



# FASEB

Federation of American Societies  
for Experimental Biology

## Representing Over 110,000 Researchers

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October 3, 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 an Update to the Current OLAW Guidance Disclaimer (NOT-OD-23-157)**

Submitted electronically via portal and e-mail: [olaw@mail.nih.gov](mailto:olaw@mail.nih.gov)

Dear Dr. Wolff,

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide comments on the Request for Information ([NOT-OD-23-157](#)) regarding updates to the Office of Laboratory Animal Welfare's (OLAW) guidance disclaimer. As a coalition of 26 member societies spanning a broad range of scientific disciplines, we appreciate OLAW's recognition that varying interpretations of guidance language can cause a significant administrative burden for institutions and their investigators. In many cases, this disproportionately affects decision-making processes for resource-limited and risk-averse institutions that view advisory language as mandatory and therefore require additional measures to mitigate potential noncompliance. Clarifying OLAW's intent in publishing guidance documents is a vital step in ensuring institutions retain the flexibility to use other strategies to comply with statutory requirements. As a result, stakeholders can devote more attention to research activities, such as finding ways to enhance animal care and welfare.

Please find FASEB's comments on the proposed revision to the current guidance disclaimer below.

Proposed Revision: *A guidance document is a statement of general applicability issued by an agency to inform the public of its policies. OLAW is responsible for advising awardee institutions concerning the implementation of the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy V.A.3.). OLAW's guidance expands upon statutory and regulatory requirements of Public Law 99-158, Sec. 495, and the PHS Policy, including incorporated references. Unless specific statutory or regulatory requirements are cited, the following guidance represents OLAW's interpretations for meeting the outcome-based requirements in the PHS Policy. However, an institution may use an alternative approach if the approach satisfies the requirements of the Policy.*

FASEB Response:

FASEB views the proposed revision to OLAW's guidance disclaimer as a positive change that clarifies the purpose of guidance documents while providing the necessary flexibility to use alternative strategies to comply with regulations. Specifically, we appreciate that the updated version provides general information that can be adapted to a broad range of institutional settings rather than using prescriptive language. Phrases included in the previous disclaimer such as "recommendations," "best practices," "advice," and "current thinking" are frequently misinterpreted as binding language, resulting in undue institutional requirements to prevent possible noncompliance. While we value institutions' prudent approach to following OLAW guidance, excessive obligations pose a substantial burden to individual investigators, Institutional Animal Care and Use (IACUC) members, and animal care staff. This decreases research productivity and diverts time away from essential animal care activities. FASEB appreciates OLAW removing such phrases and emphasizing that institutions may adopt individual approaches that suit their unique needs while fulfilling policy requirements. Ultimately, this flexible approach is consistent with the scientific community and OLAW's commitment to advance scientific research and ensure the humane care and use of animals.

Thank you for the opportunity to offer comments on the revised guidance disclaimer. OLAW's active engagement with animal research stakeholders is essential in developing updated guidance that improves policy compliance, reduces administrative burden for institutions of all sizes, and prioritizes animal welfare.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary-Ann Bjornsti". The signature is written in a cursive, somewhat stylized font.

Mary-Ann Bjornsti, PhD  
FASEB President