



The American Physiological Society

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May 14, 2014

Patricia A. Brown, VMD, MS, Director
Office of Laboratory Animal Welfare
National Institutes of Health
RKL 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892

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

Dear Dr. Brown,

The American Physiological Society (APS) appreciates the opportunity to comment on the Request for Information: Invitation to Comment on Proposed Guidance Regarding Significant Changes to Ongoing Animal Activities. The APS is a professional society of more than 11,000 physiologists who are greatly invested in animal research. The humane use of animals in research is critical to helping us understand basic biological systems and processes, which is essential both to our efforts to diagnose and cure disease as well as to answer important questions about how various organisms adapt to their environments. The APS strongly supports efforts to ensure that federally-funded researchers can pursue important lines of research involving animals in an optimal regulatory environment.

We are grateful the Office of Laboratory Animal Welfare (OLAW) has offered the opportunity to comment on the topic of Institutional Animal Care and Use Committee (IACUC) review of significant changes to animal research protocols. Although, it can be argued that most IACUCs already fulfill all the points outlined in the Proposed Guidance, there is some concern that the proposal may lead some IACUCs to increase the workload unnecessarily.

For the most part, Sections A and B change little in the manner by which IACUCs currently function. Nevertheless, there is some concern about the statement pertaining to approving ranges of variables: "If the investigator chooses to use a single value rather than a range, he or she is required to adhere to that standard." This could be interpreted to mean that an investigator whose protocol said that a sample of 100 μ l of blood would be collected would be out of compliance if 125 μ l was collected due to variability in blood drop size. We recommend that the guidance be revised to incorporate some allowance for experimental variability in the review of procedures. Also, the use of Designated Member Review for approval of amendments should be more heavily emphasized, particularly for protocols where

the procedures that have the potential for significant pain or distress have already been approved.

We are particularly concerned about Section C, regarding the review of non-significant changes. The statement that the IACUC should be informed of changes handled by the IACUC staff is confusing since IACUCs already reassess protocol changes as part of their ongoing oversight, and the IACUC's operations are themselves subject to review semi-annually during the required inspections. By far the most common non-significant changes are the addition or subtraction of personnel to the Animal Use Protocol. Moreover, the primary issues to be considered with new personnel are that they be enrolled in the institution's Occupational Health Program and that they have completed mandated training. Occupational health enrollment and training can easily be verified by the IACUC staff. Furthermore, in addition, the adequacy of training is monitored by veterinarians, IACUC staff and IACUC members during laboratory and semi-annual visits. The least burdensome way to provide IACUC oversight of these kinds of non-significant changes is for IACUCs to review them when protocols come up for periodic review.

As currently written, the guidance in Section C could be read to require that non-significant changes must be reported to the IACUC during regularly scheduled meetings. This interpretation will increase administrative burden rather than reduce it. Therefore, Section C should be edited to clarify that ongoing protocol review is the appropriate opportunity for the IACUC to validate the inclusion of non-significant changes.

Thank you for your attention to our comments. The APS will be happy to provide additional information if needed.

Sincerely,

A handwritten signature in cursive script that reads "David M. Pollock".

David M. Pollock, PhD
President