



May 2, 2023

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

RE: Request for Information (RFI) on Update to NOT-OD-05-034 Guidance on Prompt Reporting of Noncompliances to OLAW [NOT-OD-23-063]

Submitted electronically via portal and via e-mail: olaw@mail.nih.gov

Dear Dr. Brown,

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide comments on the Request for Information (RFI) ([NOT-OD-23-063](#)) seeking input on proposed changes to guidance on prompt reporting of noncompliances. As a coalition of 26 scientific member societies representing a broad range of research disciplines, we commend the National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW) and their efforts to fulfill the 21st Century Cures Act by clarifying reporting guidance originally outlined in [NOT-OD-05-034](#). Importantly, we appreciate OLAW's commitment to updating this guidance in a manner that considers ways to advance animal welfare while also providing the necessary flexibility to institutions. This approach ensures potential welfare concerns or situations are resolved quickly and effectively. In finalizing noncompliance reporting guidelines, FASEB encourages sustained commitment to the foundational principles of the Public Health Service (PHS) Policy: institutional self-evaluation, self-monitoring, and self-reporting. Furthermore, to foster a transparent and responsible research ecosystem, we urge OLAW to actively engage with the extramural research community during the guidance implementation phase. This includes disseminating final guidance through various channels, raising awareness of modifications, and providing adequate time for institutions to make appropriate adjustments before new requirements go into effect.

Please find FASEB's comments regarding proposed changes to OLAW's prompt reporting guidance below.

Information to be reported:

FASEB recommends that information required for reporting noncompliances should be material that directly impacts animal welfare or programmatic functions of the Institutional Animal Care and Use Committee (IACUC), as intended by PHS Policy IV.F.3. Accordingly, FASEB strongly agrees and appreciates the proposed change to not require the inclusion of PHS award numbers on noncompliance reports unless specifically requested by OLAW. This information does not directly affect animal well-being and is frequently exploited by outside interest groups through open records requests laws to intimidate individual investigations and institutional leadership. However, as currently written, it is

unclear why the National Science Foundation (NSF) is omitted from this new change and therefore required to provide award numbers in noncompliance reports. Disclosure of NSF award numbers would not enhance animal welfare and, more importantly, this discrepancy causes confusion for investigators that may be dually funded by PHS agencies and NSF. Therefore, this guidance is inconsistent with the 21st Century Cures Act which seeks to harmonize requirements between funding agencies and alleviate administrative burden. FASEB recommends the guidance state that award numbers are not required on noncompliance reports, regardless of funding source. Should NSF award information be required for animal welfare purposes, we recommend this be clearly justified in the final guidance to mitigate potential misunderstandings.

Similarly, FASEB encourages removing the requirement to identify the funding source on noncompliance reports to facilitate improved reporting and further streamline administrative processes. While we appreciate OLAW's goal to protect laboratory animals and assess PHS Policy effectiveness within institutional animal care programs, listing the funding source on noncompliance reports does not advance either of these objectives. In many cases, funding source identification creates difficulties for institutions. For example, several institutions combine multiple funding sources and projects into one protocol, which makes the process of specifying funding source(s) on each report both challenging and time-consuming, particularly for small and under-resourced institutions. Another institutional challenge relates to whether reporting is required for partial PHS funding such as salary support. FASEB fully supports swift reporting to OLAW as part of the scientific community's commitment to responsible research and laboratory animal welfare. However, the rationale for certain reporting requirements remains unclear and inconsistent with OLAW's mission. To simplify the reporting process and ensure it remains impartial, FASEB strongly encourages the final guidance only require items that directly impact animal welfare and/or operational IACUC functions. This includes removing the requirement to list both the award number and funding source.

Additional examples of situations not normally reported:

FASEB concurs with the proposed list of "Additional examples of situations not normally reported" and appreciates the range of potential situations that may occur. However, to minimize confusion, we encourage the final guidance to clarify the first bullet related to animal injury due to social housing. First, the term "minor" holds varying connotations in terms of the species and research involved. FASEB recommends including additional language that differentiates between "major" and "minor" injury to enable IACUCs to oversee program activities more efficiently. Secondly, while we appreciate OLAW's efforts to harmonize reporting guidance with that of the United States Department of Agriculture, FASEB is concerned that the language listed in the "exception" of the first bullet point will increase administrative burden. Given the frequency of animal injury and subsequent separation due to socially incompatible animals—particularly in rodents—requiring noncompliance reports for each instance would significantly increase the level of paperwork involved and, in turn, increase potential targeting by animal rights groups through public records requests. FASEB encourages OLAW to modify this "exception" to state that housing-related injuries are *only* reportable if there is no IACUC-approved protocol and/or institutional Standard Operating Procedure in place that addresses how to appropriately handle these occurrences. This clarification reinforces the prior statement in the bullet related to "...proper introduction and subsequent ongoing monitoring occurred" and is consistent with a central tenant of PHS

Policy on self-monitoring by emphasizing the role of the IACUC to use their professional judgment to make decisions.

Recognizing the evolving dynamics of IACUCs and institutional animal care programs, FASEB also recommends OLAW establish a mechanism that reviews the list of “reportable examples” and “non-reportable examples” once every five to 10 years. A periodic evaluation of listed examples has dual benefits. First, this process will ensure guidance aligns with the current understanding of animal biology as well as other existing recommendations, such as the *Guide*. Secondly, a review mechanism will provide an opportunity for the extramural community to share feedback on proposed updates, including potential challenges institutions face in implementing the guidelines. FASEB endorses regular engagement with the research community to ensure mutual understanding and compliance with the full range of laws and regulations overseeing research with animals.

Conclusion

FASEB commends OLAW for their continued efforts to implement changes that reduce administrative burden while maintaining sound scientific practices and optimal animal care. As stated previously, to further this aim, we encourage providing sufficient time for institutions, IACUCs, and animal care programs to make adjustments before the guidance goes into effect. Ideally, this would be approximately one year after the publication date. FASEB welcomes the opportunity to partner with OLAW to facilitate guidance dissemination and promote awareness of potential changes.

Sincerely,

A handwritten signature in black ink, appearing to read "K. Kregel". The signature is fluid and cursive, with the first name "Kevin" and last name "Kregel" clearly distinguishable.

Kevin Kregel, PhD
FASEB President