

NIH consideration of certain research proposals involving human-animal chimera models

The National Institutes of Health (NIH) is seeking public comments on the proposed scope of certain human-animal chimera research that will be considered internally by an NIH steering committee and on a proposal to amend Section IV and Section V of the NIH Guidelines for Human Stem Cell Research.

You may provide comment to one or all of the topics in the comment boxes below. For more information, see [NIH Guide Notice NOT-OD-16-128](#) or [Federal Register notice](#)

How to Submit a Response

Responses will be accepted through September 6th, 2016. NIH will consider all public comments before taking next steps. No proprietary, classified, confidential, or sensitive information should be included in your response. Comments received, including any personal information, will be posted without change to http://grants.nih.gov/grants/rfi/responses_57.cfm. Comments may also be mailed to: Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, 301-496-9838.

To ensure consideration, responses must be submitted by: September 6, 2016 11:59:59 PM EDT

(* = Required fields)

*Name

Karen Perritt

For each individual, please submit the name and function of that other individual.

Name of Organization

Type of Organization

Not Applicable

Function

Member of the Public

Please comment on the proposed scope of research (e.g., grant applications, contract proposals, intramural research protocols, etc.) to be considered by an NIH steering committee to provide programmatic input to the director of the relevant Institute or Center (or equivalent NIH official responsible for funding decisions). The NIH proposes the scope of research to include research in which:

- human pluripotent cells are introduced into non-human vertebrate embryos, up through the end of the gastrulation stage, or
- human cells are introduced into post-gastrulation non-human mammals (excluding rodents), such that there could be either a substantial contribution or a substantial functional modification to the animal brain by the human cells.

I object strongly to the NIH's proposal to rescind its moratorium on funding of research involving human-animal chimeras. I do not want my tax dollars being used for grossly unethical research involving the creation and manipulation of part-human, part-animal beings whose very existence blurs the line between human and non-human animals. This proposed research raises all the ethical problems of human embryonic stem cell research in general and serious additional problems related to the creation of human-animal beings with partly or substantially human brains and/or human gamete.

NIH also proposes to revise the Guidelines to:

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- 1) expand the existing prohibition on introducing human pluripotent stem cells into blastocyst stage nonhuman primate embryos to include pre-blastocyst stage nonhuman primate embryos, and
- 2) expand the prohibition on research involving the breeding of animals where the introduction of hESCs or human induced pluripotent stem cells may contribute to the germ line to include any human cells that may result in the formation of human gametes.

Therefore, NIH is requesting public comment on the following proposed changes to the Guidelines.

Sections IV and V of the Guidelines currently state:

IV. Research Using hESCs and/or Human Induced Pluripotent Stem Cells That, Although the Cells May Come from Eligible Sources, is Nevertheless Ineligible for NIH Funding

This section governs research using hESCs and human induced pluripotent stem cells, i.e., human cells that are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers. Although the cells may come from eligible sources, the following uses of these cells are nevertheless ineligible for NIH funding, as follows:

- a. Research in which hESCs (even if derived from embryos donated in accordance with these Guidelines) or human induced pluripotent stem cells are introduced into non-human primate blastocysts.
- b. Research involving the breeding of animals where the introduction of hESCs (even if derived from embryos donated in accordance with these Guidelines) or human induced pluripotent stem cells may contribute to the germ line.

V. Other Research Not Eligible for NIH Funding

- a. NIH funding of the derivation of stem cells from human embryos is prohibited by the annual appropriations ban on funding of human embryo research (Section 509, Omnibus Appropriations Act, 2009, Pub. L. 111-8, 3/11/09), otherwise known as the Dickey Amendment.
- b. Research using hESCs derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes, is not eligible for NIH funding.

The NIH is proposing to amend the Guidelines as follows:

IV. Research Not Eligible for NIH Funding:

- a. Research in which human pluripotent stem cells are introduced into non-human primate embryos up through the end of the blastocyst stage, is not eligible for funding.
- b. Research involving the breeding of animals where the introduction of human cells may contribute to the germ line, is not eligible for funding.
- c. NIH funding of the derivation of stem cells from human embryos is prohibited by the annual appropriations limitations on the funding of human embryo research (see e.g. Section 508, Omnibus Appropriations Act, 2016, Pub. L. 114-113, 12/18/15), otherwise known as the Dickey Amendment.
- d. Research using hESCs derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes, is not eligible for NIH funding.

I object strongly to the NIH's apparent lack of consideration for the ethical issues implicated by this research. Indeed, the NIH pledged to "undertake a deliberative process to evaluate the state of the science in this area, the ethical issues that should be considered, and the relevant animal welfare concerns associated with these types of studies" when the moratorium was put in place in 2015. Yet, to date there is no evidence of any discussion of the ethical issues involved in creating partly human animals. I strongly urge you to maintain the current moratorium on funding research involving the creation and manipulation of human-animal chimeras.

Attachments:

The following file extensions are accepted: PDF, XLS, XLSX, DOC, DOCX

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Notes:

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