualifies this project as “a more rigorous research program.”

¹ Steensma, T. D., McGuire, J. K., Kreukels, B. P., Beekman, A. J., & Cohen-Kettenis, P. T. (2013). Factors Associated With Desistence and Persistence of Childhood Gender Dysphoria: A Quantitative Follow-Up Study. *Journal of the American Academy of Child & Adolescent Psychiatry*, 52(6), 582–590. doi: 10.1016/j.jaac.2013.03.016

² Jiska Ristori & Thomas D. Steensma (2016) Gender dysphoria in childhood, *International Review of Psychiatry*, 28:1,13-20, DOI: 10.3109/09540261.2015.1115754

³ Singal, J. (2016, July 25). What's Missing From the Conversation About Transgender Kids. *The Cut*. Retrieved from <https://www.thecut.com/2016/07/whats-missing-from-the-conversation-about-transgender-kids.html>

⁴ Kennedy, P. (2008, March 30). Q&A with Norman Spack: A doctor helps children change their gender. *The Boston Globe*. Retrieved from http://archive.boston.com/bostonglobe/ideas/articles/2008/03/30/qa_with_norman_spack/?page=2

⁵ Project Information - NIH RePORTER - NIH Research Portfolio Online Reporting Tools Expenditures and Results. (n.d.). Retrieved from https://projectreporter.nih.gov/project_info_Like.cfm?aid=8965408&icde=47720996

⁶ No studies examining suicidality were counted

⁷ The Center for Transyouth Health and Development. (2019, October 14). Retrieved from <https://www.chla.org/the-center-transyouth-health-and-development>

⁸ Child and Adolescent Gender Center Clinic. (n.d.). Retrieved from https://www.ucsfbenioffchildrens.org/clinics/child_and_adolescent_gender_center/

⁹ Gender Development Program. (n.d.). Retrieved from <https://www.luriechildrens.org/en/specialties-conditions/gender-development-program/>

¹⁰ Yee-Ming Chan, MD, PhD: Boston Children's Hospital. (n.d.). Retrieved from <http://www.childrenshospital.org/directory/physicians/c/yee-ming-chan>

¹¹ Olson-Kennedy, J., Chan, Y.-M., Garofalo, R., Spack, N., Chen, D., Clark, L., ... Rosenthal, S. (2019). Impact of Early Medical Treatment for Transgender Youth: Protocol for the Longitudinal, Observational Trans Youth Care Study. *JMIR Research Protocols*, 8(7). doi: 10.2196/14434 p.2

¹² Ibid. p.7

¹³ “Since 2008, medical care for transgender youth has generally followed guidelines developed by professional consensus, given the paucity of empirical research, particularly in the US setting.” Protocol for the Longitudinal, Observational Trans Youth Care Study. 2019 July 19

¹⁴ Adams, S. (2019, August 17). Teenagers who identify as transgender taking 'puberty blocker' drugs 'may suffer from weaker bones'. *Daily Mail*. Retrieved from <https://www.dailymail.co.uk/debate/article-7368017/Teenagers-identify-transgender-taking-puberty-blocker-drugs-suffer-weaker-bones.html>

¹⁵ Braun, H., Nash, R., Tangpricha, V., Brockman, J., Ward, K., & Goodman, M. (2017). Cancer in Transgender People: Evidence and Methodological Considerations. *Epidemiologic reviews*, 39(1), 93–107. doi: <https://10.1093/epirev/mxw003>. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5868281/>.

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- ¹⁶ Blok, C. J. M. de, Wiepjes, C. M., Engelen, K. van, Adank, M. A., Koen, Barbé, E., ... Nienke M Nota. (2019, May 14). Breast cancer risk in transgender people receiving hormone treatment: nationwide cohort study in the Netherlands. Retrieved from <https://doi.org/10.1136/bmj.11652>.
- ¹⁷ Zhu H., Zhu X., Zheng L., Hu X., Sun L., Zhu X. The role of the androgen receptor in ovarian cancer carcinogenesis and its clinical implications. *Oncotarget*. 2016; 8: 29395-29405. Retrieved from <http://www.oncotarget.com/index.php?journal=oncotarget&page=article&op=view&path%5B%5D=12561&path%5B%5D=39803>.
- ¹⁸ Steensma, T. D., McGuire, J. K., Kreukels, B. P., Beekman, A. J., & Cohen-Kettenis, P. T. (2013). Factors Associated With Desistence and Persistence of Childhood Gender Dysphoria: A Quantitative Follow-Up Study. *Journal of the American Academy of Child & Adolescent Psychiatry*, 52(6), 582–590. doi: 10.1016/j.jaac.2013.03.016
- ¹⁹ IOM (Institute of Medicine). 2011. *The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding*. Washington, DC: The National Academies Press. Retrieved from: https://www.ncbi.nlm.nih.gov/books/NBK64806/pdf/Bookshelf_NBK64806.pdf p. 8