



July 28, 2023

Submitted electronically via <https://rfi.grants.nih.gov/?s=6409fca785d3c85c200bb392>

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

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

To Whom It May Concern:

COGR is an association of over 200 public and private U.S. research universities and affiliated academic medical centers and research institutes. COGR's member institutions are leaders in the conduct of basic and applied research involving animals, which results in important scientific advances that benefit the health and well-being of animals and humans. One area of significant interest and expertise among COGR member institutions is ensuring that research using animals is conducted in a manner that ensures proper protections for animal health, safety, and welfare, while also reducing unnecessary burden on researchers and research institutions.

COGR appreciates the Office of Laboratory Animal Welfare's (OLAW) issuance of the *Request for Information (RFI) on Clarification of Animal Activities Exempt from PHS Policy Requirements for IACUC Review* ([NOT-OD-23-119](#)) ("RFI") and values the opportunity to offer these comments.

As the RFI states, Section 2034(d) of the 21st Century Cures Act "directed the NIH to conduct a review of applicable regulations and policies for the care and use of laboratory animals and to make revisions, as appropriate, to reduce administrative burden on investigators" while maintaining research integrity and protecting the health, safety, and welfare of research animals. Despite this directive, this RFI contains no such revisions.

Instead, the RFI is effectively a reiteration of OLAW's long-standing interpretations of the scope and applicability of the PHS Policy as set forth in OLAW's [FAQs on the PHS Policy on Humane Care and Use of Laboratory Animals](#).¹ This approach creates confusion as to how this proposed clarification statement

¹ The FAQs that correspond to numbered items in the RFI are as follows: Items 1 & 2 – FAQ A.1; Item 4 – FAQ A.4; Item 5 – FAQ A.6; Item 6 – FAQ A.8; Items 7 & 8 – FAQ A.2.; Items 9 & 10 – FAQ A.3.; Item 11 – FAQ A.8; and Item 12 – FAQ A.13.

differs from or adds to current guidance. Accordingly, COGR respectfully suggests that rather than re-issuing the same guidance in a different format, OLAW instead update its current FAQs with any new information or needed clarifications. To this end, we offer comments on select items that would benefit from clarification.

Specific Comments

“Animal Activities that may be exempt from IACUC review and approval, as they apply to the PHS Policy, include:”

Comment: The wording of this statement is confusing because some of the activities noted do not fall within the jurisdiction of the PHS Policy but may be subject to IACUC protocol review per non-PHS Policy requirements. We suggest modifying this statement to read as follows: “Animal activities that may be exempt from the PHS Policy requirements for IACUC review.” This wording conforms with that used elsewhere in the RFI.

RFI Item 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.

Comment: Many vendors make surgically modified animals generally available to the research community, and COGR supports OLAW’s statement that the purchase of such animals is not subject to IACUC review as prescribed by the PHS Policy. Despite the clarity of this directive, the next sentence confusingly states that IACUC review and approval is required “if the animal modification ***requires a custom request from the vendor*** for a funded or supported activity.” [***Emphasis added.***] It is unclear what is meant by “a custom request from the vendor.” This phrase should be modified to make clear that ordering a surgically modified animal of a type that the vendor regularly supplies to the research community is not a “custom request.” Rather, a custom request is one that asks the vendor to surgically modify an animal in a manner that the vendor does not regularly undertake. Finally, we also suggest modifying this item to clarify that it contemplates only “activities that are funded or supported by PHS or by another federal agency with which OLAW has an agreement to provide oversight for animal research activities.”

RFI Item 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.

Comment: COGR supports OLAW’s statement that animal-based reagents or antibodies from commercial suppliers that are offered for general sale are not customized. However, the second sentence of this statement seems to imply that an item’s nature as “customized” or “not customized” depends on whether it is produced “specifically at the request of a principal investigator.” This characterization fails to take account of the “just-in-time” supply chain approach the vendors employ per which stock is produced in real-time as orders are received. COGR urges OLAW to clarify that an item’s status as “custom” does not

depend *when* the item is produced, but instead on *whether the ordered item is one that is routinely supplied* by a vendor (i.e., non-custom) and not unique to the vendor's product lines.

RFI Item 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.

Comment: To avoid confusion, COGR recommends deletion of this item as the circumstances it describes are not an example of an activity that is exempt from IACUC review, but rather a statement that dual IACUC review is not required.

RFI Item 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.

Comment: To avoid confusion, COGR recommends that this item be revised to make clear that it is referring to review by the IACUC at the prime awardee foreign institution when animal activities are conducted at a different foreign institution.

Conclusion

We thank you for the opportunity to submit these comments, and we appreciate your consideration of our suggested clarifications to the current FAQs. We believe these clarifications would help avoid confusion and aid institutional compliance. Please contact Kristin West, Director, Research Ethics and Compliance at kwest@cogr.edu with any questions concerning this transmittal.

Sincerely,



Matt Owens
President