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NIH Study Harming Young Children New Parent Coalition Urges Immediate Moratorium

April 9, 2019: In an urgent request sent just four days ago to Dr. Jerry Menikoff, Director of the Office for Human Research Protections (OHRP), the [Kelsey Coalition](#) called for an immediate moratorium on a \$5.7-million taxpayer-funded NIH study, *The Impact of Early Medical Treatment in Transgender Youth*.

This NIH study is a five-year observational experiment in which children are treated with powerful drugs to treat a non-medical condition. The basis for inclusion in the study is little more than a child's self-identification as transgender. There is no control group.

The OHRP responded yesterday that the Office will "start a review."

Young children in the study are given puberty-blocking drugs; older children, cross-sex hormones. There is neither FDA approval, nor a single safety study, to support the use of these medications by healthy children and adolescents. According to Dr. Michael Laidlaw, medical consultant to the Coalition, "These drugs will radically alter their endocrine systems, impact sexual function, and fertility, while putting them at increased risk of developing other serious medical health conditions."

Dr. Laidlaw sent Dr. Menikoff information that he obtained through a recent Freedom of Information Act (FOIA) request:

In 2017, the protocol was changed mid-study: the minimum age for cross-sex hormone inclusion was decreased from age thirteen to age eight. According to the 2018 progress report, 19 children have been recruited into the new 8-12 year-old cohort.

The Kelsey Coalition contends this trial is unethical and violates laws protecting human subjects. Dr. Michael Laidlaw, Dr. William Malone, and Mr. Hacsí Horvath signed the letter to OHRP on behalf of the Coalition. A copy of the letter is available upon request.

The Kelsey Coalition urges concerned citizens to support their call for an immediate moratorium. A [detailed action plan](#) can be found on their website.

The Kelsey Coalition is a national group representing hundreds of parents whose transgender-identifying children have been harmed by physicians, therapists, and clinics. Dr. Michael Laidlaw is a board-certified endocrinologist practicing in California and serves as the medical consultant for the Kelsey Coalition. Dr. William Malone is the Medical Director of the St. Luke's Endocrinology and Diabetes Clinic. Mr. Hacsí Horvath is an expert in research synthesis methods, critical appraisal and public health guideline development. During his career at the University of California, San Francisco (UCSF), Horvath managed the Cochrane Review Group on HIV/AIDS, and worked closely for many years with World Health Organization (WHO) colleagues to develop and update global HIV guidelines.