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May 5, 2023

Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B5 Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

Re: Request for Information (RFI) Update to Guidance on Prompt Reporting of Noncompliances to OLAW (NOT-OD-23-063)

Submitted electronically to <https://rfi.grants.nih.gov/?s=631f14d7056d000039002cd2>

The Association of American Medical Colleges (AAMC) appreciates the opportunity to provide feedback to the National Institutes of Health (NIH) and the Office of Laboratory Animal Welfare (OLAW) on a proposed update to Guidance on Prompt Reporting of Noncompliances.

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 157 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened the AAMC's U.S. membership and expanded its reach to international academic health centers.

Our member organizations are committed to the ethical and responsible use of animals in medical research. The RFI notice was broadly disseminated to the research leadership of our member institutions. Further, the AAMC has communicated with the National Association for Biomedical Research (NABR), which also has an extensive network of animal care professionals and researchers, and we agree with NABR's comments. We submit here a general comment and several specific statements responsive to OLAW's request.

General Comment

The request for information in NOT-OD-23-063 seeks responses on proposed changes to two specific areas of the 2005 notice, "Guidance on Prompt Reporting to OLAW Under the PHS Policy on Humane Care and Use of Laboratory Animals," or NOT-OD-05-34. Those areas are on the "information to be reported" for noncompliance and "additional examples of situations not normally

reported.” The RFI notice’s background explains, “After a comprehensive review, OLAW has determined that certain guidance on reporting requirements in NIH Guide Notice NOT-OD-05-034 is still applicable and will remain unchanged.”

OLAW cites the impetus for this review as the 21st Century Cures Act (PL 114-255), section 2034(d) to reduce administrative burden. Implementation of that section led to the 2019 interagency report, *Reducing Administrative Burden for Researchers: Animal Care and Use in Research*.¹ From that thorough review of the existing reporting requirements, OLAW determined that two areas (“examples of reportable situations” and “clarifying the reporting timeframe”) would not be changed, and that comments are only requested on the relatively minor changes to the two areas mentioned above.

We appreciate that OLAW and NIH are moving methodically through the process of administrative reforms. But as the AAMC has noted in earlier comments, we believe that the overall response has been too incremental and reserved given the scope envisioned by Congress to “make revisions, as appropriate, to reduce the administrative burden on investigators while maintaining the integrity and credibility of research findings and the protection of research animals.” The AAMC would encourage the NIH and other agencies to engage with the research community in a more extensive overhaul of the current compliance system, for a more effective and responsive deployment of resources that would better ensure animal welfare.

The following comments respond to the specific areas invited by the RFI.

On “Information requested” for Reporting Noncompliance

In this reform, OLAW proposes:

Award numbers for NSF awards must be included with noncompliance reports. PHS award numbers need not be included with reports of noncompliance unless requested by OLAW or if determined to be applicable by the reporting institution. However, the funding source (PHS, NASA, VA) must be identified for all reports to OLAW.

The AAMC strongly agrees with the revision to not require Public Health Service award numbers for the information to be reported, as the PHS award numbers are irrelevant to the matter of concern and the best interest of laboratory animal care. NIH and OLAW should work with the other covered agencies to determine if requirement to provide their award numbers can also be modified.

On “Additional examples of situations not normally reported”

As a first example of situations not normally reported, OLAW suggests these additions, with a stipulated exception (e.g., that would require reporting):

- Minor animal injury by conspecifics during social housing when proper introduction and subsequent ongoing monitoring occurred.

¹ https://olaw.nih.gov/sites/default/files/21CCA_final_report.pdf

- **Exception:** Euthanasia of an animal, or injury requiring medical treatment and extended or permanent separation from the group must be reported.

Since standards of animal care, including the *Guide for the Care and Use of Laboratory Animals*,² call for the socialization of naturally gregarious animals, then it must be accepted that injuries (major or minor) may occur as animals are grouped together. The AAMC therefore agrees with the proposal. The exception as described is imprecise, as “medical treatment” can include relatively minor or anodyne care.

The AAMC supports the other proposed examples for situations that do not require being reported:

- Expired medications identified after the expiration date, but not administered to animals after expiration.
- Brief and infrequent excursions of low environmental relative humidity, or minor temperature fluctuations, when no animal health or welfare issues resulted; and a program of required daily monitoring was in place.
- Any isolated noncompliant incident involving animal activities not supported by the PHS, NSF, NASA, or VA, and the incident is not part of a functional, programmatic, or physical area that could affect activities supported by these agencies.

Again, the AAMC believes that much of this language, while acceptable, could likely be replaced by more overarching, performance-based standards that rely on the professionalism and dedication of the IACUC and animal care specialists, and we urge OLAW and NIH to consider more extensive reforms.

We are grateful for the opportunity to provide comment, and for OLAW’s continuing engagement with the research community. Please feel free to contact me or my colleague Stephen Heinig, Director of Science Policy (sheinig@aamc.org) with questions about these comments.

Sincerely,



Ross McKinney, Jr., MD
Chief Scientific Officer

cc: David J. Skorton, MD, AAMC President and Chief Executive Officer

² <https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf>