



FASEB

Federation of American Societies
for Experimental Biology

Representing Over 130,000 Researchers

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October 5, 2021

Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
BG 6700B Rockledge Drive, Room 2530
6700 B Rockledge Drive
Bethesda, MD 20817
Attn: Patricia Brown, VMD

RE: Request for Information on Clarifying the Reporting Requirements for Departures from the Guide for the Care and Use of Laboratory Animals [NOT-OD-21-161]

Submitted electronically via web portal and 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-21-161](#)) seeking input on reporting requirements for departures from the Guide for the Care and Use of Laboratory Animals (*Guide*). As a coalition of 30 life science societies representing more than 130,000 biomedical researchers, FASEB recognizes the challenge in addressing the concerns of numerous stakeholders and appreciate your efforts to communicate updated guidance in a timely fashion. The goals of the 21st Century Cures Act (CCA) Section 2034(d) to reduce administrative burden in animal research remain a key priority for our member societies, and we understand the importance of balancing this goal with consideration for animal welfare and scientific objectives. As implementation of the 21st CCA continues, we encourage the National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW) to leverage the diverse perspectives of the scientific community to ensure future policy updates consider stakeholder needs and address potential information gaps.

FASEB applauds OLAW's creation of a [designated website](#) for 21st CCA action items with relevant information on policies, laws, guidance, and resources. The reporting requirements table and flowchart located on the dedicated page, "[Departures from the Guide](#)," are particularly beneficial resources, considering this topic continues to be a significant source of confusion and administrative effort for investigators and Institutional Animal Care and Use Committee (IACUC) administrators. To further streamline communications, we strongly recommend the office collaborate with the newly established National Academies of Sciences, Engineering, and Medicine (NASEM) [Standing Committee for the Care and Use of Animals in Research](#), whose purpose, in part, is to facilitate discussion with stakeholders on potential updates to the *Guide*. Cross-organizational partnerships

will enhance communication between stakeholders and, more broadly, enable federal offices to establish parallel guidelines that foster enhanced research productivity.

FASEB offers the following comments to aid OLAW in its efforts to clarify guidance on departures from the *Guide*. A central emphasis of these comments is reporting requirements for “should” statements. These recommendations expand upon the Federation’s prior comments—including the [2017 report, *Reforming Animal Research Regulations*](#)—and serve as actionable steps agencies could take to promote regulatory efficiency, sound science, and optimal animal welfare.

Reporting in the semi-annual report to the IO is required for:

2. An IACUC-approved deviation from a should statement without a specifically described Guide exception and lacking established performance standards

Good science and humane animal care are complementary objectives. Scientists remain committed to each of these goals but are frequently hindered by the numerous conflicting, outdated, or inconsistent federal regulations. Most importantly, the majority of existing policies and guidelines do not improve animal welfare, including the requirement to report deviations from “should” statements in the *Guide* in the semi-annual report, despite receiving IACUC approval.

While the *Guide* serves as the leading standard for institutional animal care and use programs, FASEB maintains its [previously-stated recommendation](#) to amend the Public Health Service Policy IV.B.3c (and the respective FAQ, C7) and no longer consider deviations from “should” statements as reportable items. This modification is particularly necessary for IACUC-approved deviations, a redundant requirement that is inconsistent with the *Guide*’s language and intent. Per the OLAW website, the *Guide* is written broadly such that recommendations can be applied across diverse settings. Furthermore, the *Guide* defines “should” statements as “strong recommendations” for fulfilling requirements and specifically recognizes that “...*individual circumstances might justify an alternative strategy*” (pg. 8). This approach presumes that users—including scientists, IACUC members and administrators, veterinarians, and breeders—will apply professional judgment in making decisions regarding animal care protocols. Therefore, OLAW’s requirement to disclose IACUC-approved *Guide* deviations in the semi-annual report both undermines the role of IACUCs and conflicts with the purpose of the 21st CCA aimed at minimizing administrative burden and reducing duplicative policies.

