



May 13, 2014

Office of Laboratory Animal Welfare
National Institutes of Health
RKL 1, Suite 360, MSC 7982
6750 Rockledge Drive
Bethesda, MD 20892

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

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

Dear Dr. Brown:

The American Psychological Association (APA) appreciates the opportunity to comment on the National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW) Proposed Guidance Regarding Significant Changes to Ongoing Animal Activities (NOT-OD-14-063). The APA Committee on Animal Research & Ethics (CARE) has reviewed the proposed guidance and assessed the potential impact of these interpretations of the Public Health Service (PHS) Policy on the conduct of nonhuman animal research in psychology. As a standing committee of APA committed to the humane treatment of laboratory animals for nearly 90 years and representing a membership of over 130,000 researchers, educators, clinicians, consultants, and students, CARE has been involved in developing and updating guidelines for the care and treatment of nonhuman animals in research. Because research with laboratory animals is an integral component of the science of behavior, APA has strongly supported past efforts to improve laboratory animal welfare while ensuring that proposed regulations, policies, and guidance do not compromise scientific research or increase regulatory or administrative burden with little if any impact on the welfare of the animals in research.

APA appreciates OLAW's efforts to reduce the burden on investigators and institutions by facilitating greater autonomy within local Institutional Animal Care and Use Committees (IACUCs). However, APA is concerned that the proposed guidance on what is considered a significant change to an ongoing animal activity that requires IACUC review could have the opposite result of increasing burdens on both investigators and IACUCs, with negligible, if any, impact on the welfare of research animals.

Our primary concern is that contrary to its intent, the proposed guidance adversely affects an IACUC's ability to use its own discretion in establishing a policy for determining significance and for implementing an effective oversight mechanism (i.e., full, designated, or administrative review). In contrast to previous OLAW guidance on the topic (Lab Animal, 24(9), 24-26, 1995; OLAW FAQ D9, and NIH-OD-03-046), the language in

Sections A and B of the proposed guidance is ambiguous and contradictory and diminishes the utility of the guidance. The examples below are illustrative of our concerns.

In keeping with Public Health Service Policy (PHS Policy), the preamble to the proposed guidance states:
The IACUC has the authority to approve ranges of variables as long as it can determine that the range does not interfere with the welfare of the animal or the range is scientifically justified.

Yet, Section A defines significant changes as “... all changes that involve anesthesia, analgesia ... substances delivered to the animal.” APA believes that the guidance should clearly state that only changes beyond the approved range(s) and types of agents/substances should be considered significant

Although Section B defines “changes” in animal numbers as a significant change, Section C considers total increase of less than 10% of the number reviewed and approved by the IACUC as a minor change that may be addressed administratively. Thus, APA recommends that the guidance in the two sections be made consistent.

Section C of the proposed guidance recommends that changes that are not significant may be handled by IACUC staff without IACUC review and approval. But it also requires that the IACUC be informed about minor changes that were handled administratively. APA believes that the requirement to provide the IACUC with detailed lists of very minor change puts an undue burden on IACUC staff.

APA thanks OLAW for this opportunity to share our comments on the proposed guidance. We appreciate the fine balance between ensuring the welfare of laboratory animals while reducing unnecessary regulatory and administrative burdens on the research enterprise. We offer our concerns and suggestions in order to ensure that any proposed guidance is clear and unambiguous, does not inadvertently overburden investigators and IACUCs, and does not hamper scientifically and ethically sound research with nonhuman animals. If you have any questions, or if we can provide any further information, please feel free to contact me at 202-336-6000, or by email at sbreckler@apa.org.

Sincerely,



Steven J. Breckler, PhD
Executive Director for Science
American Psychological Association