



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Laboratory Animal Welfare: Draft Report on Recommendations to Reduce Administrative Burden on Researchers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice; request for comments.

SUMMARY: The National Institutes of Health (NIH) is seeking input on the draft report by the 21st Century Cures Act Working Group on Reducing Administrative Burden to Researchers for Animal Care and Use in Research. The draft report 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. It describes the proposed actions that the working group has identified 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 working group has identified is open for public comment for a period of 60 days. Comments must be submitted electronically at <https://grants.nih.gov/grants/rfi/rfi.cfm?ID=83> and must be

received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure consideration.

FOR FURTHER INFORMATION CONTACT: Patricia Brown, Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research, National Institutes of Health, Suite 2500, 6700B Rockledge Drive, Bethesda, MD 20892-6910, 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 seek input on the draft report by the 21st Century Cures Act, Section 2034(d) Working Group on Reducing Administrative Burden to Researchers for Animal Care and Use in Research.

Section 2034(d) of the 21st Century Cures Act (P.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. NIH OLAW, USDA, and FDA formed a Working Group to: (1) identify overlapping regulations and policies; (2) take steps to reduce such identified regulations and policies; and (3) take actions to improve coordination, as directed by the US Congress. Input is

sought on the draft report of the Working Group and others within the federal government and the proposed recommendations to reduce the administrative burden associated with research activities with laboratory animals while maintaining appropriate protections and scientific integrity. The draft report is available at https://olaw.nih.gov/sites/default/files/21CCA_draft_report.pdf.

Dated: November 16, 2018.

Francis S. Collins,

Director,

National Institutes of Health.

[FR Doc. 2018-26557 Filed: 12/6/2018 8:45 am; Publication Date: 12/7/2018]