August 25, 2016

Carrie D. Wolinetz, Ph.D.
Associate Director
Office of Science Policy
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

VIA: http://grants.nih.gov/grants/rfi/rfi.cfm?ID=57

Dear Dr. Wolinetz:

The Association of American Universities (AAU), the Association of Public and Land-grant Universities (APLU) and the Council on Governmental Relations (COGR) thank you for the opportunity to comment on Federal Register Document number 2016-18601, 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.

In addition to funding recommendations and evaluations of the initial Scientific Review Group and the relevant Institute or Center's (ICs) Advisory Council or Board, a proposed steering committee would provide programmatic input on proposed research with chimeras to the director of the relevant NIH ICs.

Our organizations generally support the proposed changes. The NIH workshop held on November 5, 2015 to review the state of the science and scientific opportunities related to human-animal chimera research was beneficial and we appreciate NIH's considerable deliberations on this issue. We are pleased to see NIH taking actions which are consistent with the recommendations made by the International Society for Stem Cell Research. Research combining human and animal cells is being conducted in the private sector and abroad. The U.S. should position itself to build upon recent advances in stem cell research and gene editing techniques. As indicated in the notice, these models may be valuable for the study of disease pathology and have the potential to address the critical shortage of donor organs.

We also encourage NIH to further consider having the newly created steering committee include in its considerations what criteria would need to be met before allowing introduction of human cells into non-human primate embryos. Additionally, we ask NIH to take into account the implications of this funding prohibition on similar research using gene editing tools (e.g., CRISPR/Cas-9). One of the important areas of ongoing consideration and discussion is whether to allow germline genetic modifications in humans using gene editing tools, and if so under what circumstances, for what purposes, with what safeguards, after what preclinical data, etc. If NIH funding for such gene editing research involving animals would be prohibited as an interpretation or extension of the proposed revision, the ability to pursue information from non-human models in order to answer questions about the effects of heritable genetic modifications would be severely constrained.

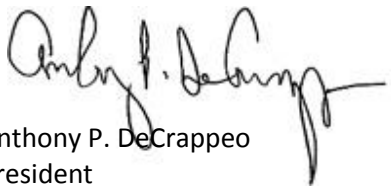
Regarding the NIH Steering Committee formed by the proposed policy, we urge NIH to allow for the inclusion of non-federal members. Academic researchers in the field are in a strong position to "monitor new developments and provide analysis and advice" to NIH leadership, in accordance with the special committee's charge.

Thank you for the opportunity to comment. Please contact Lizbet Boroughs, Jennifer Poulakidas or Lisa Nichols should the Office of Science Policy wish to follow-up on our letter.

Sincerely,

Mary Sue Coleman
President
Association of American Universities

Peter McPherson
President
Association of Public and Land-grant Universities



Anthony P. DeCrappeo
President
Council on Governmental Relations

AAU is an association of 60 U.S. and two Canadian preeminent research universities founded to develop and implement effective national and institutional policies supporting research and scholarship, and public service in research universities. APLU is a research, policy, and advocacy organization with a membership of 235 public research universities, land-grant institutions, state university systems, and affiliated organizations in the U.S., Canada, and Mexico. COGR is an association of over 190 research universities and affiliated academic medical centers and research institutes that concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions.