



**Association of
American Medical Colleges**
655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399
T 202 828 0400 F 202 828 1125
www.aamc.org

Oct. 22, 2023

Office of Laboratory Animal Welfare
Office of the Director
National Institutes of Health
Bethesda, MD

**Re: Request for Information on an Update to the Current OLAW Guidance Disclaimer,
[NOT-OD-23-157](#)**

The Association of American Medical Colleges (AAMC) appreciates this opportunity to comment to the NIH Office of Laboratory Animal Welfare (OLAW) on proposed changes to OLAW's Guidance Disclaimer. While the AAMC is pleased to see that OLAW has responded to the call to review and clarify this document, we have concerns detailed in this letter that the proposed language could erroneously imply that a guidance document itself, rather than the underlying regulations and policies, could be used by OLAW to determine an institution's noncompliance.

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.

The AAMC appreciates that OLAW is reviewing this Guidance Disclaimer, as part of its efforts to comply with the 21st Century Cures Act (P.L. 114-255) to review applicable regulations and policies for the care and responsible use of laboratory animals and "to make revisions, as appropriate, to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals." A review of the Disclaimer, which communicates important information to researchers, animal care providers and institutions about the purpose and limitations of agency policies and guidelines, was one of the recommendations of a multi-association workshop and report hosted by AAMC in 2017.¹

¹ Federation of American Societies for Experimental Biology, Association of American Medical Colleges, and the Council on Governmental Relations, with the Assistance of the National Association for Biomedical Research, [Reforming Animal Research Regulations: Workshop Recommendations to Reduce Regulatory Burden](#), 2017.

OLAW's current Guidance Disclaimer, as posted, states:

OLAW develops, monitors, and exercises compliance oversight relative to the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy). One of OLAW's primary functions is to advise awarding units and awardee institutions concerning the implementation of the PHS Policy. OLAW often provides this advice by responding to policy-related questions submitted by such units and institutions. The following Notices provide guidance that represents OLAW's current thinking on these topics. This guidance is based on OLAW's experience with the subject matter and draws on best practices followed by the biomedical community regarding the use of research animals. Unless specific statutory or regulatory requirements are cited, the Notices should be viewed as recommendations in that an institution may use an alternative approach if the approach satisfies the requirements of the PHS Policy.²

The proposed Disclaimer, with our highlights of two key sentences, more directly states:

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.

The statement, "OLAW's guidance expands upon statutory and regulatory requirements..." is problematic, as it implies guidance has the force of regulation or statute, in contradiction of the well-understood purpose of guidance documents issued by federal agencies and OLAW's earlier statements to the Health Research Extension Act of 1985 (HREA, P.L. 99-158). As colleagues at the National Association for Biomedical Research (NABR) have pointed out, the statement is also not in keeping with recent Office of Management and Budget (OMB) direction, "...guidance documents should only clarify existing obligations; they should not be a vehicle for implementing new, binding requirements..."³ We urge OLAW revise that statement, perhaps by replacing the term "expands upon" with "addresses" or "advises upon" to reflect its interpretation and advice on regulations, consistent with the Disclaimer's second sentence.

Overall, the AAMC notes appreciatively that the revised disclaimer more succinctly describes the purpose of a guidance document and OLAW's advisory responsibilities. The revision also removes reference to "current thinking" and "best practices" that was problematic for researchers, care

² <https://olaw.nih.gov/node/624>

³ OMB, Memorandum for Regulatory Policy Officers at Executive Departments and Agencies, Oct. 31, 2029, as cited by NABR.

providers, and institutions ensuring that their local circumstances comply with regulatory or statutory requirements. The AAMC strongly approves of the concluding sentences specifying that institutions may find alternative approaches yielding outcomes that satisfy policy and regulatory requirements.

The AAMC is again grateful for the opportunity to provide comments, and for continuing engagement with the research community. We also take this opportunity to thank Dr. Pat Brown, who recently retired as OLAW director, for her years of service and dedication to the protection of animal welfare and biomedical research, and to extend best wishes to Dr. Axel Wolff as acting director. We look forward to continued engagement with OLAW.

Please feel free to contact me or my colleagues, Stephen Heinig, Director of Science Policy (sheinig@aamc.org) or Heather Pierce, JD, MPH, Senior Director for Science Policy and Regulatory Counsel (hpierce@aamc.org), with questions about these comments.

Sincerely,

A handwritten signature in blue ink, appearing to read "Ross McKinney, MD". The signature is stylized and includes a circled "MD" at the end.

Ross McKinney, MD
Chief Scientific Officer

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