

Supporting Statement A for

Assurance (Interinstitutional, Foreign, and Domestic) and Annual Report. OD.

OMB Number 0925-0765 and Expiration Date: 11/30/2022

Date: October 30, 2023

Check off which applies:

- New
- Revision
- ✓ Reinstatement with Change
- Reinstatement without Change
- Extension
- Emergency
- Existing

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ATTACHMENTS

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A. Justification

Abstract: The Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research, Office of the Director, National Institutes of Health (NIH) is requesting approval for a **reinstatement with change** for the information collection requirements of the Paperwork Reduction Act of 1995. The purpose of the Assurance (Interinstitutional, Foreign, and Domestic) and Annual Report is to provide OLAW with documentation to satisfy the requirements of the Health Research Extension Act (HREA) of 1985 (Public Law 99-158 section 495 as codified in 42 U.S.C. 289d), illustrate institutional adherence to Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), and enable OLAW to carry out its mission to ensure the humane care and use of animals in PHS-supported research, testing, and training, thereby contributing to the quality of PHS-supported activities. **Delay of the submission for OMB approval was multifactorial and due to human error and unforeseen circumstances including personal illness.** Office of Management and Budget (OMB) approval is requested for 3 years.

A.1 Circumstances Making the Collection of Information Necessary

The Health Research Extension Act (HREA) of 1985 (Public Law 99-158 section 495 as codified in 42 U.S.C. 289d) states that the Director of NIH shall require each applicant for a grant, contract, or cooperative agreement involving research on animals that is administered by the NIH or any national research institute to provide assurances satisfactory to the Director of NIH that the applicant meets the requirements of the guidelines established in section 495 and has an animal care committee that meets the requirements of section 495. In addition, 42 CFR 52.8 states that the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) applies to all health-related research project grants administered by the PHS or its components. The PHS Policy section IV.A. defines the required elements to be included in written Assurances and Annual Reports to meet 42 U.S.C. 289d legal requirements.

OLAW is responsible for the implementation, general administration, and interpretation of the PHS Policy as codified in 42 CFR 52.8; the PHS Policy implements the HREA. The PHS Policy requires entities that conduct research involving vertebrate animals using PHS funds to have an Institutional Animal Care and Use Committee (IACUC), provide assurance that requirements of the Policy are met, and submit an annual report. **Institutions in foreign countries comply with PHS Policy or provide evidence that acceptable standards will be met.** An institution's animal care and use program is described in the Animal Welfare Assurance (Assurance) document and sets forth institutional compliance with PHS Policy.

A.2 Purpose and Use of the Information Collection

Institutions conducting research, testing, and training involving animals with PHS funds will continue to complete the Assurance and Annual Report forms which provide a uniform, organized format for efficiency of document completion and review. As required documents for compliance with PHS Policy and the HREA, the Assurance documents (Domestic, Foreign, and Interinstitutional) describe institutional compliance and Annual Reports (Domestic and Foreign) provides the institutions the opportunity to inform OLAW of changes to the institution's program for animal care and use. This request is for approval of a reinstatement with change with edits to existing documents and addition of new documents for three years.

In this submission, documents from the original OMB-approval have minimal edits that provide clarification on instructions for increased efficiency of completion and review. Edited documents are Attachment 1: Domestic Annual Report; Attachment 2: Domestic Assurance; Attachment 4: Foreign Assurance; Attachment 5: Interinstitutional Assurance for Domestic Performance Site; and Attachment 6: Interinstitutional Assurance for Foreign Performance Site. Section A.15 provides additional detail regarding the edits. Note: Regarding the two types of Interinstitutional Assurance forms, there is one form for Domestic Performance sites and a separate form for Foreign Performance sites due differences in the expected oversight since the laws, regulations, and policies in foreign countries differ from those of domestic institutions.

Since OMB approval of the initial documents was granted, the PHS Policy and HREA remain unchanged and a small change in the Animal Welfare Act and Regulations was made that allows an institution's animal care and use committee to eliminate annual protocol reviews and complete a full protocol review every three years which is consistent with PHS Policy requirements. This eliminated one previously included prompt for a description of the annual protocol review procedures in Attachment 2: Domestic Assurance. Of the existing documents, Attachment 4: Foreign Assurance included several new sections. A section specifying that foreign institutions will report compliance issues to OLAW is added to emphasize this existing expectation of all foreign institutions. Next, a description of items to be included in the Annual Report to OLAW has been added to Attachment 4: Foreign Assurance since institutions with Foreign Assurances and any future institutions that obtain Foreign Assurances will be required to submit an Annual Report to OLAW to better align with domestic institution requirements who already submit an Annual Report to OLAW. The final addition to Attachment 4: Foreign Assurance is a new section that requires the institution to provide a description of the oversight of the animal activity that is being conducted at their institution. This is a new section to the document, but it not a new requirement since animal activity oversight is already being provided. The additional section prompts the institution to provide a description of this oversight. Review of this additional information will strengthen the NIH OLAW's understanding of the foreign institution's animal care and use program.

