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Date: 11/15/2019

Regarding: False Claims Act. Requesting Investigation into Suspected Grant Fraud in NIH Project #1R01HD082554, "The Impact of Early Medical Treatment in Transgender Youth"

Dear Office of Inspector General, U.S. Department of Health & Human Services:

This letter concerns suspected grant fraud in the grant awarded for NIH Project #1R01HD082554, "The Impact of Early Medical Treatment in Transgender Youth". We believe there has been a violation of the False Claims Act.

The issue being that a study was published in JAMA Pediatrics in 2018 entitled "Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults Comparisons of Nonsurgical and Postsurgical Cohorts" by Dr. Johanna Olson-Kennedy, et al. (attached) This study references funding via the NIH grant 1R01HD082554-01A1 (p. 436). However the content of the study is entirely different than the aims for which the grant was funded (see appendix of this letter under Specific Aims). Specifically the published study is of mastectomies of the healthy breasts of minor and adult females with gender dysphoria, yet the grant protocol makes no mention of any surgeries of any kind, nor any sort of survey about surgeries. The main intent of the published study appears to be to obtain insurance payments for minors who have undergone mastectomies. There are additional problems and discrepancies between the grant application protocol and the published article which are detailed below.

The study is striking insofar as 33 minor females (under the age of 18) had surgical resection of completely healthy breasts. They did not have breast cancer for example or other physical ailments as indications for breast resection. They had a condition of the mind whereby their internal sense about "gender" varied with their physically female bodies. The authors state that "16 [subjects] were 15 years or younger" with the youngest being 13. Breasts are organs that once resected can never be replaced. As such this is a life altering surgery not to be taken lightly. This is particularly true at such a young age as 13 and 14 years old, whereby these girls cannot fully comprehend the long term consequences of their decision. The plans and considerations for these surgical subject minors are mentioned nowhere in the grant application.

The article also discusses a "Chest Dysphoria Scale" which is nowhere referenced in the grant proposal. This is a scale which the study authors admit was generated "based on the clinical experience of the first author" (p.433) and is "not yet validated" (p. 435). One wonders how a non-validated survey about a condition labeled "chest dysphoria" (which is not a valid medical diagnosis) could ever be used to establish anything scientific? The grant monies were not awarded for such a dubious purpose.

Statutes regarding the special protection of minors involved in human experiments are found under 45 CFR Part 46 - Protection of Human Subjects, Subpart D Additional Protections for Children Involved as Subjects in Research. Again, the grant protocol makes no mention of studying any surgeries of any type, neither in its aims nor study design nor anywhere in the application. A review of any study of the resection of healthy organs of minors or any survey of such surgeries would require special examination for children defined as those "who have not attained the legal age for consent to treatments or procedures involved in the research" (45 CFR p. 145). This would be the case for the majority of minors in the study. Under §46.407 it states "HHS will conduct or fund research that the IRB does not believe meets the requirements of §46.404, §46.405, or §46.406 only if: ...(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment" determines it is ethically sound (p. 146). It is clear that this statute for the safeguarding of children was deliberately avoided. Rather there was a deliberate attempt to circumvent such safeguarding. Any attempt to circumvent this statute is both unethical and fraudulent.

The purpose of the mastectomy for minors article becomes clear once one examines the statements about insurance reimbursements. The authors state "many insurance plans continue to impose a mandatory age requirement of 18 years for chest surgery [mastectomy], as well as the use of testosterone for a full year prior to surgery to ensure the best results...We hope to inform future revisions of existing guideline recommendations regarding...minors seeking surgical interventions" (p. 432). So it appears that the plan at the outset was to create a non-validated survey to help circumvent existing protections for minors, and thereby change the guidelines so that girls as young as 13 can have mastectomies of healthy breasts paid for by insurance companies.

In conclusion, it would seem that the authors were anxious to get a study published in the literature in order to insure that surgeons would be reimbursed for the resection of the healthy breasts of minor girls. This is ethically a very dubious purpose. In terms of using these particular grant monies towards the study, the authors of this letter believe it to be a fraudulent use and are recommending an investigation as such.

Thank you for reviewing this letter.

Sincerely,

Handwritten signature of Michael K. Laidlaw, MD in black ink.

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Attachments:

1. Appendix
2. Article: Olson-Kennedy J, et al. "Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults Comparisons of Nonsurgical and Postsurgical Cohorts" JAMA Pediatrics 2018
3. Specific Aims and Study Design from Grant Application 1R01HD082554
4. 45 CFR Part 46

## Appendix

The following is from pages 163-164 of the grant application under “Specific Aims”.

“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.”

“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.”

“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.”