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Executive Director*

November 13, 2020

Dr. Kay Carter-Corker

Director, National Policy Staff

Docket No. APHIS-2017-0062

Regulatory Analysis and Development, PPD

APHIS, Station 3A-03.8

4700 River Road Unit 118

Riverdale, MD 20737-1238

RE: Docket No. APHIS-2019-0001- AWA Research Facility Registration
Updates, Reviews, and Reports

Dear Dr. Carter-Corker:

Public Responsibility in Medicine and Research (PRIM&R) appreciates the opportunity to comment on the United States Department of Agriculture's notice of proposed rulemaking and request for comments that appeared in the *Federal Register* on September 17, 2020, to amend the Animal Welfare Act (AWA) regulations governing research facilities by removing duplicative and unnecessary information requirements.

PRIM&R is a nonprofit organization dedicated to advancing the highest ethical standards in the conduct of research. Since 1974, PRIM&R has served as a professional home and trusted thought leader for the research protections community. Through educational programming, professional development opportunities, and public policy initiatives, PRIM&R seeks to ensure that all stakeholders in the research enterprise appreciate the central importance of ethics to the advancement of science. We serve the animal research community, specifically, by providing professional and educational support to members and staff of Institutional Animal Care and Use Committees (IACUCs) in their critical work of ensuring the ethical care and use of research animals.

PRIM&R agrees with the USDA's assessment that the changes proposed would reduce duplicative requirements and administrative burden on research facilities while maintaining research integrity and oversight. We are pleased to see that the USDA, NIH, and FDA are working together to find ways to align their rules to reduce administrative burden on investigators as outlined in the 21st Century Cures Act.

Registration of Research Facilities – We agree that the requirement for research facilities to update their registration every three years is burdensome and is covered by the requirement to notify the USDA of any changes within 10 days of the change. Eliminating this requirement will decrease administrative burden on the research facilities as well as USDA, allowing the USDA to focus on new applications and submitted changes.

We also support both the proposed elimination of the inactive status category and fees for reinstatement. We encourage the USDA to ensure that the process of reinstatement is performed as quickly as possible so as not to delay research.

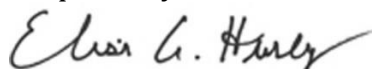
We are concerned about the provision that the Deputy Administrator may initiate a cancellation of a research facility's registration, and advise that the final language in the regulations should make clear how a facility would come to the attention of the Deputy Administrator (e.g., multiple contact attempts, no activity at the physical address), as well as how the USDA would formally notify the facility that its registration was under consideration to be cancelled or was cancelled.

IACUC Review of Activities Involving Animals – We are highly supportive of the change to section 2.31(d)5 to remove the annual review of activities and replace it with a complete review not less than every three years. This change harmonizes the AWA regulations and the PHS policy regulations enforced by OLAW and will ultimately reduce burden on the investigators and the IACUC. We believe that substantial shifts in experimental procedures and care of animals will be captured with the every-three-year complete review. Outside of this change, IACUCs also will continue to provide oversight of research and animal welfare through: requiring daily assessment of animals and provision of veterinary care; review and approval of any significant changes; review of adverse event reports; and semi-annual program and facility reviews. In addition, the IACUC still maintains the authority to review the protocol or any aspect of the research or care of the animals at any time, should there be a concern.

Annual Report – We are supportive of the proposed change in requirement for a hard copy signature of the CEO or IO on the annual report. With the move to digital submission, and in the age of COVID-19 restrictions and remote working rules, it is burdensome and unnecessary to require hard copy signatures.

Thank you again for the opportunity to comment. PRIM&R stands ready to provide any further assistance or input that might be useful during this process. Please feel free to contact me directly at 617.303.1872 or ehurley@primr.org.

Respectfully submitted,



Elisa A. Hurley, PhD, Executive Director

cc: PRIM&R Public Policy Committee, PRIM&R Board of Directors