



**DEPARTMENT OF HEALTH & HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH**

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June 2, 2025

To: Office of Management and Budget (OMB)

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

From: Jane J. Na, 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: January 31, 2027

The National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW) requests OMB approval of non-substantive changes to the Foreign Annual Report form from information collection 0925-0765 that was last approved on January 10, 2024. The Foreign Annual Report is one of several forms previously 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 (Policy) and the Health Research Extension Act (HREA) of 1985. The PHS Policy requires that institutions conducting PHS-funded research, testing, and training involving animals have an approved Animal Welfare Assurance (Assurance) on file with OLAW. Institutions complete an Assurance form that OLAW reviews and once it is found to be acceptable, it can be approved. The institution is required to submit an Annual Report to OLAW as long as they have an approved Domestic or Foreign Assurance.

https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202310-0925-002.

There are four types of changes on the Foreign Annual Report form. The changes include addition of instructional text, addition of prompts for institutions to provide agency-level information regarding current funding, clarifications via word order changes or reduction of words, and addition of examples to clarify requested information. All changes aim to reduce burden on institutions and NIH OLAW personnel by minimizing follow-up communications required for form completion to enable OLAW review and acceptance of the Foreign Annual Report.

Regarding changes that add instructional text, the first addition recommends that the foreign institution refer to the currently approved Foreign Assurance document and any previously submitted Foreign Annual Report. This will help institutions provide consistent information across institutional

documentation to reduce the need for OLAW to request clarification when information provided on the Foreign Annual Report is inconsistent with other documents. The second addition of instructional text is included with item “VI. Description of Oversight” to explain that institutions should only respond if their Foreign Assurance approval occurred after June 1, 2024. Only these Foreign Assurances include institutional responses to the newly added Assurance form section “Description of Oversight,” and if institutions haven’t provided OLAW with this description, there are no changes to the “Description of Oversight” available to be reported on the Foreign Annual Report. The Description of Oversight is a newly added section on the OMB-approved Foreign Assurance form that requests a description of the institution’s oversight and responsibilities related to activities involving live, vertebrate animals. To maintain a manageable workload for OLAW personnel related to Foreign Assurance and Foreign Annual Report document review, foreign institutions are providing the Description of Oversight on the new Foreign Assurance form as new and renewal Foreign Assurances are required. The renewal process for approved Foreign Assurances occurs if the foreign institution is still conducting live, vertebrate animal activities that are funded by eligible funding agencies prior to expiration; the period of Assurance approval may be no longer than five years. Eligible funding agencies include all PHS entities and entities that agree to comply with PHS Policy and have a Memorandum of Agreement with OLAW such as the National Science Foundation (NSF) and National Aeronautics and Space Administration (NASA). Although institutions were not previously required to include a description of their oversight in their Foreign Assurance, providing oversight is not a new requirement since foreign institutions obtaining a Foreign Assurance must commit to the International Guiding Principles for Biomedical Research Involving Animals https://olaw.nih.gov/sites/default/files/Guiding_Principles_2012.pdf which states that a system of animal use oversight should be implemented in each country. The added instructions on the Foreign Annual Report are intended to reduce burden on OLAW staff and institutions by preventing the necessity for additional communications to provide clarifications and obtain a revised Annual Report. There is no change to the information requested and no increase in burden on the respondent as a result of these proposed changes.

In “I. Funding,” options were added for institutions to provide agency-level information regarding current PHS funding. An approved Assurance is only required if an institution is conducting live, vertebrate animal activities that are funded by the PHS, NSF, or NASA. PHS components include the Biomedical Advanced Research and Development Authority (BARDA), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and NIH, but the OLAW staff only have direct access to grants and cooperative agreements information for NIH so knowing which funding entities the institution states they are conducting animal work for assists staff with following up with funding entities to determine eligibility for renewal of the Foreign Assurance. Foreign institutions that are not conducting animal work for eligible funding entities will not undergo Assurance renewal. The information requested on the Foreign Annual Report form is essentially the same information as previously requested, but the change requests that their response specify the PHS funding component(s) involved instead of just indicating PHS funding. This is information the institution already has, so there is no significant change to burden on the respondent as a result of this proposed change.

Clarifications via word order changes or reduction of words are the most frequent type of change on the Foreign Annual Report form and do not change the meaning of the text. These changes appear in “III. Accreditation,” “IV. Certification,” “V. Institutional Commitment,” “VI. Description of Oversight,” and “IX. Other Changes.” The word order changes and word reductions have been made to provide clearer

information to obtain accurate information. There is no change to the information requested and no increase in burden on the respondent as a result of these proposed changes.

Addition of examples to clarify requested information appear in “VII. Authorized Institutional Official,” “VIII. Institutional Contacts,” and “X. Signature.” With last year’s Foreign Annual Reports, we identified that institutions sometimes provide the last name first and the first name second, so to reduce confusion over the order of names being provided, “(First, Last)” was added to every instance of “Name” when prompting for an individual’s name. Last year, we also noted that people with degrees/credentials do not provide this information and when prompted with examples to demonstrate what information was being requested, appropriate responses are generally provided. To reduce the follow up communication necessary to obtain the requested information, examples “(e.g., M.D., Ph.D.)” were added to every occurrence when prompted for Name and Credentials. There is no change to the information requested and no increase in burden on the respondent as a result of these proposed changes.

In addition to the four types of changes, the footer on each page of the Foreign Annual Report form is updated from v2023 to v2025 to assist OLAW personnel identify the version of the document.

Enclosed is a copy of the Foreign Annual Report to OLAW with proposed changes, and Foreign Annual Report to OLAW with proposed changes in track changes.

Please let me know if you have any questions.

Sincerely,

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National Institutes of Health
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