



October 19, 2023

RE: COGR Response to **Request for Information (RFI) on an Update to the Current OLAW Guidance Disclaimer**

*NOTE: Per OLAW's instructions, responses were limited to 500 words and required to be submitted using the OLAW-provided form with no provision for the attachment of additional files.*

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The RFI cites the report [\*Reducing Administrative Burden for Researchers: Animal Care and Use in Research\*](#) ("Report"), which correctly recognized the need for OLAW to ensure that the role of its guidance is clearly understood by the institutions it oversees. The proposed disclaimer, however, does not provide this added clarity when it states:

"OLAW's guidance expands upon statutory and regulatory requirements of Public Law 99-158 [Health Research Extension Act of 1985], Sec. 495, and the PHS Policy on the Human Care and Use of Laboratory Animals." ("Statement")

Contrary to well-established legal limits on the regulatory powers of administrative agencies, the Statement confusingly and incorrectly suggests that OLAW, *through guidance*, can add to and/or increase the requirements of the Health Research Extension Act of 1985 and the PHS Policy on Humane Care and Use of Laboratory Animals.<sup>1</sup>

The Statement also runs contrary to the Report's explicit charge that OLAW:

[R]eview its disclaimer concerning current guidance *to emphasize* that "unless specific statutory or regulatory requirements are cited, the guidance *should be viewed as recommendations* in that an institution may use an alternative approach if the approach satisfies the requirements of the PHS Policy." [*Emphasis added*].

To provide clarity regarding the scope and purpose of its guidance, we urge OLAW to abandon

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<sup>1</sup> See, generally, *West Virginia v. EPA*, 597 U.S. \_\_\_\_ (2022) ("Agencies have only those powers given to them by Congress, and 'enabling legislation' is generally not an 'open book to which the agency [may] add pages and change the plot line.'" (quoting E. Gelhorn & P. Verkuil, "Controlling *Chevron*-Based Delegations," 20 *Cardozo L. Rev.* 989, 1101 (1999)); *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000) (an administrative agency's power to regulate "must always be grounded in a valid grant of authority from Congress" and the agency "must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." (citing *U.S. v. Bacto-Unidisk* and cases cited therein, 394 U.S. 784, 800 (1969)).

the currently proposed disclaimer text and either:

- Adopt the language of the Directive as its disclaimer (i.e., “Unless specific statutory...”);  
or
- Pattern its disclaimer after those used by FDA and OHRP.

For example, the FDA guidance disclaimer succinctly states:

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

Our suggested approach will provide institutions with needed clarity regarding the scope and purpose of OLAW’s guidance, which, in turn, will help them to ensure that such guidance is appropriately employed to support vital research projects, while promoting the health, safety, and welfare of laboratory research animals.

COGR appreciates the opportunity to comment on this Request for Information. Please contact Kristin West, Director of Research Ethics and Compliance at [kwest@cogr.edu](mailto:kwest@cogr.edu) if you have questions.