



October 27, 2023

The Honorable Bill Cassidy, MD
Ranking Member
Senate Committee on Health,
Education, Labor, and Pensions
Washington, D.C. 20510

RE: Modernizing the National Institutes of Health (NIH)

Ranking Member Cassidy,

Thank you for the opportunity to respond to your Request for Information on Modernizing the National Institutes of Health (NIH). Founded in 2002, the International Society for Stem Cell Research (ISSCR) is an independent not-for-profit organization that fosters the exchange of information and ideas related to stem cells, including professional and public education regarding research standards, ethics, and the responsible translation of stem cell research to the clinic. Many of our members work, or have worked, in NIH-funded labs or are the recipients of NIH grants.

What are the biggest ethical challenges facing the biomedical research community today? How is, or is not, NIH currently working to address these issues? What more could NIH do to lead in this space?

One area where the NIH has led in incorporating ethical considerations into biomedical research funding is research that uses human fetal tissue (HFT), that is, tissue taken from fetal remains after fetal demise. Use of HFT in research dates to the 1930s and has led to numerous scientific and medical advances that have improved human health, including the development of vaccines against polio, rubella, measles, chickenpox, adenovirus, and rabies, as well as treatments for debilitating diseases such as rheumatoid arthritis, cystic fibrosis, and hemophilia. HFT has unique properties that other research materials cannot yet replicate. It contains essential cell types used to study infectious diseases like COVID-19 and HIV. Studies using HFT were pivotal in screening efforts to identify FDA-approved drugs to protect fetuses from Zika virus, allowing for healthy births. Its availability also facilitates research on normal human development and the causes underlying congenital and inherited disorders such as those of the heart and nervous system, which in turn may provide unique insights into birth defects or some adult disease states.

Decades of thoughtful deliberation on research with HFT has informed the development of an ethical and legal framework at NIH that permits valuable medical research to progress, enabling the discovery of therapies that would not otherwise have been possible. The existing framework provides appropriate and rigorous oversight. By ensuring that use of HFT does not affect decision-making about pregnancy termination, it does not increase the number of abortions. Further, HFT is obtained pursuant to federal legal regimes, professional standards, and with donor consent. The framework requires that:

- Donors must have made the decision to terminate the pregnancy before they consider whether to donate the fetal remains.
- Principal investigators also certify that they “had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy.”
- Donors must provide written informed consent to donation, without any restriction regarding the recipient of the tissue.



- Physicians are required to disclose their own interest in the research and any known medical risks to the woman.
- Principal investigators are required to sign a statement that they are aware that “the tissue is human fetal tissue; the tissue may have been obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth; and the tissue was donated for research purposes” and certify that this information has been shared with other members of the research team.

Further, the NIH requires additional documentation of the use of HFT from elective abortions to ensure that it is utilized for research only when scientifically justifiable, and in the least amount possible to achieve the scientific outcomes. Finally, while federal law allows for reimbursement of expenses due to collection, transport, and processing of HFT, it prohibits individuals from profiting from acquiring, receiving, or transferring fetal tissue for research.

Scientists, ethicists, and government advisory bodies have repeatedly scrutinized the use of HFT in research and have consistently concluded that HFT is an essential resource for biomedical research, one that in many cases cannot be replicated using alternate methods or tissues. The robust framework that the NIH has constructed ensures that research using HFT is scientifically meritorious, legal, and ethically sound. Efforts to modernize NIH’s approach to ethical considerations in biomedical research should acknowledge the success of its ethical framework for research with HFT.

Respectfully,

Amander Clark, PhD
President
ISSCR