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

Title

UC Comments on NIH/OLAW's RFI on Proposed Guidance to Assured Institutions on Cephalopod Care and Use (NOT-OD-23-176)

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December 21, 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 Proposed Guidance to Assured Institutions on Cephalopod Care and Use (NOT-OD-23-176)

To whom it may concern:

I write on behalf of the University of California (UC) system regarding the Request for Information (RFI) on Proposed Guidance to Assured Institutions on Cephalopod Care and Use ([NOT-OD-23-176](#)) issued on September 7, 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. We appreciate this opportunity to provide input on the proposed guidance for use of cephalopods in research and teaching. Although UC has not been engaged in a significant volume of cephalopod research, we support the regulatory initiative to grant cephalopods the protections that reflect the accumulated scientific evidence on their cognition and biological mechanisms of pain. At the same time, we believe that the Office of Laboratory Animal Welfare (OLAW) needs to clarify some aspects of the proposed application of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) to cephalopod use.

As a member of the Council on Governmental Relations (COGR) and National Association of Biomedical Research (NABR), UC supports the comments that these organizations have submitted on their members' behalf. In addition, we submit the following comments and recommendations for your consideration.

OLAW authority to apply the U.S. Government Principles and the PHS Policy to cephalopods

1. The Background section of the RFI states, “[U.S. Government Principles](#) II, III, IV, and IX outline practices that can be applied to [cephalopods] despite the current gaps in

knowledge.” However, since the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training were issued by OSTP, we believe OLAW lacks the authority to expand their application directly to cephalopods. It is unclear whether OLAW is proposing this expansion unilaterally or plans to work across agencies to harmonize the inclusion of cephalopods in all frameworks regulating animal research.

2.

UC recommends:

- The final guidance include a detailed explanation as to whether or why, and how U.S. Government Principles I, V, VI, VII and VIII can also be applied to the care and use of cephalopods.
3. UC would like clarification on whether OLAW (as an entity under NIH) has been delegated the authority to revise the PHS Policy. While OLAW is responsible for providing guidance and interpretation of the PHS Policy, the directive for institutions to begin overseeing cephalopod care and use should come from an entity with the authority to implement such a directive. UC is concerned that not directly addressing this matter will establish precedent not necessarily beneficial to the animal research community.

While OLAW acknowledges that the application of and compliance with the PHS Policy for the use of cephalopods is “problematic,” some of the issues can be resolved by revising the Policy’s definition of an “Animal.” The Policy currently defines an “Animal” as “Any live, vertebrate animal...”

UC recommends:

- Revising this definition to include cephalopods. For example, “Any live, vertebrate *or cephalopod* animal...”
- Revision of the PHS Policy to clearly identify which of the Principles must be applied to the care and use of cephalopods.

Comments on the proposed guidance

“OLAW recognizes that there is tremendous variation in the life history, reproductive strategies, development, and captive breeding challenges among the several hundred known cephalopod species. Care requirements will necessarily differ based on these biological and environmental factors. In addition, cephalopod use varies with research aims (please see the OLAW Cephalopods in Research webpage for selected resources on these topics). Institutions have the discretion to develop institutional guidance that works best for their needs but should base their requirements on the U.S. Government Principles, as well as the most current data and professionally accepted standards.”

- UC recommends including a statement encouraging institutions to develop cephalopod care and use policies and Standard Operating Procedures (SOPs) in close consultation with the Principal Investigators (PIs) that will be working with the animals, as they are likely to have

- specific knowledge and expertise pertaining to the species of cephalopod they propose to use.
- While the RFI states that ad hoc consultants would be allowed to assist with oversight activities, UC recommends also including a statement that encourages an institution to seek assistance from ad hoc consultants if their veterinarian(s), Institutional Animal Care and Use Committee, and/or PI are unsure of appropriate standards of care for a particular species of cephalopod.

“Institutions using cephalopods are expected to provide appropriate husbandry and veterinary care by employing research, husbandry, veterinary care, and physical plant staff with qualifications and training relevant to the species being used.”

- Since the word “employing” can imply that institutions are expected to hire staff and veterinarians with cephalopod experience, as opposed to training their current employees, UC recommends use of the term “utilizing” or “identifying” in the final guidance. This change would clarify that current employees may be trained on cephalopod care and use.
- UC recommends rephrasing part of the statement above to “research, husbandry, veterinary care, *and/or* physical plant staff.” This change would give institutions greater flexibility to develop a cephalopod program that fits their researchers’ needs. For example, this would allow staff members to fulfill more than one cephalopod care role (e.g., a researcher that also provides husbandry).
- UC recommends rephrasing part of the statement above to “qualifications and training relevant to *their roles and* the species being used.” This revision clarifies that the staff involved in cephalopod care and use need to be qualified and have training relevant only to their position. For example, physical plant staff would not require training in daily husbandry, and husbandry staff would not require training in repairing malfunctioning aquarium equipment.

Thank you for the opportunity to comment on NOT-OD-23-176. UC appreciates NIH and OLAW’s continuing efforts to ensure the health and well-being of animals used for research and teaching. We look forward to continued engagement on this important issue.

Sincerely,



Deborah Motton, Ph.D.
Executive Director
Research Policy Analysis and Coordination

University of California, Office of the
President