In this submission, three new documents were added – Attachment 3: Foreign Annual Report; Attachment 7: Interinstitutional Assurance Triad for Domestic Performance Site; and Attachment 8: Interinstitutional Assurance Triad for Foreign Performance Site. In the past three years, scrutiny regarding oversight of animal activities being conducted by foreign institutions has increased due to the COVID 19 pandemic. OLAW plans to increase oversight of foreign institutions preceded the pandemic and given the current climate with heightened awareness of foreign animal activities, implementation of enhancements to the program of assurances, especially for foreign institutions, is timely. Attachment 3: Foreign Annual Report requests information to detail any changes in funding or changes to the Assurance document since the initial Foreign Assurance approval or renewal or since their last submitted Annual Report to OLAW. The Foreign Annual Report to OLAW will provide OLAW with timelier notification of changes in the Foreign Assurance including changes in the Institutional Official and/or contacts.

Attachment 7: Interinstitutional Assurance Triad for Domestic Performance Site and Attachment 8: Interinstitutional Assurance Triad for Foreign Performance Site were added to accommodate additional scenarios when Interinstitutional Assurance documentation between three institutions is necessary. As with

the original Interinstitutional Assurance forms, the Interinstitutional Assurance Triad forms have one form for domestic performance sites and one form for foreign performance sites.

The current Interinstitutional Assurance documents only allow completion by two institutions and when more than two institutions are involved, additional Interinstitutional Assurances must be completed which is inefficient. The new Interinstitutional Assurance Triad forms are included to reduce the duplicative paperwork in situations when three different institutions are involved. For example, in addition to the prime awardee, there may be a subawardee or paid or unpaid collaborator that is conducting animal activity at an institution with a Domestic or Foreign Assurance. Currently, two sets of the original Interinstitutional Assurance forms would be completed, and the institution with a Domestic or Foreign Assurance would have to review and sign both sets of documents. The addition of Attachment 7 and Attachment 8 alleviates the need for two sets of documents and enables all three organizations (i.e., awardee organization, additional organization, and institution with a Domestic or Foreign Assurance) to sign one document. Attachment 7 and 8 are not replacement documents for the existing Interinstitutional Assurance forms (attachment 5 and 6). Instead, the new documents, Attachment 7 or 8, may be used in place of Attachment 5 or 6 when three versus two institutions need to complete the Interinstitutional Assurance documentation. Attachments 5 and 6 will continue to be used when only two institutions are involved in completion of the Interinstitutional Assurance documentation.

The documents provide the required information necessary for the NIH OLAW to provide institutional oversight according to the PHS Policy and the HREA and to determine that research, teaching, and training with vertebrate animals is being conducted responsibly in accordance with applicable laws, regulations, and guidance. Without submission of the Assurance or Annual Report to OLAW, animal welfare and scientific progress may be negatively impacted due to lack of OLAW's ability to provide oversight.

A.3 Use of Information Technology and Burden Reduction

OLAW contacts institutions to request new and renewal Assurance and Annual Report completion by email. To reduce the number of email inboxes, OLAW no longer maintains the separate email inbox olawdocs@mail.nih.gov for submission of documents. Currently, the general email address olawdoa@mail.nih.gov is used for both correspondence and submitting Assurance documents. Institutions submit their completed Assurance documents and Annual Reports electronically to the OLAW email inboxes olawdoa@mail.nih.gov (Correspondence and Assurance documents) and olawarp@mail.nih.gov (Annual Reports). Electronic submission via email is an efficient and economical method that permits timely transmission.

