FASEB
Federation of American Societies for Experimental Biology

Representing Over 130,000 Researchers

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October 1, 2019

Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
RKL 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982
Attn: Patricia Brown, VMD, MS

RE: Reducing Administrative Burden for Researchers: Animal Care and Use in Research Final Report

Dear Dr. Brown:

The Federation of American Societies for Experimental Biology (FASEB) thanks the 21st Century Cures Act Section 2034(d) Working Group (Working Group) for the development of the final report, *"Reducing Administrative Burden for Researchers: Animal Care and Use in Research."* As a coalition of 29 life science societies representing more than 130,000 biomedical researchers, we recognize the challenge in collecting and addressing the concerns of numerous stakeholders and appreciate your efforts to communicate this report in a timely fashion.

Biomedical progress and responsible animal care must be complementary objectives. Therefore, we appreciate the Working Group's commitment to balancing animal welfare oversight with streamlining administrative requirements. While your efforts to maximize public engagement throughout the two-year implementation process are laudable, the research community remains uncertain about numerous policies and thus hesitant to implement beneficial changes for fear of noncompliance. The absence of clear direction from the federal agencies for two additional years risks magnifying this problem.

As presented, the report provides interim steps towards the fulfillment of the charge defined by the 21st Century Cures Act rather than a clear plan to resolve inconsistent or duplicative policies, eliminate overlapping regulations, or other actions to improve coordination of policies pertaining to laboratory animals. Thus, while the Working Group's efforts were to coordinate oversight and collaboration among agencies, the real goal of the law – review and revision of existing policies – remains incomplete. In keeping with the Working Group's collaborative endeavors, FASEB offers the following comments and suggestions for consideration during development of an implementation strategy.

First, as highlighted in our previous comments regarding this issue, FASEB is pleased to see clarification of and opportunity for future public comments on the following issues:

- Requirements and flexibility for semi-annual inspections, consistent with USDA regulations (e.g. substitution of AAALAC site visit for semiannual evaluation)

- Acceptable mechanisms for Institutional Animal Care and Use Committees (IACUCs) protocol review (e.g. designated member review (DMR) and full committee review (FCR))
- Guidelines for IACUC reports to the Institutional Official (IO) concerning departures from the National Academies *Guide for the Care and Use of Laboratory Animals (Guide)*
- Requirements for grant-to-IACUC protocol congruence
- Examples of reportable situations, pursuant of NOT-OD-05-034

However, we remain concerned about the projected timeline and lack of focus towards review and revision of agency policies. Webinars hosted by FASEB and the Council of Government Relations (COGR) in March 2019 in coordination with representatives from NIH OLAW and USDA revealed a lack of understanding among institutions, IACUC administrators, and investigators regarding various regulations. Chief among these concerns were the following: alternatives to annual renewals for post-approval monitoring, use of estimates to statistically justify group size in accordance with The *Guide*, and protocol rewrite for triennial review.

Therefore, prior to releasing updated guidance, we encourage the agencies to issue a publicly available Frequently Asked Questions (FAQs) document to clarify and address the following common queries:

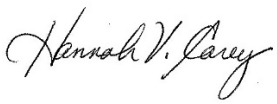
- Is NIH OLAW in favor of utilizing Veterinary Verification and Consultation (VVC) for approving significant changes to a previously approved protocol? What are the best approaches to document and incorporate VVC changes into a protocol?
- Is a veterinarian required for DMR?
- Is a veterinarian required for VVC?
- When adding an agent to a protocol, can this be done through VVC in coordination with a health/safety member, or is DMR required?
- If a veterinarian approves a modification using VVC, but the change is not something previously approved by the IACUC, is this considered a noncompliance?
- If the IACUC has pre-approved a standard procedure (SP) library, can those SPs be added by VVC, as long as the pain/distress does not increase?
- Is a protocol re-write required for triennial review? How can amendments be incorporated?
- The *Guide* indicates a statistical analysis for group size "should" be used. Are ranges/estimates acceptable?
- Is continuing review a responsibility of the Principal Investigator (PI) or IACUC? In what scenarios is it required for the PI to inform the IACUC of protocol changes?
- Per USDA guidelines, would retrospectively moving an animal into a different pain category be considered a noncompliance?

Finally, FASEB recommends publication of OLAW blog similar to those of other Institutes and Centers, such as NIH's Center for Scientific Review "Review Matters" blog, the Office of Extramural Research

"Open Mike" blog, and the National Institute of General Medical Sciences "Feedback Loop" blog, to foster regular dialog with the research community. Clear communication is consistent with NIH's mission to reach all interested stakeholders with accessible information. Likewise, frequent correspondence from OLAW through a blog or related public platform will facilitate engagement with biomedical researchers, promote understanding of Animal Welfare Act and Public Health Service Act policies, and prevent communication gaps with the animal research community.

FASEB thanks the Working Group for the development of the report and urges continued transparent engagement with animal research stakeholders to ensure clear understanding of the process. Our comments highlight our predominant concern about the agencies' timeline for implementation and discloses recommended interim actions. We recognize that many of these policies will have to be addressed at the institutional level; however, funding agencies can and should play a role in encouraging institutions to address these challenges. Similarly, it is the agencies' responsibility to fulfill the charge delineated by Section 2034(d) of 21st Century Cures Act. Please let us know how we can assist in these efforts, and we look forward to engaging with our 29 member societies to continue fostering the development of guidelines aimed at reducing administrative burden in animal research.

Sincerely,



Hannah V. Carey, PhD
FASEB President