



February 20, 2019

Patricia Brown, VMD, MS
Office of Laboratory Animal Welfare
Office of Extramural Research
National Institutes of Health, Suite 2500
6700B Rockledge Drive
Bethesda, MD 20892-6910

Re: Laboratory Animal Welfare: Draft Report on Recommendations to Reduce Administrative Burden on Researchers (83 FR 63268)

Dear Dr. Brown,

The Council on Governmental Relations (COGR) is an association of 188 public and private U.S. research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions. We appreciate the opportunity to comment on the draft report, *Reducing Administrative Burden for Researchers: Animal Care and Use in Research*.

As indicated in [Federal Demonstration Partnership's Faculty Workload Survey Research Reports](#), research involving the care and use of laboratory animals is associated with high-levels of administrative work. We appreciate agency efforts to review existing federal requirements with the goal of reducing investigator burden while maintaining the protection of research animals in accordance with section 2034(d) of the 21st Century Cures Act. The draft report acknowledges the October 2017 report by COGR, the Federation of American Societies for Experimental Biology (FASEB), the Association of American Medical Colleges (AAMC), and the National Association for Biomedical Research (NABR), *Reforming Animal Research Regulations: Workshop Recommendations to Reduce Regulatory Burden*, and addresses a number of the report's recommendations and areas that otherwise have the potential to reduce administrative burden, among them:

- NIH OLAW “plans to review and update the guidance on non-pharmaceutical grade compounds to further clarify the options for IACUC review.”
- “USDA will propose, through notice and comment rulemaking, a regulatory change to ‘remove the requirement that IACUCs conduct ‘continuing reviews of activities covered by [the Animal Welfare

Act] at appropriate intervals . . . but not less than annually,’ and, instead, insert a requirement that IACUCs conduct a three-year de novo review of activities.”

- As the term “de novo review” can be interpreted to mean that a new protocol must be submitted and as the term is not used in any other federal agency’s regulations, we would recommend that the language be revised to state that a “complete review” will be conducted at least once every three years. This would be consistent with PHS Policy IV.C.5. and further ensure burden reduction.
- “NIH OLAW and USDA plan to allow annual reporting to both agencies on the same reporting schedule...and will explore the development of a single reporting portal.”
- “NIH OLAW plans to review the guidance in NIH Guide Notice [NOT-OD-05-034](#) on reporting requirements to refine and update examples of reportable situations, examples of situations not normally reported, the timeframe for reporting, and the information to be reported. Provision of the grant number in the noncompliance report will also be reevaluated.”
 - We suggest that prompt reporting include only those incidents that jeopardize the health or well-being of animals.
- “NIH OLAW plans to review 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.’ Similarly, USDA will “include a statement in its policy manual to explain that such policies are clarifications or interpretations of the AWA and Animal Welfare Regulations, which are the only legally binding requirements.” We would suggest that disclaimers be prominently noted.
- NIH OLAW and USDA plan to engage with DOD and the VA about options for harmonizing requirements to reduce administrative burden.
- NIH OLAW “in coordination with USDA will support the continued development of industry-led training and resources”; “continue to support the efforts of the IAA to create a repository of IACUC best practices”; and “continue to support the efforts of the FDP members to create CUSP as a repository of best practices for standard procedures used for research with animals.”
- NIH will “consider updates to simplify its sample animal study protocol form.”
- “NIH OLAW, in coordination with USDA, plan to review and develop resources to support IACUCs’ use of existing options that streamline protocol review and significant changes to approved protocols without compromising animal welfare.” “The agencies plan to provide updated resources on what is exempt from IACUC review.”
 - We would further recommend that OLAW and USDA define the types of studies involving low-risk, noninvasive, or minimally invasive procedures that would be eligible for administrative or single member (expedited) review, without concurrence by the full IACUC as recommended in the report by COGR and other organizations.
- “NIH OLAW plans to allot a minimum of 60 days for comments to significant policy guidance. This will include any new interpretations of the PHS Policy, NAS Guide, or the AVMA Guidelines for the

Euthanasia of Animals. Such guidance will focus on high risk animal welfare concerns affecting institutions.”

- It is important to provide a minimum 60 days for comment for all guidance, not just the significant policy documents that are cited. Increases in administrative work can result from small incremental changes as well as more significant changes to policy and guidance.
- Regarding recommendations that USDA amend the language of Policy #12 for literature searches to be consistent with the AWA and Animal Welfare Regulations and that Policy #14 be modified to allow multiple operative procedures at the discretion of the IACUC, the draft report indicates that “The policy manual was removed from the USDA website in July 2018, and the policies are inoperative, while USDA conducts a review to ensure conformity with the AWA and Animal Welfare Regulations; harmonize with NIH OLAW guidance; and reduce investigator burden where possible.” The FASEB/AAMC/COGR/NABR [report](#) makes the following recommendations:
 - “Amend the language in USDA Animal Care Policy #12 with respect to literature searches to be consistent with AWR §2.31(d)(1)(ii), which charges the IACUC to determine “that the principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources...”
 - “Revise USDA Animal Care Policy #14 to reflect the language in AWA §2143 and AWR §2.31(d)(1)(x)(A-C), allowing approval of multiple survival operative procedures at the discretion of the IACUC and as justified for scientific and animal welfare reasons.”

