



# FASEB

Federation of American Societies  
for Experimental Biology

## Representing Over 130,000 Researchers

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The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to review and comment on the draft report, “*Reducing Administrative Burden for Researchers: Animal Care and Use in Research.*” Overall, this report addresses the major concerns raised in our 2017 report, “*Reforming Animal Research Regulations: Workshop Recommendations to Reduce Regulatory Burden.*”

Specifically we were pleased to see the following:

- Enhancement of existing options to streamline protocol review (e.g., encouraging greater use of designated member review (DMR) for “low risk” protocols)
- USDA harmonization with PHS Policy in requiring three year de novo review of planned animal activities rather than annual review
- OLAW reevaluation and elimination of grant number submission with noncompliance reports
- USDA elimination of three year registration renewal
- OLAW provision of a minimum 60-day comment period for significant policy guidance

While the above-mentioned proposals offer significant steps forward, the way in which proposed actions are stated leaves the timelines for updates and/or implementation unclear. Therefore, FASEB recommends the report be revised to clearly indicate when the following reviews and updates will be available for public comment:

- Guidance on non-pharmaceutical grade compounds to clarify options for IACUC review
- Examples of reportable situations pursuant of NIH Guide Notice NOT-OD-05-034
- USDA policy manual, website, and policy operability to ensure conformity with AWA and NIH OLAW guidance

Requirements listed in several policies, including Policy #12 and #14, are often contradictory, leading to confusion for IACUC administrators and institutions. For example, Policy #12 strongly requires investigators to perform literature searches to demonstrate compliance with consideration of alternatives to painful/distressful procedures. However, this is inconsistent with USDA’s final rule §2.31 (d) (ii), which requires only that “The principal investigator...has provided a written...description of the methods and sources...to determine that alternatives were not available.” The emphasis on literature searches is not only a significant burden for investigators but generally a poor approach to address the underlying issue of why a specific procedure is necessary to accomplish the scientific aim. Therefore, FASEB recommends amending language in USDA Animal Care Policy #12 to be consistent with AWR§2.31 (d)(1)(ii).

In addition, FASEB does not agree that animal welfare will be negatively affected if PHS Policy IV.B.3.c were revised to ensure that “should” statements of the NAS Guide (*Guide*) are not deemed departures or deviations with respect to IACUC-approved alternatives strategies. Furthermore, the report inaccurately

states that “should” statements in the *Guide* are “standards of animal care and practiced universally.” This is inconsistent with the *Guide* language. The *Guide* defines “should” statements as “a strong recommendation for achieving a goal,” and distinguishes how certain research projects justify the use of alternative strategies. Thus, we recommend the Working Group eliminate the requirement to include such strategies in the semiannual report to the Institutional Officer (IO), and ensure these are not viewed as deviations from the *Guide*. We encourage the Working Group to provide clear examples of how alternative strategies used by IACUC will negatively impact animal welfare. A related issue is that the *Guide* only reflects knowledge on best practices at the time of its publication; there is no mechanism for updates as a function of new knowledge.

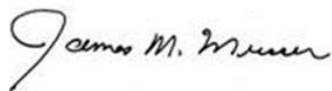
Regarding NIH Grants Policy 4.1.1.2, the report mentions that grant-to-protocol congruency is only required at the first time of award, though this is not specified on the NIH OLAW website nor the NIH Grants Policy Statement. We recommend eliminating the grant-to-protocol congruency consistent with the Common Rule for human research. The two documents are written at separate times, often months apart, and rarely display differences yet remain one of the largest burdens for investigators. Should this not be possible, we encourage NIH to clarify when grant-to-protocol congruency is required.

In response to the suggestion to apply a risk-based methodology for new and continuing protocols, FASEB disagrees with the report’s justification in using different regulation for human subject versus animal subject research. Animals used in research require 24/7 care as mandated by the AWA and the PHS Act. Such care actually offers *greater* opportunity to monitor subjects’ welfare. Thus, animal research studies should be permitted similar flexibility for exemptions and/or expedited review as human research. FASEB also encourages NIH OLAW to amend the protocol review requirements and provide examples of studies that would categorize as low-risk, noninvasive, or minimally invasive as this risk-based approach is more administratively efficient and does not compromise animal protection.

Finally, FASEB disagrees with the Working Group’s conclusion that the reduction of IACUC inspections to once per year rather than twice would negatively impact animal welfare. These inspections rarely identify “programmatic” concerns that would not have already been identified by animal care, veterinary staff, or post-approval monitoring during routine daily checks. Moreover, scheduling semi-annual inspections requires several hours of work, and must be done weeks in advance, which takes time away from the daily oversight and welfare of animals. Thus, the benefit gained from the information gathered from semiannual inspections does not outweigh the burden of scheduling and performing the review.

FASEB appreciates the opportunity to comment on the proposed actions, and encourages the Working Group to take the above comments into consideration when finalizing this important document.

Sincerely,

A handwritten signature in cursive script that reads "James M. Musser".

James M. Musser, MD, PhD  
FASEB President