DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Laboratory Animal Welfare: Coordination and Harmonization of Regulations and Policies

AGENCY: National Institutes of Health, HHS.

ACTION: Notice; request for comments.

SUMMARY: The National Institutes of Health (NIH) is seeking information to improve the coordination of regulations and policies with respect to research with laboratory animals as required by the 21st Century Cures Act, Section 2034(d). The request for information is a coordinated effort of the Director of the National Institutes of Health in collaboration with the Secretary of Agriculture and the Commissioner of Food and Drugs to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals.

DATES: The Request for Information regarding the proposed actions that the agencies have identified to improve coordination and harmonization of regulations and policies is open for public comment for a period of 90 days. Comments must be submitted electronically at *https://grants.nih.gov/grants/rfi/rfi.cfm?ID=71* and must be received by June 12, 2018 to ensure consideration.

FOR FURTHER INFORMATION CONTACT: Patricia Brown, Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research, National Institutes of Health, Suite 360, 6705 Rockledge Drive, Bethesda, MD 20892–7982, phone: 301–496–7163, email: *olaw@od.nih.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This request for information is a coordinated effort of the Director of the National Institutes of Health in collaboration with the Secretary of Agriculture and the Commissioner of Food and Drugs to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals.

Section 2034(d) of the 21st Century Cures Act (Pub. L. 114–255) was enacted December 13, 2016 and requires that the NIH in collaboration with the United States Department of Agriculture (USDA) and the Food and Drug Administration (FDA) complete a review of applicable regulations and policies for the care and use of laboratory animals and make revisions to reduce administrative burden on investigators. In carrying out this effort, the law requests that NIH seek put to identify ways to ensure regulations and policies are not inconsistent, overlapping, or unnecessarily duplicative.

In carrying out the review, NIH OLAW, USDA, and FDA are currently reviewing the following reports and surveys:

- Reforming Animal Research Regulations: Workshop Recommendations to Reduce Regulatory Burden, 2017, Report of an April 17, 2017 workshop organized by Federation of American Societies for Experimental Biology (FASEB), the Association of American Medical Colleges, and the Council on Governmental Relations, with support from the National Association for Biomedical Research, *http://www.faseb.org/Portals/2/PDFs/opa/2017/FASEB-Animal-Regulatory-Report-October2017.pdf.*
- Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century, 2016, National Academies, *https://www.nap.edu/catalog/21824/optimizing-the-nations-investment-in-academic-research-a-new-regulatory.*
- Reducing Investigators' Administrative Workload for Federally Funded Research, 2014, National Science Board, National Science Foundation, *https://www.nsf.gov/pubs/2014/nsb1418/nsb1418.pdf.*
- 2012 Faculty Workload Survey Research Report, 2014, Federal Demonstration Partnership (FDP), *https://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_087667.pdf.*
- Findings of the FASEB Survey on Administrative Burden, 2013, FASEB, *http://www.faseb.org/portals/2/pdfs/opa/6.7.13%20FASEB%20NSB%20Survey%20findings.pdf.*

We are seeking the input of interested stakeholders concerning proposed actions that the agencies have identified to improve coordination and harmonization of regulations and policies. The responses received will provide critical information for final recommendations and implementation.

II. Information Requested

Input is sought on each of the following proposed actions that the agencies are considering:

1. Allow investigators to submit protocols for continuing review using a risk-based methodology.
2. Allow annual reporting to OLAW and USDA on the same reporting schedule and as a single report through a shared portal.
3. Harmonize the guidance from NIH and USDA to reduce duplicative considerations of alternatives to painful and distressful procedures.
4. Provide a minimum 60-day comment period for new OLAW policy guidance.
5. Other approaches not previously mentioned.

Feedback is sought on whether the following tools and resources are or would be helpful for reducing burden on investigators:

1. Encourage the use of sections of the AAALAC International program description in applicable parts of the OLAW Animal Welfare Assurance, for institutions accredited by AAALAC International.
2. Encourage the use of the FDP Compliance Unit Standard Procedures as a repository of best practices for standard procedures used for research with animals.
3. Encourage the use of the IACUC Administrators Association repository of best practices by IACUCs.
4. Encourage the use of new or existing tools to streamline protocol review through use of designated member review (DMR), DMR subsequent to full committee review, and/or Veterinary Verification and Consultation.
5. Expanded IACUC training activities that focus on reducing burden on investigators.

Dated: March 8, 2018.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2018–05173 Filed 3–13–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant