



**Association of
American Medical Colleges**
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September 2, 2016

Office of Science Policy
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Re: Request for Public Comment on the 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 (NOT-OD-16-128)

The Association of American Medical Colleges (AAMC) is pleased for the opportunity to comment on proposed changes to the NIH Guidelines for Human Stem Cell Research and the suggested scope for a steering committee to provide input on certain human-animal chimera research proposals. The AAMC is a not-for-profit association representing all 145 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic and scientific societies. Through these institutions and organizations, the AAMC represents nearly 160,000 faculty members, 83,000 medical students, 115,000 resident physicians, and thousands of graduate students and postdoctoral trainees in the biomedical sciences.

The AAMC has long supported federal funding for stem cell research and the establishment of guidelines to ensure that such research is conducted under a rigorous and credible ethical framework. With specific regard to research involving the introduction of human pluripotent cells into early stage embryos of non-human vertebrate animals, or "chimeras," we recognize that such research offers important scientific opportunities with potential benefits to health and medicine. The Association also recognizes—as we believe members of the research community and the public recognize—that there are clearly moral and ethical dimensions to experimentation involving incorporation of human stem cells into other developing animal organisms and to the applications of such research, although there may not be consensus on particular practices. Any reasonable concerns in pursuing this research should be addressed through an open, transparent, and responsible deliberative process.

The AAMC, therefore, supports the NIH proposal to ensure that responsible processes for review, deliberation and oversight are in place, and are guided by the NIH and the research community. Our support is consistent with past experience of research with recombinant DNA and other advances, which in their time also raised questions of ethics and public responsibility. We also note that in the absence of NIH support, the creation and development of chimeric models could continue to take place in disparate, private laboratories, supported through various

funding streams. NIH's involvement at this stage provides an opportunity for further development of community standards and norms in this emerging field.

The AAMC commends the NIH for holding a workshop with stakeholders in the research community to discuss the potential value of human-animal chimera research in studying human development and disease pathology, and the field's progress. We thank NIH for assessing and updating the Guidelines for Stem Cell Research to keep pace with scientific advances and emerging areas of research interest, and agree with the proposed modifications to (1) expand the existing prohibition on introducing human pluripotent cells into non-human primate embryos to include the pre-blastocyst stage and (2) clarify that NIH will not fund research involving the breeding of animals where the introduction of any type of human cell may result in the formation of human gametes.

The AAMC appreciates that the NIH's revised proposal is also reflective of recently issued guidelines on chimera research from the International Society for Stem Cell Research, and represent a move toward the broader harmonization of guidance for stem cell researchers.

The AAMC supports the development of a steering committee to provide programmatic input to NIH Institute and Center Directors on human-animal chimera research proposals which fall under certain topics, as identified by NIH in conjunction with responses to this Notice from the external research community. As noted above, such an advisory model has been successful in the past in reviewing research proposals and functioning as a level of additional oversight for sensitive areas of research, independent of the scientific review process. It is also critical that this committee continue to evaluate the current state of the science and provide relevant analysis to NIH leadership so that any policies and guidelines are created with knowledge of the most recent developments and discoveries.

The AAMC strongly encourages NIH to expand participation of this committee to non-Federal employees, in order to benefit from the inclusion of researchers with technical expertise on this topic present at institutions nationwide.

The AAMC again appreciates the opportunity to comment on this proposal, and the attention of NIH to ethical considerations and responsible science. We would be happy engage our member institutions and work with the NIH as it moves forward on this issue. Please feel free to contact Stephen Heinig, Director of Science Policy (sheinig@aamc.org) for further information about the AAMC's position.

Sincerely,



Alex Ommaya, DSc
Acting Chief Scientific Officer