

United States Senate

WASHINGTON, DC 20510-2101

September 30, 2016

Dr. Francis Collins
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Collins:

We write with concerns and questions regarding the National Institutes of Health's (NIH) proposed policy changes to fund research that involves introducing human cells into early animal embryos resulting in organisms that are both human and animal, often referred to as "chimeras." American taxpayers fund the NIH, and we are concerned at the prospect of those dollars advancing research that goes beyond the bounds of responsible and ethical research.

On August 5, 2016, the NIH asked for public comments on a proposal to reverse a funding moratorium instituted in September 2015 to allow funding for research in which human pluripotent cells are introduced into animal embryos. The proposed changes included the creation of an internal steering committee to provide recommendations on funding certain types of chimera research. The comment period closed on September 6, 2016, which gave the public and experts only one month to comment on a technical and controversial proposal.

We recognize the important and unique role NIH has as the world's largest public funder of biomedical research. The NIH is a leader in conducting and supporting ground-breaking research to find new treatments and cures for diseases that affect millions of Americans each year. We support the agency's mission to prevent diseases and conditions and find new treatments and cures, but the NIH also has a responsibility to uphold the values of the Americans who fund its research.

In order to better understand the proposed changes and their effects from both an ethical and scientific perspective, we request responses to the following questions:

Human-Animal Chimera Research

1. Chimera research could include research in which human cells potentially make a substantial contribution or cause a substantial functional modification to the brain of an animal, including other mammals. The NIH proposal opened up the

possibility of doing such research on non-human primates, which would be a significant change.

- a. Where is the ethical dividing line between acceptable and unacceptable influence of human cells on an animal brain? In other words, how much is too much?
 - b. Since there is still a significant amount we do not know about the brain and how human cells will influence an animal brain, how will the NIH determine what projects are unethical before funding research that goes too far?
 - c. What feedback did NIH receive with respect to the scope of chimera research?
2. At what point is chimera research involving human cells in an animal embryo considered human embryo research? Has NIH considered this question and, if so, please outline what standards, if any, have been established.
 - a. The Dickey-Wicker Amendment prohibits using taxpayer dollars for research that creates or destroys a human embryo and any research funded by NIH has to comply with this Amendment. In proposing the human-animal chimera research policy changes, what consideration has NIH given ensuring that such research is in compliance with the Dickey-Wicker Amendment?
 3. The proposed changes would prohibit the breeding of any animals in which human cells may contribute to the germ line. What steps will researchers be required to take in order to prevent such breeding, and how will the NIH ensure compliance with this prohibition?

The Policymaking Process

1. In September 2015, NIH instituted a temporary ban on funding for research that proposed to introduce human pluripotent cells into animal embryos. A one-day workshop was held in November 2015 on the topic of chimera research. What other actions has NIH taken with respect to the consideration of ethical and legal issues and implications related to chimera research prior to issuing the proposed policy changes?
2. How many comments has NIH received regarding this proposal? What were the most common concerns with the proposed revised policy?
3. How does NIH plan to take these comments into consideration prior to making a decision?

NIH Steering Committee

4. NIH is proposing that a steering committee would consider any research in which human cells could substantially contribute to an animal brain, or there is substantial functional modification to an animal brain. How are “substantial contribution” and “substantial functional modification” defined?

5. Why did NIH choose to include only federal employees as members of the steering committee? What stakeholder feedback did NIH receive on this issue?
6. How is NIH structuring the committee to ensure that there is a balance of scientific and bioethical interests?
7. Is committee membership restricted to experts from the NIH, or will the committee include members from other agencies within the Department of Health and Human Services or other Federal departments?
8. How will committee members be selected? How long will individual members serve on the committee?
9. Will the committee consult with any outside experts prior to issuing recommendations?
10. Since the committee will not be subject to the Federal Advisory Committee Act (FACA) will any portion of the committee's deliberation process be made public? Will the committee's recommendations be made public?

Thank you in advance for your attention to this request. Should you have any additional questions or comments, please have your staff contact Liz Schwartz at 202-224-3424. We request a response by October 14, 2016.

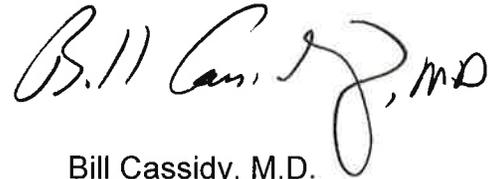
Sincerely,



Mike Enzi
U.S. Senator



Pat Roberts
U.S. Senator



Bill Cassidy, M.D.
U.S. Senator