COGR strongly endorses the planned efforts outlined above. We look forward to, and would emphasize the need for, additional details and the opportunity to comment on the revised guidance documents and potential rule changes proposed and would welcome a timeline for anticipated action and completion.

We would also ask that the working group reconsider their position on the following recommendations made by COGR, FASEB, AAMC and NABR in the report *Reforming Animal Research Regulations: Workshop Recommendations to Reduce Regulatory Burden*:


- Revising FAQ C7 and PHS Policy IV.B.3.c to ensure that IACUC-approved alternative strategies from ‘should’ statements in the Guide are not deemed departures or deviations and are not required to be included in the semiannual report to the Institutional Official.
 - IACUC-approved alternative strategies provide necessary flexibility while maintaining strong animal protections. Furthermore, the Guide indicates that a “should” statement “indicates a strong recommendation for achieving a goal” and the Committee recognized that “circumstances might justify an alternative strategy.” This language suggests that the authors of the Guide did not consider alternative strategies as exceptions, but rather as likely events.
- Eliminating “the requirement for verification of protocol and grant congruency in NIH Grants Policy 4.1.1.2.”

- Both the Common Rule and the NIH, through NOT-OD-19-050, have eliminated this requirement for human subjects research. As indicated in the preamble to the revised Common Rule, “The grant application is often outdated by the time the research study is submitted for IRB review and contains detailed information about the costs of a study, personnel, and administrative issues that go beyond the mission of the IRB to protect human subjects. Therefore, experience suggests that review and approval of the grant application is not a productive use of IRB time.” The same principle applies to IACUCs and animal research. While OLAW has indicated that this only needs to be done “at the first time of competitive award,” it is not clear what purpose establishing congruency serves. Institutions understand that all work with animals must be reviewed (usually in the form of a protocol). Since a single protocol may encompass more than one funding source, programmatic emphasis should be placed on ensuring that all use of animals is included on the protocol, not the proposed studies that may never be conducted because of previous results or changes in direction since the time one of the grants was written.
- Recommendations to reduce administrative burdens in parallel with reductions made in human subject research may have been misinterpreted. We agree that animal oversight differs from human oversight. Continuous husbandry, housing and medical care are required and provided. The recommendations that were made and should be considered on their merit are:
 - To increase flexibility in the protocol review process by introducing exempt and expedited-like categories that could facilitate the review process and provide IACUCs greater time to consider more complex protocols. While DMR permits this to some extent, a specific statement could help many institutions.
 - To simplify the Institutional Assurance to OLAW. The Federal Wide Assurance is fewer pages and asks that institutions assure that policies are in place to protect human subjects. The policies are not reviewed by the Office of Human Research Protection. The recommendation was that for AAALAC accredited institutions, accreditation should be considered in lieu of providing details of a previously peer-reviewed program. Harmonization of relevant questions between AAALAC and agencies would reduce overall work.
- Seek to “amend §2143(b)(3) of the AWA and §495(b)(3) of the HREA to require only an annual inspection by the IACUC. This will eliminate significant administrative work for investigators and IACUC members and allow staff to better focus their efforts on the daily oversight and welfare of animals.”
 - As indicated in the report by COGR and other organizations, these inspections are onerous and rarely identify concerns. Acknowledging that this change would require changes in the respective laws, reducing the semiannual process to annual would reduce redundant work of daily observations of animal care staff, periodic visits by post-approval monitoring staff, and the use of technology to continuously monitor distant sites.
- Engage an external advisory group, including individuals involved with oversight responsibility at the institutional level such as administrators, IACUC members, veterinarians and investigators. As agencies

proceed with plans outlined in the report we believe it would be beneficial to all parties to work together to overcome potential obstacles and ensure burden reduction.

Thank you again for the opportunity to comment on the draft report. We look forward to ongoing federal efforts to streamline, harmonize and modify regulations, policies and guidance documents governing the care and use of animals in research to reduce administrative work while maintaining strong protections, and to continued engagement on the report and proposed actions. Science and the scientific community benefit when researchers can spend more time conducting their research and animals used in research receive high standards of care. Please contact Dr. Lisa Nichols, Director, Research and Regulatory Reform at lnichols@cogr.edu with any questions or for further discussion.

Sincerely,

A handwritten signature in blue ink that reads "Wendy D. Streit". The signature is written in a cursive style with a large, stylized "W" and "S".

Wendy Streit

President, COGR