



Animal Welfare Institute

900 PENNSYLVANIA AVENUE, SE, WASHINGTON, DC 20003 · 202-337-2332 · AWIONLINE.ORG

October 20, 2023

Re: Response to Request for Information (RFI) on an Update to the Current
OLAW Guidance Disclaimer, NOT-OD-23-157

Dear OLAW Staff:

The Animal Welfare Institute (AWI) appreciates the opportunity to submit comments on the proposed update to the OLAW Guidance Disclaimer. The Animal Welfare Institute is generally supportive of allowing flexibility in how animal welfare requirements are satisfied; we recognize that all situations are different and that there may be cases where alternatives could be more protective of animal welfare than those suggested by rigid guidelines. We see the value in case-by-case analysis of what is best for laboratory animals under the particular circumstances at issue, as long as the animals' welfare remains the focus of that analysis.

With regard to the proposed language "*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 Animal Welfare Institute would request the additional language set forth below:**

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 (including the requirement that any alternative would be no less protective of animal welfare than the approach suggested by the guidelines).

We believe this language would appropriately emphasize that the analysis should be centered on animal care rather than on administrative procedures. While the 21st Century Cures Act was passed in part to reduce administrative burdens, it explicitly requires the maintenance of "the integrity and credibility of research findings and protection of research animals."¹ This proposed language would also help ensure that the guidelines set by OLAW are properly understood as a *minimum* threshold for animal welfare, with investigators able to *increase* welfare standards as appropriate, and places the focus on the consequences for the animals rather than on the specific methods used.

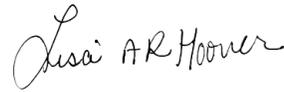
Whether or not itself binding, the language used in guidance documents must be carefully chosen as it may influence how IACUCs choose to comply with PHS Policy requirements following the 21st Century Cures Act. As noted above, we must ensure that efforts to reduce administrative burden do not reduce protections for research animals. Flexibility and use of alternatives can be used to better tailor research to species-specific needs and to strengthen research design. However, it is essential to guard against the possibility that such flexibility could improperly be used to undermine the protections required by in the applicable statutes and PHS Policy.

Thank you for your consideration.

Sincerely,



Joanna Makowska, PhD
Director & Senior Scientist, Applied Animal Behavior
Animals in Laboratories Program



Lisa Hoover, JD, MA, MLS
Senior Policy Analyst
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¹ 21st Century Cures Act, Public Law No: 114-255 §2034. Retrieved from <https://www.congress.gov/bill/114th-congress/house-bill/34>