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U.S. Department of Health and Human Services (HHS)

Title

UC Comments in Response to NIH/OLAW's RFI on Clarification of Animal Activities Exempt from the PHS Policy Requirements for IACUC Review (NOT-OD-23-119)

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OFFICE OF THE VICE PRESIDENT – RESEARCH AND INNOVATION

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July 31, 2023

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

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

Dear Sir or Madam:

I write on behalf of the University of California (UC) system regarding the Request for Information (RFI) on Clarification of Animal Activities Exempt from the Public Health Service (PHS) Policy Requirements for Institutional Animal Care and Use Committee (IACUC) Review ([NOT-OD-23-119](#)) issued on April 25, 2023.

The [UC system](#) – comprised of ten campuses, six academic health centers, an Agriculture and Natural Resources division, and three affiliated U.S. Department of Energy national laboratories – stands at the forefront of cutting-edge research and technology development. The UC system supports the integrity and credibility of research findings and protection of research animals, as expressed in the 21st Century Cures Act. UC is committed to animal health, safety, and welfare, while simultaneously reducing administrative burden. We appreciate this opportunity to provide input on animal activities that may be considered exempt from PHS Policy requirements for IACUC review.

UC also appreciates the National Institutes of Health (NIH) Office of Laboratory Animal Welfare's (OLAW) efforts to reduce administrative burden for researchers and research administrators. UC agrees that clarification on which animal activities are exempt from PHS Policy requirements would benefit the research community and align with the goals of the 21st Century Cures Act.

We submit the comments and recommendations below for your consideration. In addition, as a member of the Council on Governmental Relations, UC supports the comments that the Council has submitted on its members' behalf.

The term “exempt” is used in this notice and may cause confusion.

This term “exempt” is frequently used by those involved with human subjects research to describe a study that has minimal risk to the human subject and is exempt from some of the requirements of the Federal Policy for the Protection of Human Subjects, but still requires a limited review by an Institutional Review Board (IRB) to confirm that the study is “exempt” (45 CFR § 46.104). Applying the term “exempt” to describe animal subjects use that does not require IACUC review and approval may be confusing, particularly for researchers and research administrators that are involved in both animal and human subjects research. UC recommends that OLAW use a clearer and more explicit phrase, such as, “animal activities that do not require IACUC review and approval,” to describe the list of examples in NOT-OD-23-119.

Recommendations for the examples provided

UC appreciates the inclusion of examples to clarify which animal activities do not require IACUC review and approval. We offer the following suggestions on these examples.

RFI Example #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.”

Both sentences in this example are confusing. In the first sentence, the phrase “IACUC determines” implies that some level of committee review precedes the determination of whether a “purely observational” field study is “unlikely to alter or influence the biology, behavior or ecology of the study animals or other species.” In practice, this decision is usually made by an IACUC administrator or veterinarian, and the IACUC is only made aware of the proposed study if it is likely to “alter or influence the biology, behavior or ecology of the study animals or other species.” UC recommends clarifying that this determination does not need to be made by the IACUC itself.

In the second sentence, UC agrees that “purely observational” and “behavioral” studies carry the potential “to impact the health or safety of personnel or the animal’s environment,” but we do not agree that this potential is the same for behavioral and purely observational field studies. Unless a behavioral study can also be described as purely observational, it is much more likely to “alter or influence the biology, behavior or ecology of the study animals or other species” and warrant IACUC oversight. Since the word “behavioral” is not explicitly defined in NOT-OD-23-119, PHS Policy, or the *Guide*, UC recommends removing the words “...or behavioral” from the end of the sentence to avoid confusion.

RFI Example #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.”

UC recommends OLAW include a detailed example of a situation where a researcher may purchase an animal that underwent a standard, commercially available surgical procedure by the vendor, but does not require review or approval from their IACUC to make the purchase. As mentioned in the example, any subsequent use of the surgically modified animal does require IACUC review and approval, so UC is unsure of what circumstances may lead to this situation or how it will reduce administrative burden. Is the purpose of this example to notify researchers and their IACUCs that it is the responsibility of the vendor to review the surgical procedures they will perform? If so, UC recommends the example clarify that vendors are required to obtain their IACUC’s review and approval to conduct either custom or standard surgical procedures on animals, while researchers only need to obtain their IACUC’s review and approval to purchase animals that underwent a custom surgical procedure.

RFI Example #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.”

UC recommends clarification that when collaborating, at least one of the research institutions’ IACUCs must conduct a review and approval of the animal activity if at least one of the collaborators receives funding from any of the federal entities that OLAW oversees.

Synchronization of OLAW and USDA-APHIS requirements for vertebrate animals used in a field setting.

While not within the scope of the Information Requested in NOT-OD-23-119, UC would like to take this opportunity to recommend an additional change that may help reduce administrative burden for researchers and research administrators. We recommend that OLAW and U.S. Department of Agriculture Animal and Plant Health Inspection Service (USDA-APHIS) synchronize requirements and definitions for vertebrate animals used in a field setting.

The Background section in NOT-OD-23-119 states that an animal is subject to the PHS Policy requirements (including IACUC review and approval) if the activity “alters or influences the biology, behavior or ecology of the study animals or other species (e.g., capture and release or banding).” However, USDA-APHIS considers an activity where animals are captured, non-invasively marked (e.g., ear tag) and subsequently released to be a field study, and field studies are not subject to the requirements of the Animal Welfare Act, including IACUC review and approval. Even though OLAW requires IACUC review for capturing, tagging, and releasing animals, USDA-APHIS would consider the same animals to have been used for a field study and not subject to the Animal Welfare Act. The USDA-APHIS [Tech Note 41-35-083](#) defines a field study as “a study

conducted on free-living wild animals in their natural habitat. However, this term excludes any study that involves an invasive procedure, harms, or materially alters the behavior of an animal under study.” Further, USDA-APHIS has stated that animals used for a “field study” should not be included in the Annual Report submitted by institutions. Managing these discrepancies is burdensome for both researchers and research administrators when counting and reporting the number of animals used in the field.

Thank you for the opportunity to comment on NOT-OD-23-119. UC is appreciative of NIH and OLAW’s continuing efforts to reduce administrative burden for researchers and research administrators. We look forward to continued engagement on this important issue.

Sincerely,

A handwritten signature in black ink, appearing to read 'DM Motton', is written over a thin horizontal line.

Deborah Motton, Ph.D.
Executive Director
Research Policy Analysis and Coordination
University of California, Office of the
President