

Supporting Justification Statement for HHSAR 370.401

1. Circumstances Making the Collection of Information Necessary

Performance of HHS mission requires the use of live vertebrate animals. Before awarding a contract to any contractor which will need to use live vertebrate animals, the CO is required to verify that the contractor holds a valid Animal Welfare Assurance from the Office of Laboratory Animal Welfare (OLAW) within NIH. Contractors are required to file the appropriate forms to obtain this approval. The applicable clauses are found at HHSAR 352.270-5a (Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals), and the clause at 352.270-5b (Care of Live Vertebrate Animals).

2. Purpose and Use of Information Collection

The application will be used to assess the contractor's ability to comply with the requirements of humane animal treatment with approval from OLAW.

3. Use of Improved Information Technology and Burden Reduction

All data submitted by contractors (100%) is requested to be submitted electronically.

4. Efforts to Identify Duplication and Use of Similar Information

Each contractor is required to obtain this approval before performing contract work on live vertebrate animals. The terms of each approval are negotiated with OLAW and must be periodically renewed. There is no duplication of such application except as required by the periodic renewals.

5. Impact on Small Businesses or Other Small Entities

The requirements of the Animal Welfare Assurance apply regardless of the size of the contractor. The data being requested is being provided by the contractor pursuant to the contract requirements. Any burden would be the same for any size entity and is necessary for performance of the specific contract. The contract price would reflect the contract requirements. Thus there is no additional burden or excessive burden placed on small businesses.

6. Consequences of Collecting the Information; Less Frequent Collection

Collection efforts by contractors are in response to specific contract requirements that are drafted to address specific missions of HHS. While a contractor might hold several contracts involving the use of live vertebrate animals, only one AWA is required to approve the facility and protocols. Thus in most cases each contract would have a single application to OLAW for purposes of gathering the data necessary for the approval. Depending on the circumstances, the AWA will need to be reviewed periodically and will result in an additional application.

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

- There are no special circumstances related to collection of this information.

- There are no requirements to report information to the agency more often than quarterly.
- Generally contractors will be required to provide the requisite information after award and more than thirty days after award. In certain specific situations within HHS emerging requirements could dictate a quicker turn-around in order to allow the research to progress. In those cases the data might be required to be submitted with proposals or shortly after contract award. These situations would be the exception to the general practice and would be justified within the contract file documentation.
- Contractors will not be required to submit more than an original and two copies of any document. In virtually all cases an electronic submission is sufficient.
- Contract laws and regulations dictate record retention requirements for contracts. Any retention of records by the contractor would be subject to privacy and other laws and regulations and would be addressed in the request for clearance that is submitted on behalf of the contractor for the specific contract requirement.
- It is not expected that any contractor would be required to use a statistical data classification that has not been reviewed and approved by OMB; any assertion of confidentiality in the data would be covered by contract clauses, specifically those found in FAR Part 27 and HHSAR Part 327. Likewise contract clauses would address security requirements and the government's rights to further use the data.
- The protection of contractor proprietary, trade secret, or other confidential information and the government's right to use that data are covered by contract-specific clauses.

8. Comments in Response to the Federal Register Notice/Outside Consultation

A 60-day Federal Register Notice was published in the *Federal Register* on March 2, 2015, vol. 80, No. 407; pp. 11273-74 (see attachment). No public comments related to data collection were received.

9. Explanation of any Payment/Gift to Respondents

Contractors are reimbursed pursuant to the terms of each respective contract. No gifts are ever involved.

10. Assurance of Confidentiality Provided to Respondents

The release of any information provided by a contractor is governed by the provisions of the Freedom of Information Act (5 USC 552) (FOIA).

11. Justification for Sensitive Questions

No sensitive questions are asked of contractors under this data collection.

12. Estimates of Annualized Hour and Cost Burden

12A. Estimated Annualized Burden Hours

Annual reporting and recordkeeping hour burden

- a. Number of respondents 36
- b. Total annual responses 41
 - 1. Percentage of these responses collected electronically 100%
- c. Total annual hours requested 111
- d. Current OMB inventory 0
- e. Difference 111
- f. Explanation of difference
 - 1. Program change New Collection
 - 2. Adjustment

12B. Estimated Annualized Burden Costs

Annual reporting and recordkeeping cost burden (*in thousands of dollars*)

- a. Total annualized capital/startup costs 0
- b. Total annual costs (O&M) \$5474
- c. Total annualized cost requested \$5474
- d. Current OMB inventory 0
- e. Difference \$5474
- f. Explanation of difference
 - 1. Program change New Collection
 - 2. Adjustment

13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

There are no capital costs associated with this collection.

14. Annualized Cost to Federal Government

There are no incremental costs to the government for this collection.

15. Explanation for Program Changes or Adjustments

This is a new collection effort so there are no changes or adjustments.

16. Plans for Tabulation and Publication and Project Time Schedule

A final rule is anticipated to be submitted for publication within 60 to 90 days. This does not require any statistical or other analysis.

17. Exceptions to Certification for Paperwork Reduction Act Submissions

“There are no exceptions to the certification.”

For reference only. The following is taken directly from the language of the data collection request:

There are three types of assurances covered here, each with different response and preparation times.

The annual reporting burden for Domestic Assurances is estimated as follows:

Respondents: 5

Responses per respondent: 2

Total annual responses: 10

Preparation hours per response: 8

Total response burden hours: 80

The annual reporting burden for Inter-Institutional Assurances is estimated as follows:

Respondents: 30

Responses per respondent: 1

Total annual responses: 30

Preparation hours per response: 1

Total response burden hours: 30

The annual reporting burden for Foreign Assurances is estimated as follows:

Respondents: 1

Responses per respondent: 1

Total annual responses: 1

Preparation hours per response: 1

Total response burden hours: 1

The previous numbers had combined the data.