

February 12, 2021

The Honorable Norris Cochran
Acting Secretary
Department of Health and Human Services
200 Independence Ave S.W.
Washington D.C., 20201

RE: Proposed Rule: Establishment of Safeguards and Program Integrity Requirements for Health and Human Services-Funded Extramural Research Involving Human Fetal Tissue (RIN 0991-AC15)

Dear Acting Secretary Cochran:

On behalf of the scientific, medical, and patient communities dedicated to advancing medical knowledge and improving human health, we write to urge you to withdraw the proposed rule (RIN 0991-AC-15) on extramural research involving human fetal tissue (HFT). The proposed rule would impede promising biomedical research that could lead to new treatments for serious diseases, including COVID-19.

As we mentioned in our [letter](#) to then President-Elect Biden, HFT has contributed to numerous scientific and medical advances and remains a crucial resource for biomedical research. Cells derived from HFT are currently being used to support the development of multiple treatments and vaccines for COVID-19. HFT has unique and valuable properties that often cannot be replaced by other cell types. It is crucial for developing vaccines and studying infectious diseases like COVID-19, Zika, HIV, and other viruses. It is also critical for ongoing clinical research on potential treatments for amyotrophic lateral sclerosis (ALS), spinal cord injury, and Parkinson's disease. While some have argued that advances in recent years have reduced the need for HFT in certain areas of research, it remains crucial for many others.

If the proposed rule is finalized, it could delay scientific advances, vaccines, and anti-viral therapies that otherwise would have been developed under the longstanding rules enabling HFT research. The proposed prohibition on the use of federal funds for the procurement of HFT for research would increase the institutional cost of research using HFT at a time when research institutions are strained for resources due to the ongoing pandemic. The procurement of biospecimens and other research materials is essential for the conduct of research and should be a permissible use of federal research funding.

Furthermore, by prescribing new consent procedures, the proposed rule would significantly constrain the use of HFT in research with unnecessary procedural barriers to obtaining fetal tissue from most healthcare facilities in the United States. The proposed additional processes surrounding consent are unnecessary to ensure adequate informed consent for tissue donation. Informed consent occurs consistently in healthcare settings across the country, including hospitals, research facilities, clinics, and other medical facilities. There is no ethical basis to prohibit the use of biospecimens from facilities that are compliant with existing federal rules governing the donation of biospecimens.

The longstanding oversight process for HFT research ensures that HFT research was scientifically meritorious, legal, and ethically sound. This ethical and legal framework remains the standard for HFT research. It already requires robust informed consent and prohibits individuals from profiting from the acquisition, receipt, or transfer of HFT for research. Therefore,

we encourage you to withdraw the proposed rule and immediately revoke the other 2019 policy changes for HFT research that we noted in our [letter](#) to President-elect Biden.

As organizations representing scientists, clinicians, and patients driven by a desire to improve the health and well-being of all, we appreciate your commitment to public health, biomedical research, and evidence-based policies. We look forward to working with you and thank you for considering our views on the significance of research using human fetal tissue.

Sincerely,

Academic Pediatric Association
AIDS Action Baltimore
AIDS Alabama
AIDS Cure Research Collaborative
AIDS Foundation Chicago
Alliance for Aging Research
American Academy of Neurology
American Academy of Pediatrics
American Association for the Advancement of Science
American Association of Colleges of Pharmacy
American Brain Coalition
American Institute of Biological Sciences
American Pediatric Society
American Society for Reproductive Medicine (ASRM)
American Society of Hematology
American Thoracic Society
Americans for Cures
Association of American Medical Colleges
Association of American Universities
Association of Independent Research Institutes
Association of Medical School Pediatric Department Chairs
Association of Nurses in AIDS Care
Association of Public & Land-grant Universities
Axis Advocacy
Boston University
Cascade AIDS Project
Coalition for the Life Sciences
Columbia University Irving Medical Center
Community Education Group
Conference of Boston Teaching Hospitals
Council on Governmental Relations
Duke University
Elizabeth Glaser Pediatric AIDS Foundation
Equality California
Equity Forward
Fred Hutchinson Cancer Research Center
GLMA: Health Professionals Advancing LGBTQ Equality
Global Healthy Living Foundation
Harvard University
HealthHIV
HIV Medicine Association
HIV+Aging Research Project-Palm Springs

Infectious Diseases Society of America
International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)
International Society for Stem Cell Research
ISCT, International Society for Cell & Gene Therapy
Jacobs Institute of Women's Health
Johns Hopkins University
Martin Delaney Collaborative for HIV Cure Research Community Advisory Board
Martin Delaney Collaboratory for an HIV Cure BEAT-HIV
Massachusetts General Hospital
Medical College of Wisconsin
Medical Students for Choice
NASTAD
National Alliance for Eye and Vision Research
National Alliance on Mental Illness
National Women's Health Network
New York University
Northwestern University Feinberg School of Medicine
Pediatric Policy Council
Princeton
Research!America
Rutgers, The State University of New Jersey
Silver State Equality-Nevada
Society for Maternal-Fetal Medicine
Society for Pediatric Research
Society for Reproductive Investigation
Society of Family Planning
Society of Toxicology
Stanford University
Stony Brook University
Texans for Cures
The American Society for Cell Biology
The Michael J. Fox Foundation for Parkinson's Research
The New York Stem Cell Foundation
The Wistar Institute
Treatment Action Group
Treatment Education Network
Tuberous Sclerosis Alliance
UC Davis
UC San Francisco
UCLA
Union of Concerned Scientists
University at Buffalo
University of California San Diego
University of California System
University of Chicago Medical Center
University of Massachusetts Medical School
University of Michigan
University of Oregon
University of Washington
US People Living with HIV Caucus
Weill Cornell Medicine
Yale University