A.4 Efforts to Identify Duplication and Use of Similar Information

OLAW is the only office tasked with oversight of PHS-funded activities involving animals in compliance with 42 U.S.C. 289d and the PHS Policy. The United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) is tasked with enforcing the Animal Welfare Act and implementing the Animal Welfare Regulations for warm-blooded animals used in research but excludes rats, mice, and birds bred for use in research. Although not all institutions attain accreditation by AAALAC International, an independent accrediting body, institutions that are accredited may reuse wording from their AAALAC animal program description in the Assurance document and vice versa. Because OLAW, USDA APHIS, and

AAALAC have distinct missions and purposes for information collection, much of the information requested of an institution is specific to each requesting entity and therefore, non-duplicative.

A.5 Impact on Small Businesses or Other Small Entities

Small businesses or other small entities without an animal care and use program of their own using PHS funds for research involving animals are subject to PHS Policy requirements. This type of entity completes an Interinstitutional Assurance, which links the awardee entity with an Assured institution, domestic or foreign, where the animal activity will be conducted. The Interinstitutional Assurance certifies that the specified funded animal activity will be conducted in compliance with the PHS Policy. In this case, only the completion of the concise Interinstitutional Assurance is required.

A.6 Consequences of Collecting the Information Less Frequently

The PHS Policy requires that institutions using PHS funds for research involving animals submit a new Assurance for approval periods no longer than five years and report to OLAW once a year in the Annual Report. This frequency of reporting is required because of the ongoing commitment to protect the welfare of animals used in research. OLAW staff must be apprised of changes to the institution's animal care and use program as these changes may affect animal welfare. Semiannual program evaluations and facilities inspections by Institutional Animal Care and Use Committees (IACUCs) are required to safeguard continued animal welfare, and annual reporting to OLAW ensures that IACUCs conduct these reviews. Less frequent reporting has a strong likelihood of negatively impacting animal welfare and may result in the reduction of the quality of PHS-supported activities, slow the advancement of science, and hinder progress to improve human and animal health.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Once the funding component identifies that an award will be made, the funding component will request that OLAW negotiate an Assurance (Interinstitutional, Foreign, or Domestic) if the institution(s) do not already have an Assurance in place. Due to the timing of the award process, an institution may submit their response to the request to negotiate an Assurance in fewer than 30 days from the initial request. However, there is no requirement that the information be submitted within 30 days.

A.8.1 Comments in Response to the Federal Register Notice

In accordance with 5 CFR 1320.8(d), a 60-day notice for public comment was published on December 15, 2022 Vol. 87, No. 240 pages 76631-76632 in the *Federal Register*. There were no public comments received.

A.8.2 Efforts to Consult Outside Agency

Representatives from domestic and foreign large and small academic institutions, contracting research organizations, and small companies were consulted regarding the frequency of collection, the clarity of instructions, approximate duration to complete each document, and format. There are no circumstances that preclude consultation with representatives of those from whom information is to be obtained.

A.9 Explanation of Any Payment of Gift to Respondents

No payment or gifts are provided to respondents.

A.10 Assurance of Confidentiality Provided to Respondents

The information is private to the extent permitted by law. Personally identifiable information may consist of full name, email address, work address, telephone number, and name of workplace. Information submitted to OLAW is accessible only to authorized OLAW staff and stored in a database system that requires PIV-card login and system privileges. The database system is for internal use within OLAW and only accessible to authorized OLAW staff and, when necessary, NIH information technology staff. **Hard copy documents are no longer stored in the secure, card access file room in the OLAW office as we have transitioned to electronic-only records.**

A.11 Justification for Sensitive Questions

None of the information collection required by the PHS Policy is of a sensitive nature.

A.12.1 Estimates of Hour Burden Including Annualized Hourly Costs

The number of respondents is updated based on changes in the average number of annual Assurance counts. The average number of hours for each of the rows is provided based on previous and projected estimated time for document completion.

Table 12-1 Estimated Annualized Burden Hours

Form Name	Type of Respondents	Number of Respondents	Number of Responses Per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Domestic Assurance	Renewal and New	235	1	30	7,050
Domestic Annual Report	All Domestic	890	1	90/60	1,335
Foreign Assurance	Renewal and New	67	1	90/60	101
Foreign Annual Report	All Foreign	335	1	1	335
Interinstitutional Assurance for Foreign Performance Site or Interinstitutional Assurance Triad for Foreign Performance Site	Foreign	46	1	30/60	23

Interinstitutional Assurance for Domestic Performance Site or Interinstitutional Assurance Triad for Domestic Performance Site	Domestic	750	1	30/60	375
TOTAL			2,323		9,219

A.12.2 Annual Cost to Respondent

The annualized cost to respondents has increased due to the average increase in number of Interinstitutional Assurances; increased time for documents completed by foreign institutions; and increase in average hourly wages of individuals that complete the documents.