In addition to increased regulatory burden, reporting IACUC-approved departures from *Guide* “should” statements does not advance animal welfare. This is particularly evident given that comparable “should” statement departures are *not* subject to semi-annual reporting, including those based on established performance standards. These standards—which vary across institutions—enable animal care and IACUC staff to accommodate the wide range of variables across research protocols. Likewise, while not a formal written standard, deviations from *Guide* “should” statements based on IACUC-approved scientific reasons still imply thorough IACUC review and justification. Moreover, IACUCs maintain detailed records of research protocols and monitor animal care standards throughout a study’s duration. Finally, it is worth noting that AAALAC International refers to “should” statement departures as “suggestions for improvement,” further demonstrating that such

departures are minor and do not negatively impact animal welfare. Taken together, given the integral role of IACUC review and the AAALAC International standards for “should” statement departures, FASEB strongly encourages OLAW to harmonize reporting requirements and eliminate reporting for all “should” statement departures. This change would significantly reduce administrative effort without compromising animal welfare.

FASEB recognizes OLAW’s responsibility to ensure compliance with animal welfare regulations and acknowledges its duty to assess policies within the context of institutional flexibility. In clarifying future policies, FASEB advises OLAW to specifically ensure guidelines provide IACUCs the latitude and discretion necessary to adjust policies according to their individual needs.

Reporting to OLAW is required for:

2b. Deviations from a should statement when not based on an established performance standard

FASEB acknowledges the importance of promptly reporting noncompliance to Institutional Officials (IOs) and OLAW to ensure swift development of correction plans. However, investigators remain confused about how much to report to OLAW due to conflicting or vague language. For example, as currently written, deviations from “should” statements not based on established performance standards must be reported to OLAW, but it is unclear whether such deviations necessitate this level of reporting even when protocols are IACUC-approved. This requirement is particularly ambiguous given that IACUC-approved deviations from “should” statements—the requirements described in the previous section—must be reported in semi-annual reports to IOs but not OLAW. While we appreciate OLAW’s endeavors to specify these distinctions in the reporting requirements table on the [Departures website](#), the example provided in the RFI about reporting items to OLAW (#2b) references IACUC approval, creating confusion for users.

As a result of this uncertainty, IACUCs and IOs frequently adopt a precautionary reporting approach, sharing more information than necessary in associated paperwork. This practice is not only burdensome and time-consuming, but the information is also liable to Freedom of Information Act (FOIA) requests, a strategy increasingly utilized by animal rights groups to target individual investigators. To mitigate the risk of anti-animal research harassment against researchers and simplify reporting expectations for investigators, FASEB strongly encourages OLAW to remove reporting requirements for all “should” statement departures.

Clear articulation of reporting requirements for departures from the *Guide* is essential to facilitate compliance and preserve research integrity. To achieve this goal, FASEB encourages the office to organize listening sessions, roundtable discussions, and workshops with research stakeholders to supplement OLAW’s existing communication efforts. This will elucidate the nuances of future guidelines and resolve shared concerns before they become a noncompliance. Additionally, since institutional practices are frequently reviewed and standardized based on ongoing performance data, FASEB recommends OLAW organize roundtable discussions specifically with IACUC administrators, attending veterinarians, and other animal care staff to ensure potential policy

modifications accommodate the unique needs and challenges associated with animal welfare. Detailed examination of performance standards and “should” statements in the *Guide* can be facilitated by collaborating with the aforementioned NASEM Standing Committee.

FASEB appreciates the opportunity to offer comments on this important topic and looks forward to future updates regarding implementation of the 21CCA. Coordinated efforts to reduce administrative burden in animal research will save valuable time and resources, permitting investigators to sharpen focus towards enhancing animal care and accelerating biomedical research progress.

Sincerely,

A handwritten signature in black ink that reads "Patricia L. Morris". The signature is written in a cursive, flowing style.

Patricia L. Morris, MS, PhD
FASEB President