

Supporting Statement A for

Assurance (Interinstitutional, Foreign, and Domestic) and Annual Report. (Office of Director).

OMB # 0925-XXXX, expiration date XX/XX/XXXX

Date: September 9, 2019

Check off which applies:

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

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A. Justification

The Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research, Office of the Director, National Institutes of Health (NIH) is requesting approval for the information collection requirements of the Paperwork Reduction Act of 1995. OLAW is responsible for the implementation, general administration, and interpretation of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) as codified in 42 CFR 52.8. The PHS Policy implements the Health Research Extension Act (HREA) of 1985 (Public Law 99-158 section 495 as codified in 42 U.S.C. 289d). 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. 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. The purpose of the Assurance (Interinstitutional, Foreign, and Domestic) and Annual Report is to provide OLAW with documentation to satisfy the requirements of the HREA, illustrate institutional adherence to PHS 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. Office of Management and Budget (OMB) approval is requested for 3 years.

A.1 Circumstances Making the Collection of Information Necessary

The 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 PHS 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.

A.2 Purpose and Use of the Information Collection

OLAW Assurance documents and Annual Reports are to be completed by institutions conducting research, testing, and training involving animals with PHS funds and provide the required information necessary for OLAW to provide institutional oversight according to the PHS Policy and the HREA. The Assurance and Annual Report template forms provide a uniform, organized format for efficiency of document completion and review. OLAW Assurance Officer and staff review of these documents support the Strategic Goal to Foster Sound, Sustained Advances in the Sciences outlined in the Health and Human Services Strategic Plan for FY 2018-2022 by providing a means of assessment of an institution's animal care and use program 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. Institutions submit their completed Assurance documents and Annual Reports electronically to the respective OLAW email inboxes olawdocs@mail.nih.gov (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 Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

In accordance with 5 CFR 1320.8(d), a 60-day notice for public comment was published on June 17, 2019 Vol. 84, No. 116 page 28065 in the *Federal Register*. There were no public comments received.

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 stored in a double-locked area that requires possession of an access-controlled PIV-card and/or a physical key.

A.11 Justification for Sensitive Questions

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

A.12 Estimates of Annualized Hour Burden Including Annualized Cost to Respondents

The number of respondents is based on current and past annual Assurance counts. An email was sent to ten recent respondents to provide an estimated time for document completion and seven responses were received. An average of the estimated number of hours was calculated from the responses of the seven individuals and is reported for average burden per response.

Table 12-1 Estimated Annualized Burden Hours

Document	Type of Respondents	Number of Respondents	Number of Responses Per Respondent	Average Burden Per Response (in hours)	Annual Burden Hours
Interinstitutional Assurance	Foreign	40	1	30/60	20
Interinstitutional Assurance	Domestic	660	1	30/60	330
Foreign Assurance	Renewal and New	60	1	1	60
Domestic Assurance	Renewal	220	1	26	5,720
Domestic Assurance	New	20	1	30	600
Annual Report	All Domestic	940	1	90/60	1,410
TOTAL			1,940		8,140

Table 12-2 Annualized Cost to Respondents

Document	Type	Annual Burden Hours	Hourly Respondent Wage Rate* (\$)	Annual Respondent Cost (\$)
Interinstitutional Assurance	Foreign	20	Vet 50.59 Exec Sec 29.59 Med. Sci. 45.80 <u>Misc Hlth Pract 27.89</u> Avg. 38.47	769
Interinstitutional Assurance	Domestic	330	38.47	12,695
Foreign Assurance	Renewal and New	60	38.47	2,308
Domestic Assurance	Renewal	5,720	38.47	220,048
Domestic Assurance	New	600	38.47	23,082

Annual Report	All Domestic	1,410	38.47	54,243
TOTAL		8,140	38.47	313,145

*Bureau of Labor Statistics. May 2018. 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

Cost Descriptions	Title	Grade/Step	Salary* (\$)	% of Effort	Total Cost (\$) to Government
Federal Oversight	Director	15/9	166,500	10	16,650
	Assurance Officer	C06	179,658	75	134,744
	Assurance Officer	14/10	152,352	50	76,176
	Assurance Officer	14/1	117,191	25	29,298
	Assurance Officer	13/7 @ 75%	89,253	5	4,463
	Program Analyst	11/10	90,461	20	18,092
	Program Analyst	12/3	88,959	20	17,792
Contractor Cost	Program Assistant		107,084	20	21,417
	Program Assistant		76,572	20	15,314
Office Supplies / Printer Costs					3,000
Total					336,946

*Office of Personnel Management. January 2019. General Schedule Salary Table 2019-DCB for the Locality Pay Area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA. Available at <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2019/DCB.pdf>

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. Thirty percent of the approximately \$10,000 annual general office procurement budget is included for office supplies (paper, pens, printer toner, etc.) related to Assurances and Annual Reports.

A.15 Explanation for Program Changes or Adjustments

This is a new information collection request.

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 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