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IMMUNOLOGISTS



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May 12, 2014

Patricia Brown, V.M.D., M.S.  
Director, Office of Laboratory Animal Welfare  
National Institutes of Health  
RKL 1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892

*RE: RFI: Invitation to Comment on Proposed Guidance Regarding Significant Changes to Ongoing Animal Activities (NOT-OD-14-063)*

Submitted to: <http://grants.nih.gov/grants/rfi/rfi.cfm?ID=36>

Dear Dr. Brown:

The American Association of Immunologists (AAI), the largest professional association of immunologists in the world, appreciates having this opportunity to submit comments on the National Institutes of Health (NIH) "Proposed Guidance Regarding Significant Changes to Ongoing Animal Activities" (NOT-OD-14-063) ("Proposed Guidance").

AAI represents more than 7,800 of the world's leading research scientists and physicians who are dedicated to understanding the immune system through basic research, resulting in improved means to prevent, treat, and cure disease. Largely through funding from NIH, our members are working on some of the most critically important and promising areas of biomedical research, including:

- developing effective vaccines for influenza, HIV/AIDS, and agents of bioterrorism;
- discovering new defenses against re-emerging tuberculosis and drug-resistant bacterial infections;
- regulating debilitating autoimmune diseases such as diabetes and rheumatoid arthritis;
- developing treatments to prevent rejection of transplanted organs and bone marrow; and
- developing novel immune-based therapies for cancer.

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As you know, immunology research often utilizes laboratory animals. AAI members strongly support efforts to ensure the humane use of animals in research and take their responsibilities in this regard very seriously.

AAI is very concerned, therefore, that the Proposed Guidance will actually increase regulatory burden on research scientists and reduce the ability of investigators and Institutional Animal Care and Use Committees (IACUCs) to exercise professional judgment and utilize performance-based standards, all without benefiting the animal subjects or the outcome of the research.

As a founding member of The Federation of American Societies for Experimental Biology (FASEB), which is comprised of 26 scientific societies collectively representing over 115,000 biomedical researchers, AAI would like to endorse the comments submitted by FASEB on May 9, 2014. In particular, we endorse the notion that the Proposed Guidance is unnecessary. Further, we endorse the FASEB-recommended modifications, should OLAW decide to go forward with the Proposed Guidance, including clarifying that the definition of “significant change” should exclude a reduction in 1) the number of animals, and 2) the frequency or number of procedures administered to an animal; and removing the requirement that the entire IACUC must be informed of non-significant changes.

We appreciate having this opportunity to comment. Kindly contact me or Lauren Gross, J.D., AAI Director of Public Policy and Government Affairs ([lgross@aaai.org](mailto:lgross@aaai.org)) or (301) 634-7178, if you have any questions or if AAI can be of any assistance.

Sincerely,



Elizabeth J. Kovacs, Ph.D.  
Chair, AAI Committee on Public Affairs