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

Title

UC Comments on NIH/OLAW's RFI on Update to NOT-OD-05-034 Guidance on Prompt Reporting of Noncompliances to OLAW (NOT-OD-23-063)

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May 05, 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 Update to NOT-OD-05-034 Guidance on Prompt Reporting of Noncompliances to OLAW (NOT-OD-23-063)

Dear Sir or Madam:

I write on behalf of the University of California (UC) system with regard to the Request for Information (RFI) on the Update to NOT-OD-05-034, Guidance on Prompt Reporting of Noncompliances to OLAW ([NOT-OD-23-063](#)) issued on January 23, 2023.

The UC system – comprised of ten campuses, six academic health centers, and three affiliated U.S. Department of Energy national laboratories – stands at the forefront of cutting-edge research and technology development. UC is committed to protecting animal health, safety, and welfare in research. The UC system supports efforts to reduce the administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals, as expressed in the 21st Century Cures Act. We appreciate this opportunity to provide input on the proposed changes to the reporting requirements in the 2005 “*Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals*” ([NOT-OD-05-034](#)) (“2005 Guidance”).

UC General Comments

The background section of the RFI encourages institutions to contact OLAW with questions about specific cases. UC appreciates OLAW’s recognition of idiosyncrasies of each potentially reportable incident and the willingness to advise institutions.

As a member of the Council on Governmental Relations (COGR), UC supports the comments that the COGR has submitted on behalf of its member institutions. In addition, UC would like to expand on concerns regarding one specific provision in the RFI.

UC's Specific Comments:

The exception from the first example of situations not normally reported, as published in the RFI, states:

“Additional examples of situations not normally reported:

- *Minimal animal injury by conspecifics during social housing when proper introduction and subsequent ongoing monitoring occurred.” (“Example”)*
 - *“Exception: Euthanasia of an animal, or injury requiring medical treatment and extended or permanent separation from the group must be reported.” (“Exception”)*

UC has the following concerns with this example.

a. The scope of the Exception is overly broad.

As written, this exception would require reporting of all situations in which group housed social species from mice to non-human primates fight within their group housing and are euthanized or separated for medical treatment. For institutions managing large colonies of any species, especially group housed animals, this requirement would exponentially increase the volume of OLAW reporting and would be antithetical to the goals of the 21st Century Cures Act.

b. The wording of the Example and its Exception is too ambiguous and leaves room for misinterpretation.

- The Exception could be interpreted as OLAW overreach into veterinary care provided at Assured institutions.
- The Exception could be seen as a *preference* for single housing, but single housing is almost never in the best interest of animals.
- There is no guidance on what would be considered a “minor” animal injury, or an “extended” period of separation from a housing group, potentially leading to a wide range of interpretations.
- Would *any* injury requiring medical treatment be reportable to OLAW or only those that are followed by the “extended or permanent separation from the group”?

c. Lack of clarity on OLAW's intent and the expected level of detail in reports.

Currently, significant detail is required with each noncompliance report. It usually takes weeks to prepare these reports and internally review before institutions submit.

- Is OLAW expecting the same level of investigation or reporting into each instance of an animal being euthanized or separated due to injury?
- Does OLAW want to know about every single group housed animal that was euthanized or separated due to injury?
- What are the precise examples of incidents that OLAW would like to be alerted about and what is the rationale?

UC Recommendation:

Based on our analysis of the significant increased administrative burden the Exception would create, UC proposes that the Exception be removed, or for OLAW to clarify the intent, and narrow and define the species and/or situations that would fall under this reporting requirement.

Thank you for the opportunity to comment. We look forward to continued engagement on this important issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Deborah Motton", with a stylized flourish at the end.

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