Table 12-2 Annualized Cost to Respondents

Document	Type of Respondents	Total Annual Burden Hours	Hourly Respondent Wage Rate* (\$)	Respondent Cost (\$)
Domestic Assurance	Renewal and New	7,050	Vet 62.07 52.84 Exec Sec 34.16 32.15 Med. Sci. 52.27 49.44 Misc Hlth Pract 30.92 29.56 Avg. 44.86	316,263
Domestic Annual Report	All Domestic	1,335	44.86	59,888
Foreign Assurance	Renewal and New	101	44.86	4,531
Foreign Annual Report	All Foreign	335	44.86	15,028
Interinstitutional Assurance for Foreign Performance Site or Interinstitutional Assurance Triad for Foreign Performance Site	Foreign	23	44.86	1,032
Interinstitutional Assurance for Domestic Performance Site or Interinstitutional	Domestic	375	44.86	16,823

Assurance Triad for Domestic Performance Site				
TOTAL		9,219	44.86	443,565

*Bureau of Labor Statistics. May 2022. National Occupational Employment and Wage Estimates United States. Veterinarians, occupation code 29-1131; Executive Secretaries and Executive Administrative Assistants, occupation code 43-6011; Medical Scientists, occupational code 19-1040; Miscellaneous Health Practitioners and Technical Workers, occupation code 29-9090. Available at https://www.bls.gov/oes/current/oes_nat.htm

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

No additional costs are anticipated beyond those required for customary and usual business practices.

A.14 Annualized Cost to the Federal Government

Costs are estimated based on review hours of Assurances and Annual Reports for Assurance Officers and processing and review hours of Assurances and Annual Reports for support staff. The cost has increased due to changes in staffing due to retirements, hiring, and updates to the percent effort of staff required to assess Assurances and Annual Reports. A decrease in the estimated cost is included for office supplies (paper, pens, printer toner, etc.) related to Assurances and Annual Reports due to the decrease in printing needs.

Cost Descriptions	Title	Grade/Step	Salary* (\$)	% of Effort	Total Cost (\$) to Government
Federal Oversight	Director	15/4	171,268	10	17,127
	Assurance Officer	14/7	158,840	60	95,304
	Assurance Officer	14/6 @ 75%	154,428	10	11,582
	Assurance Officer	13/10	145,617	75	109,213
	Assurance Officer	O5	145,808	75	109,356
	Assurance Analyst	12/2	97,339	50	48,670
	Program Analyst	13/3	119,482	20	23,896
	Program Analyst	11/5	89,069	20	17,814
	Program Analyst	9/4	71,452	20	14,290
	Program Analyst	9/1	64,957	20	12,991
	Program Analyst	7/1	53,105	20	10,621
Office Supplies / Printer Costs					1,500
Total					472,364

A.15 Explanation for Program Changes or Adjustments

All documents

- Throughout, italicized instructional text is in black font to improve readability and accessibility. Previously approved forms may have included italicized instructional text in green font which has now been changed to black font.
- Documents refer to all funding entities that the NIH OLAW provides animal care and use program oversight for. In addition to providing oversight for Public Health Service funded animal work, the NIH OLAW has memoranda of understandings with the National Science Foundation (NSF) and National Aeronautics and Space Administration (NASA) for live, vertebrate animal activities. Some documents only referenced NSF and not also NASA. The MOU outlining oversight responsibility between the NIH OLAW and NASA was announced in NIH Guide Notice NOT-OD-20-095 Notice of Memorandum of Understanding Between NIH and NASA Concerning Laboratory Animal Welfare which was released on April 16, 2020. As a result of this change, there is no additional information requested and no increase of burden on the respondent.

Domestic Annual Report (attachment 1) – document with changes

- Added the term “program reviews” to replace “program evaluation” which traditionally refers to both program reviews and facility inspections
- Added instructional prompts to:
 - describe what to submit if there were any minority views to reduce submission of excess documentation in addition to the minority view
 - request completion of some items to reduce incomplete submissions on the committee roster table
 - describe what to include if an individual does not meet the qualifications of any of the required committee membership roles but will remain a committee member
- All changes should not result in a significant change of burden, and in the long run, may reduce burden time during the subsequent document review between OLAW and the institution after submission.

