



Council On Governmental Relations

*An Association of Research Institutions*

November 13, 2020

U.S. Department of Agriculture  
Animal and Plant Health Inspection Service (APHIS)  
Docket No. APHIS-2019-0001  
Regulatory Analysis and Development, PPD, Station 3A-03.8  
4700 River Road, Unit 118  
Riverdale, MD 20737-1238

*Submitted via Email Submission to Federal eRulemaking Portal at:  
<http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0001>*

**Subject: Comments Submitted in Response to the Proposed Rule Published on September 17, 2020 –  
*AWA Research Facility Registration, Updates, Reviews, and Reports***

To Whom It May Concern:

The Council on Governmental Relations (COGR) is an association of 190 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. One area of significant interest and expertise among COGR member institutions is ensuring the integrity of basic and applied animal research. This research enables fundamental knowledge that leads to new treatments and insights to improve human and animal health.

COGR appreciates the opportunity afforded by the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) to comment on the proposed rule amending Animal Welfare Act (AWA) regulations governing research facilities. This proposed rule, entitled *AWA Research Facility Registration, Updates, Reviews, and Reports*, was published in the Federal Register on September 17, 2020 ([85 FR 57998](#)) ("Proposed Rule").

### **General Comments on the Proposed Changes**

COGR member institutions take very seriously the obligation to protect the health, safety, and welfare of animals used in research, and they have rigorous animal care and use programs to ensure compliance with AWA regulations governing research facilities ([9 CFR Part 2, Subpart C](#), hereafter "Research Facility Regulations"), as well as all other federal, state and local requirements. The commentary to the Proposed Rule describes USDA's efforts to review the Research Facility Regulations and propose changes that "reduce duplicative requirements and administrative burden on research facilities" while maintaining "research integrity and oversight, and [ensuring] that research animals continue to receive humane care." COGR applauds these efforts because when unnecessary regulatory requirements are eliminated, animal research facilities can redirect resources toward

measures that directly and meaningfully advance scientific research and measures to ensure the welfare of the animals used in that research.

### **Comments on Specific Proposed Changes**

Below are comments regarding the Proposed Rule's specific changes to the Research Facility Regulations.

- **Registration of Research Facilities:** COGR fully supports the Proposed Rule's elimination of the requirement under 9 CFR §2.30(a)(1) that research facilities renew their registration every three years. As noted by the USDA in the commentary regarding this change, research institutions are already required to provide the USDA with notice of any changes to their name, address, ownership, or operations affecting their status as a research facility within ten days after such a change. COGR also supports the proposed change to 9 CFR §2.30(c)(1) that permits institutions to use APHIS Form 7033-Notification of Change to submit such changes. Removal of the registration renewal provision eliminates an unnecessarily duplicative administrative requirement.
- **Elimination of Provision that Permits Research Facilities to Request Inactive Status:** The Proposed Rule would eliminate the provision under 9 CFR §2.30(c)(2) that permits institutions that have not used/handled/transported animals for at least two years to request to be placed on inactive status. Although the removal of this provision eliminates an option for research facilities, it is an option that is rarely used by COGR member institutions. Further, this provision places continuing administrative burden both on the research facility, which is still required to file an annual report, and on the USDA, which must still retain oversight for the facility. The Proposed Rule's requirement that a research institution either be registered or unregistered provides a simpler and more efficient regulatory process for both the USDA and research institutions.
- **Duration of Registration and Cancellation:** The Proposed Rule adds a new provision to §2.30(d)(2) that states the Deputy Administrator "may cancel a registration on its own without a written request from the research facility" if the Deputy Administrator "has reason to believe that a research facility has ceased to function as a research facility." Although COGR has no objection to this new provision in principle, it respectfully requests that the USDA provide a more tangible standard for cancellation of a registration than "has reason to believe." One potential standard for consideration is cancellation when the Deputy Administrator "has developed credible evidence that demonstrates a research facility has ceased to function as a research facility." Additionally, COGR requests that the standard be revised to include a provision by which a facility can contest or appeal the cancellation of a registration that it believes has been made in error.
- **IACUC Review of Activities Involving Animals:** COGR fully endorses the Proposed Rule's amendment of 9 CFR §2.31(d)(5) to eliminate the requirement for annual continuing review of research activities involving animals and replace it with a requirement that the IACUC perform a "complete review of approved activities at appropriate intervals as determined by the IACUC, but not less than every 3 years."

Annual review of research protocols that involve animals covered under the AWA requires considerable IACUC effort and resources. Yet, the annual review process does little to provide much in the way of additional protections for research animals because the IACUC continues to have responsibility for reviewing significant changes in ongoing activities [9 CFR §2.31(d)(1)]. Elimination of the annual review requirement will enable the IACUC to reallocate oversight resources to more meaningful continuous monitoring activities and researcher education and training. This change also eliminates significant burdens on investigators by permitting them to reallocate to their scientific endeavors the time they would otherwise have spent on the paperwork associated with annual review. Further, in the case of protocols that are particularly novel or risky, the Proposed Rule provides the IACUC with the discretion to require continuing review at shorter intervals as necessary to ensure animal health, safety, and welfare. Finally, as noted in the commentary to the Proposed Rule, this change harmonizes USDA requirements with requirements for continuing review under the [\*Public Health Service Policy on Humane Care and Use of Laboratory Animals\*](#).

- **Annual Report:** Finally, COGR also supports the Proposed Rule's changes to 9 CFR §2.36(a) to eliminate the requirement for the research facility's chief executive officer (CEO) or institutional official (IO) to sign paper copies of the annual report and to permit the facility administrator to electronically submit the annual report on behalf of the CEO or IO. Electronic documentation and signatures have become the standard in the majority of business operations, and as the COVID pandemic has amply demonstrated, the use of electronic documentation and signatures is frequently a critical component of most institutions' contingency planning for their animal care and use programs.

## Conclusion

COGR members support the USDA's efforts to review regulations and policies concerning the care and use of laboratory animals and make necessary revisions to reduce administrative burden, while ensuring appropriate protections for animals' health, safety, and welfare. COGR believes that the Proposed Rule is an extremely important step in this process, and we appreciate the opportunity to comment on the Proposed Rule and voice our support for it. Please contact Kristin West, Director of Research Ethics and Compliance at [kwest@cogr.edu](mailto:kwest@cogr.edu) if you have any questions.

Sincerely,



Wendy D. Streit  
President