



FASEB

Federation of American Societies
for Experimental Biology

Representing Over 130,000 Researchers

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September 3, 2019

Francis Collins, MD, PhD
Director
National Institutes of Health
Building One, Room 118A
One Center Drive
Bethesda, MD 20814

Laura Trueman
Deputy Director, Office of
Intergovernmental and External Affairs
U.S. Department of Health and Human
Services Hubert Humphrey Building, 620E
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Collins and Ms. Trueman,

The Federation of American Societies for Experimental Biology (FASEB) appreciates the efforts of the National Institutes of Health (NIH) and Department of Health and Human Services (HHS) to develop guidance ([NOT-OD-19-128](#)) to clarify expectations for extramural investigators proposing human fetal tissue research in light of [policy changes](#) announced on June 5. We also thank the agencies for providing additional resources, including a Frequently Asked Questions (FAQs) document ([NOT-OD-19-137](#)) to help researchers navigate these changes. While we recognize that research utilizing fetal tissue requires balancing of scientific and ethical considerations, the timing of the new policy and need to update review processes to accommodate the yet-to-be established Ethics Advisory Board (EAB) have left the status of many extramural grant proposals already under review uncertain. To minimize the delay of biomedical research, FASEB offers the following feedback on the updated Guidance for your consideration.

Adjust the placement of the Ethics Advisory Board (EAB)

To maintain the integrity of the NIH peer review process, FASEB recommends modifying the placement of the EAB review to occur after assessment by the Scientific Review Group but before advisory council review. Flanking the EAB between the two-tier review system fulfills the policy's requirement for grant applications involving human fetal tissue be evaluated for ethical concerns while ensuring scientific merit prior to a funding recommendation by the respective Institute's or Center's (I/C's) advisory council. This structure corresponds with NIH's suggested change in stem cell policy. In 2016, the agency [proposed](#) lifting the moratorium on experiments involving human stem cells and animal embryos on the condition that these studies receive an additional layer of ethical review. An internal steering committee comprised of

scientists, ethicists, and animal welfare experts would consider applications receiving meritorious scores in first round of peer review and recommend to the relevant I/C's advisory council whether to fund the proposed research. We recommend streamlining resources and adopting a comparable strategy for grants utilizing human fetal tissue, a related topic with similar ethical implications.

Harmonize application requirements with animal and human subject specifications

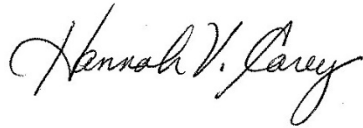
FASEB acknowledges the rationale for requiring the inclusion of a justification for use of human fetal tissue in grant proposals. However, requiring this justification within the page limitations of the Approach section (12 pages) will create unnecessary burden for applicants and may detract from the purpose of the proposed research. More importantly, the page constraint is inconsistent with NIH application requirements involving animal and human subjects which require additional explanation through the supplemental Vertebrate Animal and Protection of Human Subjects section of the Research Plan, but do not count toward the page limitation. According to [45 CFR §46.206](#), human tissue/cell lines that can be linked to living individuals are considered human subjects. Therefore, we advise regulating fetal tissue proposals under the same standard by implementing a supplemental section for the newly required fetal tissue research justification, ensuring a timely, fair, and equitable peer review process.

Modify the policy for trainees

FASEB recognizes the NIH's efforts to keep pace with the evolving field of fetal tissue research, thus we are concerned about the [restriction](#) preventing trainees supported by certain fellowship and training grant mechanisms from proposing research utilizing human fetal tissue. While early-stage scientists remain eligible to conduct research with fetal tissue if part of a mentor and/or sponsor's award, prohibiting trainees from proposing independent research could potentially hinder research progress and workforce development. Therefore, we recommend modifying this policy to allow those scientists best equipped to pursue this research to do so, using the same aforementioned EAB mechanism. Research utilizing fetal tissue has led to important medical breakthroughs in regenerative medicine and neuropathology, thus serving as an opportunity for trainees to develop the skillset necessary to address clinical challenges with national and global implications. Young scientists are vital to NIH's mission to support the advancement and sustainability of scientific resources designed to improve health. Accordingly, it is the responsibility of the agencies to ensure trainees have access to and appropriate use of such resources, including human fetal tissue.

FASEB appreciates the challenges faced by HHS and NIH leadership in evaluating and revising the policies and procedures governing research utilizing human fetal tissues that would be acceptable to a range of stakeholders. In our comments, we've highlighted several areas of concern for which questions about implementation remain among the scientists represented by FASEB's 29 member societies. When finalizing plans for implementation, we urge continued active and transparent engagement with the research community to ensure awareness of the policy as well as clear understanding of the process and projected timeline for the review of grant proposals involving research with human fetal tissue.

Sincerely,

A handwritten signature in cursive script that reads "Hannah V. Carey". The signature is written in black ink and is positioned below the word "Sincerely,".

Hannah V. Carey, PhD
FASEB President