



# FASEB

Federation of American Societies  
for Experimental Biology

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July 17, 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](mailto:olaw@mail.nih.gov)

Dear Dr. Brown,

The Federation of American Societies for Experimental Biology (FASEB) appreciates 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. Policy clarifications 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 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 may be warranted to minimize confusion and facilitate smooth implementation. FASEB commends the National Institutes of Health (NIH) Office of Laboratory Animal Welfare’s (OLAW) commitment to reduce administrative burden in accordance with the 21<sup>st</sup> Century Cures Act and encourages continued engagement with the stakeholder community to ensure the full range of institutional needs are considered when developing future policy changes.

Please find FASEB’s comments about each proposed exemption below.

- 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).**

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

IACUC members to proactively address potential investigator questions. Similarly, OLAW could consider adding language about 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 and help minimize the chance of noncompliance.

- 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). Any standards for these areas/activities that might not be consistent with the PHS Policy must not affect or pose risks to funded or supported activities. The scope of the Assurance should be clearly described in Section I, Applicability of Assurance, including any areas to be excluded.**

We agree with this exemption and have no additional comments. This clarification will help reduce administrative burden for IACUCs and assured institutions.

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

FASEB appreciates OLAW's efforts to harmonize policy guidance in accordance with evolving scientific knowledge. We recognize this is a delicate balance between upholding animal welfare, minimizing administrative burden, and adhering to PHS Policy's underlying foundation of institutional self-evaluation. While there is no universal federal policy or guidelines for research with invertebrates, FASEB supports and respects the work of AAALAC International, who in many ways laid the groundwork for how agencies and IACUCs may consider research with cephalopods. Given that many invertebrates are sentient species, we encourage the final guidance to specify that exemptions for invertebrate activities depend on the level of invasiveness proposed in the study as well as individual IACUC judgment. Such guidance provides enough latitude for local IACUCs to discern how best to proceed while also respecting the scientific community's commitment to optimal animal care and welfare.

- 4. Activities with avian or other egg-laying vertebrate species (e.g., fish, amphibians, reptiles) prior to hatching. Although avian and other egg-laying vertebrates develop backbones prior to hatching, OLAW interprets the PHS Policy as applicable to their offspring only after hatching. IACUCs should consider the potential for pain and distress of manipulation on pre-hatched vertebrates during later stages of development. IACUC oversight is required for offspring that hatch unexpectedly.**

We agree with this exemption and have no additional comments. This guidance clarifies IACUCs' role in reviewing activities with avian or other egg-laying vertebrate species while providing important stipulations that warrant specific oversight.

- 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. As recommended by the**

**Guide for the Care and Use of Laboratory Animals (Guide), studies with the potential to impact the health or safety of personnel or the animal's environment may need IACUC oversight, even if described as purely observational or behavioral.**

FASEB concurs with this exemption and appreciates 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. In finalizing this guidance, we recommend specifying that exemptions are dependent on the level of invasiveness. For example, field studies that require trapping, banding, or habituating animals to the presence of humans merit IACUC review because these conditions could alter animal biology and behavior. Therefore, to mitigate potential confusion on what classifies as invasive or environmentally disruptive, FASEB encourages providing examples for the various categories.

- 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). However, if the animal modification requires a custom request from the vendor for a funded or supported activity, it then requires IACUC review and approval. Additionally, the subsequent use of the surgically modified animal constitutes an activity that requires IACUC review.**

We agree with this exemption and have no additional comments. We appreciate OLAW's distinction between commercially available, surgically modified animals and custom requests, as this will alleviate possible misunderstandings from investigators.

- 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). These reagents and antibodies are not customized and not produced specifically at the request of a principal investigator for funded or supported activities.**

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.**

FASEB supports this exemption but recognizes that it may cause confusion with Animal Welfare Act regulations, which define an animal as "any live or dead" species used for research or teaching. We recommend acknowledging this discrepancy in the final guidance and stating that while the use of dead animals or tissues is not a violation of PHS Policy, IACUCs have the discretion to develop practices that best suit their institution's needs. This clarification is not only commensurate with PHS

Policy but also advances the 21<sup>st</sup> Century Cures Act by addressing potential confusion arising from inconsistent animal research policies.

**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.**

FASEB strongly supports this exemption and believes that sharing dead animals, animal parts, or animal-derived reagents that may be otherwise discarded is an exemplary way to promote the 3Rs. However, as previously stated, this aspect of PHS Policy diverges from Animal Welfare Act regulations. The latter 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)). To improve transparency, we recommend that the final guidance acknowledges the discrepancies between the two agencies while offering flexibility for local IACUCs to exercise their discretion. For example, OLAW could recommend that IACUCs establish an institution-specific policy regarding the procurement, utilization, and disposal of animals to avoid misunderstanding and possible noncompliance.

**11. Dual review of a protocol by more than one IACUC involving partnerships between collaborating institutions or relationships between institutional animal care programs. Collaborating Assured institutions may exercise discretion in determining which IACUC reviews protocols for animal activities performed on an award. It is recommended that if an IACUC defers protocol review to another IACUC, then documentation of the review should be maintained by both committees.**

We agree with this exemption and have no additional comments. This exemption significantly enhances research efficiency by fostering a more collaborative research environment and reducing duplicative IACUC review.

**12. Animal activities conducted at a foreign institution when the prime awardee is a foreign institution. However, the foreign institution where the animal work is performed must complete the Animal Welfare Assurance for Foreign Institutions which certifies that the institution will comply with the applicable laws, regulations, and policies of the jurisdiction in which the activities will be conducted, and that the institution will be guided by the International Guiding Principles for Biomedical Research Involving Animals. OLAW encourages, but does not require, foreign institutions to use the standards in the Guide.**

FASEB agrees with this exemption and considers this an excellent way to forge partnerships with other institutions. However, we recommend that the final guidance acknowledge how in many cases, local laws, regulations, and policies may be more stringent than in the U.S. For example, European Union regulations are stricter for research with nonhuman primates and cephalopods. By recognizing these distinctions in OLAW guidance, local IACUCs are more equipped to advise their investigators that may have international collaborations.

## Conclusion

FASEB appreciates OLAW's efforts to engage with the biomedical research community while reviewing and updating its existing guidance to reduce administrative burden. Clarification about animal activities exempt from PHS Policy requirements for IACUC review will facilitate improved IACUC processes and overall policy compliance. We look forward to seeing the final guidance and encourage OLAW to provide ample time for institutions to adjust to potential changes.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary-Ann Bjornsti". The signature is written in a cursive, somewhat stylized font.

Mary-Ann Bjornsti, PhD  
FASEB President