



November 14, 2017

Submitted via Regulations.gov and U.S. Mail

Office of Budget and Program Analysis
U.S. Department of Agriculture
Jamie L. Whitten Building, Room 101-A
1400 Independence Ave., SW
Washington, DC 20250

Re: Identifying Regulatory Reform Initiatives; 82 FR 32649

The Association of American Universities (AAU), the Association of Public and Land-grant Universities (APLU) and the Council on Governmental Relations (COGR) appreciate the opportunity to comment on reform opportunities with respect to USDA regulations, policy and guidance documents pursuant to USDA's request for comments and Executive Order 13777. Numerous reports^{1,2,3,4} have detailed significant administrative burden associated with federally funded research and, in particular, research involving the use of animals. Federal regulations and requirements are essential to the protection of animals used in research, but there are also overlapping, outdated, or ineffective regulations that do not improve animal welfare and make research far less efficient.

On April 17, 2017, COGR, the Federation of American Societies for Experimental Biology, and the Association of American Medical Colleges, with the assistance of the National Association for Biomedical Research, convened a workshop on reforming animal research regulations. As indicated in the report, the goal of the workshop was to provide actionable recommendations for promoting regulatory efficiency, animal welfare, and sound science. It was also aimed at helping to inform a review mandated by the 21st Century Cures Act which directs leadership of NIH, USDA, and the FDA to "complete a review of applicable regulations and policies for

¹ NIH Initiative to Reduce Regulatory Burden. 1999. Retrieved from:

<https://archives.nih.gov/asites/grants/06-17-2015/archive/grants/policy/regulatoryburden/index.htm>

² Federal Demonstration Partnership. 2012. Faculty Workload Survey Research Report. Retrieved from:

http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_087667.pdf

³ National Science Board. 2015. Reducing Investigators' Administrative Workload for Federally Funded Research. Retrieved from:

<https://www.nsf.gov/pubs/2014/nsb1418/nsb1418.pdf>

⁴ National Academy of Sciences. 2016. Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century. Retrieved from: <https://www.nap.edu/catalog/21824/optimizing-the-nations-investment-in-academic-research-a-new-regulatory>

the care and use of laboratory animals and make revisions, as appropriate, to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals.” Workshop participants, who are listed in the report, included university investigators, laboratory animal veterinarians, and administrators engaged in animal research or oversight; chairs and administrators of institutional animal care and use committees (IACUCs); directors of university animal welfare programs; accreditors; and representatives of associations with members who are engaged in animal research and oversight, including AAU and APLU.

The resulting report and recommendations, also attached here, include several recommendations specific to USDA regulations and requirements. These include the following:

- Revise §2.31(d)(5) of the AWA Regulations (AWR) as follows: “The IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, including a review as required in §2.31(d)(1-4) *at least once every three years*” (emphasis added). This would make review frequency consistent with the PHS Policy.
- 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. This will enhance the community’s efforts to reduce the number of animals involved in research.
- 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 §2.31(c)(3) of the AWR to state: “The IACUC may, at its discretion, determine the best means of conducting an evaluation of the institution’s programs and facilities that includes all members wishing to participate in the process. The IACUC may invite ad hoc consultants to assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report.” This would be consistent with HREA §495(b)(3)(A) which requires a “review...in all animal study areas and facilities” but does not require the participation of two IACUC members.
- USDA should consider including AAALAC International accreditation as a factor in their [inspection] risk assessment.
- NIH and other federal agencies [USDA and FDA] involved in the review of regulations and policies for the care and use of laboratory animals mandated by the 21st Century Cures Act (Cures) should appoint an external advisory group of experts engaged in animal research from entities that receive federal research awards to serve as advisors. The advisory group should include those involved with oversight responsibility at the institutional level, such as institutional administrators, IACUC members, veterinarians, and investigators engaged in animal research. This will foster progress and impartiality in the conduct of this review, which should take into account relevant regulations, policies, and guidance, along with the recommendations of this and other reports that have addressed regulatory burden associated with animal research. The committee could be designated an “expert subcommittee” of the

Research Policy Board mandated by Cures. Agencies might also consider a permanent animal research advisory group modeled after the Department of Health and Human Services Secretary's Advisory Committee on Human Research Protections.

- As part of the review mandated by Cures, all current Public Health Service (PHS) and USDA regulations, policies, guidance documents, FAQs, and interpretive rules, as well as the process for generating them, should be reviewed by an external advisory group of experts engaged in animal research from entities that receive federal research awards. This group should include those involved with oversight responsibility at the institutional level, such as institutional administrators, IACUC members, veterinarians, and investigators engaged in animal research. The purpose of this review should be to ensure that these documents emphasize matters of core importance to animal welfare identified in HREA and AWA statutory language and are consistent with current scientific and technological knowledge and approaches.
- NIH and USDA should establish a risk-based process for review of animal research protocols similar to that for human subjects research under 45 CFR 46; §46.110. Through issuance of a Notice in the Federal Register similar to the NIH Notice issued in 2014 regarding Significant Changes (NOT-OD-14-126), USDA and the NIH Office of Laboratory Animal Welfare (OLAW) could amend the protocol review requirement to define types of studies involving low-risk, noninvasive, or minimally invasive procedures. These studies could then be deemed exempt from full IACUC consideration or eligible for administrative or single member (expedited) review, without concurrence by the full IACUC.

Additional information is included in the report with respect to each recommendation. If implemented, the proposed changes would render federally funded research far more efficient while maintaining essential standards of care.

We appreciate the opportunity to comment on USDA regulatory requirements and remain available for questions or additional discussion on the comments and recommendations included in this letter and report. Please contact [Lisa Nichols](#) at COGR with questions.

About the Signatory Associations

The Association of American Universities is an association of 60 U.S. and two Canadian preeminent research universities organized to develop and implement effective national and institutional policies supporting research and scholarship, graduate and undergraduate education, and public service in research universities. The Association of Public and Land-grant Universities (APLU) is a research, policy, and advocacy organization with a membership of 235 public research universities, land-grant institutions, state university systems, and affiliated organizations in the U.S., Canada, and Mexico, that is dedicated to strengthening and advancing the work of public universities. The Council on Governmental Relations (COGR) is an association of over 190 leading research universities and affiliated academic medical centers and independent research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions.