



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

James W. Atkinson, Ph.D.

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

Name of Organization

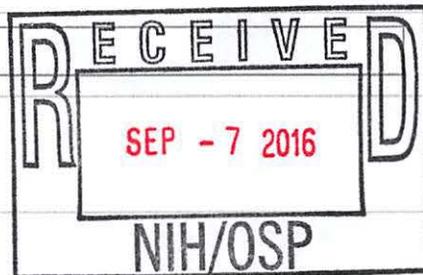
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Type of Organization

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:

- a. human pluripotent cells are introduced into non-human vertebrate embryos, up through the end of the gastrulation stage, or
- b. 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.

See attached

NIH also proposes to revise the Guidelines to:

- 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.

Attachments:

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

Attach Files: No file chosen

Description:

* To ensure the integrity of your response, please enter 413 in this box:

Notes:

Response to this request for public comment is voluntary. Responders are free to address any or all of the items listed above; respondents should not feel compelled to address all items. Please note that the text box for each topic has a maximum limit of

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500 words.

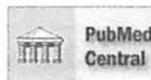
This request for public comment is for planning purposes only and should not be construed as a solicitation for applications or as an obligation on the part of the Government to provide support for any ideas identified in response to it. Please note that the United States Government will not pay for the preparation of any information submitted or for its use of that information.

Responses will be compiled and will be posted publically. We look forward to your input and hope that you will share this request for public comment with your colleagues.

Inquiries:

Please direct all inquiries via email to chimera@mail.nih.gov.

Submit



Thoughts on Proposals for Research Involving Human Embryonic Stem Cells
Under Consideration by NIH

by James W. Atkinson
Professor Emeritus of Zoology
Michigan State University

caveat: Although originally active in developmental biology I have not been involved in research in this area for over 20 years having focused my research on the biology of invertebrate animals, I have been retired for six years and have not kept up with the latest developments in the fields of developmental genetics or genomics. Nevertheless, I believe my background and understanding of the scientific processes provides a basis for the following thoughts. **However, it should be noted that I do so as a member of the public and not as a representative of my former employer, Michigan State University.**

I Proposal a. *human pluripotent cells are introduced into non-human vertebrate embryos, up through the end of the gastrulation stage*

The scientific understanding of the nature and function of human pluripotent cells including embryonic stem cells is focused upon the control of cell differentiation in space and time. That is, how descendants of such cells become specialized in function and in spatial relationships with one another to produce the tissues and organs of adult humans. The technological application of such knowledge would be concerned with prevention and/or repair of birth defects and the possible replacement of dysfunctional adult organs and tissues. The traditional approach to gaining such scientific understanding has involved the in vitro culture of human pluripotent cells (or those of other animals) and the experimental manipulation of culturing conditions. Introduction of such cells into non-human animals without the thorough understanding of how they are controlled in human embryos or even how other animals' stem cells are controlled during development is a pointless exercise. It does not reflect a scientific test of any specific hypothesis but rather is a random exercise in "let's see what happens if we...."

Proposal b. *human cells are introduced into post-gastrulation stage 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.*



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As in Proposal a, this proposal does not seek a scientific understanding of a natural process by testing specific hypotheses under controlled conditions. Rather, it suggests creating human-animal chimeras with no apparent purpose unless the hope is to produce some sort of animal source for repair and replacement of human tissues or organs. This is the stuff of science fiction horror stories! Irrespective of potential effects on the brain of such chimeras the very idea of such embryos being brought to term and possibly becoming sexually mature adults producing gametes should be anathema to anyone with any sense of the sanctity of life. Such direct manipulation of the processes of organic evolution is unethical at best (irregardless of any particular religious belief system) but is the kind of technological speculation in which unintended consequences could be disastrous to life on earth.

In my opinion no government agency should provide financial support for these proposals not only because American taxpayers are unlikely to agree to these proposals; but also because no government should be involved in the creation of new life forms with unknown potential consequences.

II. NIH proposed revision of the Guidelines

- 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.*

I support these revisions and any others that will prohibit the research proposed above (Proposals a and b)

James W. Atkinson
9/2/2016

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