



DEPARTMENT OF HEALTH & HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Office of Laboratory Animal Welfare
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February 5, 2020

To: Office of Management and Budget (OMB)

Through: Mikia P. Currie, Project Clearance Chief, NIH

From: Eileen M. Morgan, Director, Division of Assurances
NIH OD/OER/OLAW

Subject: Non-Substantive Change Request for 0925-0765
Title: Assurance (Interinstitutional, Foreign, and Domestic) and Annual Report.
Expiration Date: November 30, 2022

The NIH Office of Laboratory Animal Welfare (OLAW) requests OMB approval of non-substantive changes to two forms from our current OMB Clearance 0925-0765, the Domestic Assurance form and the Annual Report to OLAW form. These forms were recently approved for use by OLAW to collect information from institutions conducting research, testing, and training involving animals with Public Health Service (PHS) funds. These forms enable collection of required information necessary for OLAW to provide institutional oversight according to the PHS Policy on Humane Care and Use of Laboratory Animals and the Health Research Extension Act (HREA) of 1985.
https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201909-0925-002.

There are three changes on the Domestic Assurance form. The first change adjusts numbering (A, B, C to A.1., A.2., B) to emphasize the distinction between the information to be provided by the respondent. The change results in grouping the first two responses so entities that are part of the institution are listed under part A and only other institutions are listed in B. There is no change to the information requested and no additional burden on the respondent as a result of this proposed change.

The second change implements recommendations of the 21st Century Cures Act Sec. 2034(d) Working Group as outlined in the final report, Reducing Administrative Burden to Researchers for Animal Care and Use in Research https://olaw.nih.gov/sites/default/files/21CCA_final_report.pdf. To harmonize with the U.S. Department of Agriculture (USDA) reporting period and annual report deadline, specified in the Animal Welfare Act and Animal Welfare Regulations, the change adjusts the NIH OLAW reporting period from the calendar year to the federal fiscal year and adjusts the annual report deadline to OLAW from January 31 to December 1. Syncing the reporting period and due date for USDA and NIH OLAW reports will minimize time devoted to the collection of reporting data. Institutional Animal Care and Use Committees and investigators will be less burdened with administrative actions and able to attend to their animal welfare and research responsibilities. There is no change to the information requested and no increase in burden on the respondent as a result of this proposed change.

The third change on the Domestic Assurance form provides additional detail to clarify the criteria for the nonaffiliated committee member. The change assists respondents in assessing fulfillment of membership requirements and provides consistent guidance with information that is currently provided in the

previously issued NIH Guide Notice NOT-OD-15-109 and on the OLAW Frequently Asked Questions website. There is no change to the information requested and no increase in burden on the respondent as a result of this proposed change.

There are two changes on the Annual Report to OLAW form. The first change updates the hyperlink for the accrediting body, AAALAC, because the original link is no longer functional. The second change is the same as the third change described for the Domestic Assurance form since the committee roster and criteria for membership requirements is provided for institutions to submit any membership updates in the Annual Report to OLAW. There is no change to the information requested for either change and no increase in burden on the respondent as a result of this proposed change.

Enclosed is a copy of the Domestic Assurance with proposed changes, Domestic Assurance with proposed changes in red font, Annual Report to OLAW with proposed changes, and Annual Report to OLAW with proposed changes in red font.

Please let me know if you have any questions.

Sincerely,

Eileen M. Morgan
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