Domestic Assurance (attachment 2) – document with changes

- Minor changes to references and guidance for assistance with document completion:
 - swapped the numbering for paragraphs E and F (paragraphs otherwise remain unchanged)
 - prompted for whether institutional accreditation is identified as a component in the Semiannual Report
 - added description to explain anonymity
 - requested a list of changes considered to be significant
 - deleted the prompt to describe the annual review process for species regulated by the USDA which is no longer required due to the Animal Welfare Act regulations amendment

(as posted in the Federal Register notice 86 FR 66919

<https://www.federalregister.gov/documents/2021/11/24/2021-25614/awa-research-facility-registration-updates-reviews-and-reports/>)

- o added an existing FAQ as a reference regarding suspension of animal activities
- o added a request for completion of some items to reduce incomplete submissions on the committee roster table
- o added a description what to include if an individual does not meet the qualifications of any of the required committee membership roles but will remain a committee member
- The above changes assist in completion of the form and provide more detail or refer to items from the *Guide for the Care and Use of Laboratory Animals: Eighth Edition (Guide)* which was adopted by NIH after appropriate public comment periods and announced in NOT-OD-12-020 Adoption and Implementation of the Guide for the Care and Use of Laboratory Animals: Eighth Edition on December 2, 2011. The added items are not new requirements since institutions completing the Domestic Assurance have been required to implement the *Guide* since 2012. The changes to provide more detail may slightly increase the burden to the respondent but will result in a net reduction of burden during the document review between OLAW and the institution after initial submission.

Foreign Annual Report (attachment 3) - new document

- To better align with the reporting requirements followed by domestic institutions that have an approved Domestic Assurance, foreign institutions that have an approved Foreign Assurance will submit a Foreign Annual Report to OLAW that includes the following information.
 - o Funding status
 - o Attestation of noncompliance reporting to OLAW during the reporting period or whether there was no reportable noncompliance
 - o Change in accreditation or certification status; institutional commitment including laws, regulations, policies; oversight body processes; Institutional Official or institutional contacts
- As a result of these changes, additional information is requested, and there is an increase in burden to respondents since this is a new document. The Foreign Annual Report will provide the NIH OLAW with regular updates regarding the foreign institution's animal care and use program and will facilitate enhanced oversight.

Foreign Assurance (attachment 4) - document with changes

- Added a new informational section that describes the institution's responsibility to report noncompliance or suspension of animal activities to OLAW
- Added a new section for a description of oversight including information on the Institution's Animal Welfare Committee or Oversight Body and description of responsibilities for review of research using live, vertebrate animals
- Added a new informational section that describes the institution's responsibility to submit an Annual Report to OLAW
- Moved the Institutional Contacts section to appear before the signature page and made minor non-substantive formatting edits

- New informational sections serve to more directly inform foreign institutions of existing responsibilities that are already included in the PHS Policy. A new section for a description of oversight and responsibilities for review of animal research is not a new requirement since foreign institutions already 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. Although the oversight requirement is not new, providing a description requires additional information to be provided which is an increase in burden to respondents which has been accounted for with an increased estimated average response time.

All Interinstitutional Assurance (IA) documents:

- reference the responsibility of the prime awardee for compliance with PHS Policy to reinforce the information that is already included in the NIH Grants Policy Statement

The changes to IA forms and new IA Triad forms do not request additional information and there is no increase in burden to respondents.

Interinstitutional Assurance for Domestic Performance Site (attachment 5) – document with changes

- Minor updates with the majority of the changes providing additional prompts or instruction to assist with completion.

Interinstitutional Assurance for Foreign Performance Site (attachment 6) – document with changes

- The attachment 5 changes described above have also been made on this document

Interinstitutional Assurance Triad for Domestic Performance Site (attachment 7) – new document

- In addition to the Awardee Institution and Assured Institution, additional fields are added for the basic information and signature for the Institution that requires the Interinstitutional Assurance.
- The IACUC approval has its own section in the added section I.C. because this information could originate from the Awardee Institution or the Assured Institution.

Interinstitutional Assurance Triad for Foreign Performance Site (attachment 8) – new document

- The attachment 7 changes described above have also been made on this document
- Accompanying the IACUC approval field in section I.C., information is provided that explains that this information is only required when the prime awardee is a domestic institution that holds an Approved Domestic Assurance. This is information that is already included in the NIH Grants Policy Statement.

A.16 Plan for Tabulation and Publication and Project Time Schedule

This information collection does not include results that will be published.

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB control number will be displayed with an expiration date.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

None