



An Association of Research Institutions

April 28, 2023

Submitted Electronically to

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

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

**RE: *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)***

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 concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions. 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 Update to NOT-OD-05-034 Guidance on Prompt Reporting of Noncompliance to OLAW (NOT-OD-23-063)* ("RFI") in response to these mandates and values the opportunity to offer these comments. We begin by providing general comments, followed by comments on the specific items noted in the RFI.

General Comments

As noted in the RFI, both the 2016 21st Century Cures Act¹ (“Cures Act”) and the 2019 joint National Institutes of Health (NIH), U.S. Department of Agriculture Animal and Plant Health Inspection Service (USDA APHIS), and Food and Drug Administration (FDA) report [Reducing Administrative Burden for Researchers: Animal Care and Use in Research](#) (“Report”) called for review of noncompliance reporting requirements, including efforts to “refine and update examples of reportable situations, examples of situations not normally reported, the timeframe for reporting, and the information to be reported,” as well as reevaluation of the need to provide grant numbers in noncompliance reports.² Clear, unambiguous, guidance on what noncompliant events are considered reportable is essential to promoting an appropriate “signal to noise ratio” that ensures significant issues are not lost in the over-reporting and review of minor issues that do not negatively impact the health, safety, or welfare of research animals and/or that are not the result of non-compliance.

COGR members are disappointed that the extended period of review before the issuance of this RFI did not result in any substantive changes to the examples of reportable situations set forth in the 2005 Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals (“PHS Policy”) ([NOT-OD-05-034](#)) (“2005 Guidance”). Several of those examples may encompass non-serious/non-continuing instances of unintended and/or technical noncompliance that go beyond the PHS Policy requirements to report “serious or continuing noncompliance” and “serious deviation” from the provisions of the [Guide for the Care and Use of Laboratory Animals](#)³ (“Guide”). OLAW missed an opportunity to better tailor and align the examples with the PHS Policy requirements, as well as to eliminate the institutional and agency burden of reporting and reviewing isolated, non-material events.

Specific Comments on Provisions of the RFI

We offer the following comments on specific provisions of the RFI and the underlying 2005 Guidance, presented in the order in which the listed provisions appear.

(1) Background Section of RFI, Last Sentence: This sentence states: “If in doubt about whether an incident must be reported, institutions are encouraged to call OLAW to discuss the details and receive guidance on the specific incident.” COGR appreciates OLAW’s willingness to speak individually with institutions about reporting requirements for particular events, and we also appreciate that consultation is encouraged, but not required. The flexibility inherent in this approach permits institutions to primarily rely on their internal policies and procedures for IACUC and Institutional Official review, consideration, and external reporting of events, while knowing that advice from OLAW is readily available should questions arise.

¹ [Pub. L. 114-255](#). §2034(d), 130 Stat. 1033, (2016).

² Report at p. 6.

³ 8th ed. (2011).

(2) Information to be Reported: We applaud OLAW’s removal of the requirement that Public Health Service (PHS) grant numbers be routinely included in noncompliance reports. This action is an important step toward reducing unnecessary administrative burden. Unfortunately, National Science Foundation (NSF) grant numbers must still be provided, and the RFI is silent with respect to the inclusion of National Aeronautics and Space Administration (NASA) and Veterans Administration (VA) grant numbers in noncompliance reports. One of the Report’s specific directives was to consider removal of the grant number requirement. Further, such inconsistency goes against the Cures Act’s directive to NIH, FDA, and USDA APHIS to:

Identify ways to ensure such regulations and policies ***are not inconsistent, overlapping, or unnecessarily duplicative***, including with respect to inspection and review requirements by Federal agencies and accrediting associations;

Take steps to eliminate or reduce identified inconsistencies, overlap, or duplication among such regulations and policies; and

Take other actions, as appropriate. ***to improve the coordination of regulations*** and policies with respect to research with laboratory animals.⁴ (*Emphasis added.*)

Accordingly, we urge OLAW to work with the agencies for which it provides oversight – NSF, VA, NASA – to align their requirements with those of PHS and not require the provision of grant numbers. At a minimum, we recommend that OLAW provide direction as to whether VA and/or NASA grant numbers must be included in reports.

(3) Exception to Examples of Situations Not Normally Reported: COGR appreciates the examples of situations that normally need not be reported as detailed in the 2005 Guidance. We also appreciate examples provided of certain additional exceptions included in the RFI. However, some of the exceptions included in the RFI are overly broad and/or ambiguous. To this point, we offer the following suggested revisions:

- **2005 Guidance, Example of Situations Not Normally Required to be Reported:** The 2005 Guidance requires reporting of “conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and ***mechanical failures, resulting in actual harm or death to animals***,” but exempts from reporting “***infrequent*** incidents of drowning or near-drowning of rodents in cages when it is determined that the cause was water valves jammed with bedding.” (*Emphasis added*). Such events are the result of normal rodent behavior, as opposed to a sign of a non-compliant animal care and use program.

⁴ Cures Act at §2034(d)(1)-(3).

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The 2005 Guidance goes on to state that “frequent problems of this nature, . . . *must* be reported promptly along with corrective plans and schedules.” Given that the reporting exception is expressly limited to “infrequent” incidents, this exception to the exception is unnecessary and confusing, and COGR urges its deletion.

- **RFI, Additional Examples of Situations not Normally Reported:**

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

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

COGR supports OLAW’s inclusion within the list of non-reportable events of “[m]inor animal injury by conspecifics during social housing when proper introduction and subsequent ongoing monitoring occurred.” Such injuries may be the result of normal animal behavior during socialization and are not indicative of noncompliance with the Guide. However, we urge OLAW to delete the exception, which requires reporting when there is “[e]uthanasia of an animal, or injury requiring medical treatment and extended or permanent separation from the group,” because it is overly broad and unnecessary, as detailed below:

- The description of non-reportable situations is already limited to “minor” injury.
- The inclusion within the exception of any injury that requires medical treatment would mean that even application of antibiotic cream on a superficial scratch would mandate a federal report. Such requirements will result in overreporting by programs of minor issues that were properly addressed and completely unrelated to any noncompliance. The same logic applies to the exception’s inclusion of euthanasia as an indicator of noncompliance. An animal that incurs minor injuries may be euthanized because it becomes unsuitable as a study subject, thus, euthanasia alone does not mean that there was a major injury or that noncompliance occurred.
- The required reporting of extended or permanent separation of animals that were previously co-housed is puzzling because it too has no connection with any programmatic noncompliance. From time to time, any socially housed animals may have group members who are aggressive towards each other. Separating such animals is not an act of non-compliance, but rather a routine and appropriate method to prevent aggression from escalating, particularly with rodent species. In such cases,

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these animals may be housed in more suitable groups and/or receive additional types of behavioral and environmental enrichment.

Conclusion

COGR and its member institutions appreciate OLAW's efforts in response to the Cures Act and the Report to review current policies and requirements to identify ways to reduce institutional and researcher burden associated with the conduct of animal research, while ensuring the protection of research animals' health, safety, and welfare. We trust that the comments offered here will assist in those efforts, and we are grateful for OLAW's consideration of our recommendations. Please feel free to contact Kris West, Director, Research Compliance and Ethics at kwest@cogr.edu should you have any questions regarding this response.

Sincerely,

A handwritten signature in black ink that reads "M. M. Owens". The signature is written in a cursive, slightly slanted style.

Matt Owens
President