September 2, 2016

Lawrence A. Tabak,
Deputy Director, National Institutes of Health
Office of Science Policy,
National Institutes of Health, 6705
Rockledge Drive, Suite 750, Bethesda,
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Re: ***Proposed Changes to the NIH Guidelines for Human Stem Cell Research and the Proposed Scope of an NIH Steering Committee's Consideration of Certain Human-Animal Chimera Research.***

Dear Deputy Director Tabak:

We thank you for the opportunity to comment on the proposed changes to NIH *Guidelines for Human Stem Cell Research* and the proposed *Scope of an NIH Steering Committee's Consideration of Certain Human-Animal Chimera Research*. We represent a Consortium of health care providers, ethicists and advocates for persons with disabilities. Collectively we represent thousands of individuals, with deep concerns for the ethical treatment of all human beings regardless of their stage of development, as well as for the human genome and any potential alterations which may inadvertently arise. We have significant concerns for an increasing eugenic societal mentality that in the long run puts, not just individuals at risk, but all of humanity at risk. Thus, we welcome this opportunity to share our significant cautions, as well as our recognition of the positive possibilities for treatment advances if certain restrictions to the proposed changes in research are implemented.

Consortium Response to NIH Chimera Question #1

The chimeric research under consideration laudably aims to better understand and push forward therapeutic frontiers for a number of devastating diseases. Such research could potentially lead to an immunologically tolerated and readily available source of human organs and body parts for transplantation.

Even with these good intentions and solid scientific potential, research involving human-animal chimeras must be carefully designed to protect human dignity and to avoid serious ethical pitfalls, many of which were recognized as the basis for the recent NIH moratorium on human-animal chimera research. Even with clinical and laboratory safeguards in place, the potential for damage to, or alteration of, important aspects of human identity may not able to be fully foreseen, calling for a measured and conscientious approach.

In general, human-animal chimera research should be allowed to proceed only if the following conditions are met:

- Procedures related to chimera production must not involve the creation, destruction, or use of cellular derivatives from human embryos or directly-aborted human fetuses; human beings at these vulnerable stages must be safeguarded, not exploited, in both clinical and research settings. The use of induced pluripotent stem cells (iPSCs) or other sources of multipotent stem cells in chimera production could be ethically acceptable in research that does not conflict with the ethical issues identified below.

- Human pluripotent stem cells or related derivatives should not be introduced into pre- or post-gastrulation non-human embryos unless the replication of major pillars of human identity can be avoided in the brain systems of those animals.
- Research must not involve the production or reproductive use of human gametes or their progenitor lineages – the basic building blocks of human reproduction – within animals. Animals in which such lineages might unintentionally arise should never be permitted to breed, and derivation of any gametic cells or their progenitors from such animals or their corpses for reproductive purposes should be specifically prohibited.
- Stringent laboratory and clinical procedures should be in place to prevent cross-species pathogen transmission or other untoward health effects.
- Conservative limits on the growth of human-animal chimeric embryos and organ/body parts should be established until consistent outcomes and safety are clearly established.
- The NIH Human-Animal Chimera Steering Committee guidelines and the NIH Guidelines for Human Stem Cell Research should be reviewed again after a defined period has elapsed to allow for ethical evaluation of outcomes from previous policy changes.

Consortium Response to NIH Chimera Question #2

The chimeric research under consideration laudably aims to better understand and push forward therapeutic frontiers for a number of devastating diseases. Such research could potentially lead to an immunologically tolerated and readily available source of human organs and body parts for transplantation.

Even with these good intentions and solid scientific potential, research involving human-animal chimeras must be carefully designed to protect human dignity and to avoid serious ethical pitfalls, many of which were recognized as the basis for the recent NIH moratorium on human-animal chimera research. Even with clinical and laboratory safeguards in place, the potential for damage to, or alteration of, important aspects of human identity may not able to be fully foreseen, calling for a measured and conscientious approach.

Thus, we support the proposed amended guidelines (b), (c), and (d) in section IV. However, regarding amended guideline (a), we believe it important to emphasize that research should not be funded in which human pluripotent stem cells, or their derivatives, are introduced into any non-human embryos before or after gastrulation, unless these conditions are satisfied:

- Procedures related to chimera production must not involve the creation, destruction, or use of cellular derivatives from human embryos or directly-aborted human fetuses; human beings at these vulnerable stages must be safeguarded, not exploited, in both clinical and research settings. The use of induced pluripotent stem cells (iPSCs) or other sources of multipotent stem cells in chimera production could be ethically acceptable in research that does not conflict with the ethical issues identified below.
- Human pluripotent stem cells or related derivatives should not be introduced into pre- or post-gastrulation non-human embryos unless the replication of major pillars of human identity can be avoided in the brain systems of those animals.
- Research must not involve the production or reproductive use of human gametes or their progenitor lineages – the basic building blocks of human reproduction – within animals. Animals in which such lineages might unintentionally arise should never be permitted to breed, and derivation of any gametic cells or their progenitors from such animals or their corpses for reproductive purposes should be specifically prohibited.
- Stringent laboratory and clinical procedures should be in place to prevent cross-species pathogen transmission or other untoward health effects.
- Conservative limits on the growth of human-animal chimeric embryos and organ/body parts should be established until consistent outcomes and safety are clearly established.
- The NIH Human-Animal Chimera Steering Committee guidelines and the NIH Guidelines for Human Stem Cell Research should be reviewed again after a defined period has elapsed to allow for ethical evaluation of outcomes from previous policy changes.

Again, we thank you for this opportunity to express our concerns and cautions concerning the proposed changes to NIH *Guidelines for Human Stem Cell Research* and the proposed *Scope of an NIH Steering Committee's Consideration of Certain Human-Animal Chimera Research*.

Sincerely yours,

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