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July 31, 2023

Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

RE: Request for Information (RFI) on Clarification of Animal Activities Exempt from the PHS Policy Requirements for IACUC Review (NOT-OD-23-119)

Submitted electronically via portal and e-mail: olaw@mail.nih.gov

Dear Dr. Brown,

On behalf of the members of the American Society for Pharmacology and Experimental Therapeutics (ASPET), we appreciate the opportunity to provide comments on the Request for Information (NOT-OD-23-119) seeking input on proposed clarifications of animal activities that are exempt from Institutional Animal Care and Use Committee (IACUC) review.

ASPET is a 4,000-member scientific society whose members conduct basic and clinical pharmacological research and work in academia, government, industry, and non-profit organizations. ASPET members conduct research leading to the development of new medicines and therapeutic agents to fight existing and emerging diseases. ASPET is a global pharmacology community that advances the science of drugs and therapeutics to accelerate the discovery of cures for disease. We are in constant pursuit of our Mission through research, education, innovation, and advocacy.

ASPET applauds the National Institutes of Health (NIH) Office of Laboratory Animal Welfare's (OLAW) commitment to reduce administrative burden in accordance with the 21st Century Cures Act and encourages continued engagement with the stakeholder community. The policy clarifications will enable IACUC members and staff to streamline review processes while maximizing compliance, two components essential to enhancing animal care and welfare. To further strengthen policy understanding, we strongly recommend delineating the difference between "exemption" and "exception" in the final guidance. Given the Public Health Service (PHS) Policy's requirement to use the Guide for the Care and Use of Animals, specific clarification between exemptions, exceptions, and departures are warranted to minimize confusion and facilitate smooth implementation.

Please find ASPET's comments on each proposed exemption below.

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1. Animal activities conducted by institutions that do not receive funding from any of the federal entities that OLAW oversees (e.g., NIH, Centers for Disease Control and Prevention, Food and Drug Administration, Biomedical Advanced Research and Development Authority, NASA, NSF, VA).

ASPET agrees with exempting activities that are not funded or governed by PHS policy. However, considering OLAW holds several Memoranda of Understanding (MOUs) with non-PHS. We recommend the final guidance offer direction for how IACUCs consider non-PHS-funded animal activities with standing Memoranda of Understanding (MOUs). This clarification aligns with the intent of these MOUs to ensure consistent and effective oversight of animal welfare.

Additionally, ASPET recommends the inclusion of additional language regarding public-private collaborations, including studies with pharmaceutical companies. Recognizing that these organizations often possess individual animal welfare policies and practices, providing expectations and best practices for IACUC review from OLAW's perspective would be beneficial for PHS-funded investigators to help minimize non-compliance.

2. Animal activities conducted in areas that are programmatically and functionally separate, with no funded or supported animal activities (e.g., beef cattle used for food production, horses used for riding, school mascots).

We agree with this exemption and have no additional comments.

3. Animal activities involving invertebrates, unless IACUC review is specifically required by the funding agency (e.g., NASA requires IACUC review of cephalopod activities).

ASPET supports OLAW's efforts to update policy guidance with evolving scientific knowledge. Since there is a lack of universal federal policy or guidelines for research with invertebrates, ASPET supports and respects the work of AAALAC International, who has created the framework for how agencies and IACUCs may consider research with cephalopods. The final guidance should specify that exemptions for invertebrate activities depend on the level of invasiveness proposed in the study as well as individual IACUC judgment.

4. Activities with avian or other egg-laying vertebrate species (e.g., fish, amphibians, reptiles) prior to hatching.

We agree with this exemption and have no additional comments.

5. Purely observational field studies that the IACUC determines are unlikely to alter or influence the biology, behavior or ecology of the study animals or other species.

ASPET agrees with this exemption, especially the distinction between observational studies that do not alter animal biology or behavior and those that could impact the health and safety of the humans and animals involved. ASPET asks that the final guidance include examples on what classifies invasive or environmentally disruptive to prevent confusion.

6. Veterinary clinical care of a privately owned animal exclusively for the health and well-being of the animal that does not include collection or generation of data for research purposes (e.g., routine vaccinations, surgery, medical treatment).

We agree with this exemption and have no additional comments.

7. Purchase of commercially available, surgically modified animals (e.g., surgically modified animals generally available to order from a vendor).

We agree with this exemption and have no additional comments.

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8. Purchase of standard off-the-shelf animal-based reagents or antibodies from a commercial supplier that are for general sale (e.g., through a catalogue).

We agree with this exemption and have no additional comments.

9. The use of dead animals, body parts, or tissues not specifically killed for funded or supported activities.

Although ASPET supports this exemption, we note that with the Animal Welfare Act regulations define an animal as “any live or dead” species used for research or teaching. OLAW should consider acknowledging this discrepancy.

10. Sharing of dead animals, animal parts, or animal-derived reagents produced for other purposes that may otherwise be discarded. Examples include excess carcasses, formalin-preserved, or frozen tissues and cell lines.

ASPET strongly supports this exemption. However, similarly to the previously proposed exemption, there is evident discrepancy from Animal Welfare Act regulations which defines animals as “any live or dead” species, yet also defines a “research facility” as an “...entity that intends to use live animals” (9 CFR part 1.1 and part 2.30 (a)). OLAW should consider acknowledging this in the final guidance and potentially give it to local IACUCs to exercise their discretion on this issue.

11. Dual review of a protocol by more than one IACUC involving partnerships between collaborating institutions or relationships between institutional animal care programs.

We agree with this exemption and have no additional comments.

12. Animal activities conducted at a foreign institution when the prime awardee is a foreign institution.

ASPET agrees with this exemption. We strongly recommend that the final guidance acknowledge that many countries where these institutions are located have more stringent legal frameworks than in the United States and these frameworks need to be considered by the local IACUCs reviewing the international partnership.

Conclusion

ASPET always appreciates OLAW’s efforts to engage with the biomedical research community while reviewing and updating its existing guidance to reduce administrative burden. We encourage OLAW to provide ample time for institutions to adjust to potential changes.