



*Institutional Animal Care and Use Committee (IACUC)*

May 15, 2014

Re: Invitation to Comment on Proposed Guidance Regarding Significant Changes to Ongoing Animal Activities

Recent assessments of the administrative burden associated with research, such as the survey by the Federal Demonstration Partnership, have highlighted the time currently required to comply with requirements for review of animal studies. We appreciate OLAW's efforts to provide additional guidance and clarification regarding expectations of the Policy on Humane Care and Use of Laboratory Animals; however, this should be an opportunity to eliminate processes that do not contribute to appropriate animal use and regulatory compliance.

Clarification is needed for whether "ranges of variables" can be applied to anesthetics, analgesics, sedatives, and euthanasia methods. To reduce administrative burden while ensuring appropriate care, an IACUC should be able to approve proposed use of a variety of named agents within a class of agents, e.g., several acceptable anesthetic agents, and/or a range of acceptable dosages for a particular agent.

Sections A and B contradict Section C and advice previously given by OLAW regarding the significance of changes in animal numbers or procedures that do not negatively affect animal welfare. Regarding procedures, this raises the question that if a scientific objective can be reached with fewer invasive procedures than originally proposed, should investigators be forced to conduct additional invasive procedures (according to their approved protocol) while waiting for the IACUC to approve the decrease through full committee or designated member review. Section B should clarify whether the change is restricted to an increase or applies to any revision in animal numbers.

The use of "IACUC Staff" in section C is too restrictive and does not allow for other plausible review options, such as by a member who may not be IACUC staff. The use of the more general "administrative review" would give the IACUC greater flexibility for appropriate review and reduce institutional burden.

The requirement to report to the IACUC changes that are not significant and may be handled administratively, as outlined in section C, is overly burdensome. The IACUC is tasked with reviewing and overseeing important animal welfare and programmatic issues. Being required to inform the committee of correction of simple spelling errors or changes in telephone numbers seems hardly conducive to providing the appropriate care and oversight of our research animals. This could potentially detract attention from more important matters and would only contribute to the large regulatory burden our members already face.

Some examples given in Section C, such as a change in housing location or correction of typographical errors, are not appropriate. It is often necessary to move animals from one room or building to another due to repairs, pathogen status, or equipment availability. If the space is used for the same purpose and overseen by the IACUC already, there is no reason why the IACUC would need to document this change in a protocol file or through a formal review, administrative or otherwise. The same is true of updating phone numbers and correcting misspellings or grammar. These examples should be removed from the list.

We thank you for this opportunity to comment.

Sincerely,

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IACUC Chair

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