

Supporting Justification Statement for HHSAR 370.301

1. Circumstances Making the Collection of Information Necessary

Performance of HHS mission requires the support of contractors involving human subjects. Before awarding a contract to any contractor which will need to use human subjects, the CO is required to verify that the contractor holds a valid Federal Wide Assurance (FWA) approved by the Office for Human Research Protections (OHRP). The provisions are implemented via contract clauses found at HHSAR 352.270-4a (Protection of Human Subjects), the clause at 352.270-4b (Protection of Human Subjects), the provision at 352.270-10 (Notice to Offerors—Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required), and the clause at 352.270-11 (Protection of Human Subjects—Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required). This collection has the OMB reference number of 0990-0431.

2. Purpose and Use of Information Collection

Each FWA is initiated by an application process from the contractor. The application will be used to assess the contractor's compliance with the requirements of 45 CFR 46.103.

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 involving human subjects. Each approval from OHRP 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 FWA 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 human subjects, only one FWA is required to approve the facility and protocols. Thus in most cases each contract would have a single application to OHRP for purposes of gathering the data necessary for the approval. Depending on the circumstances, the FWA 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 4,644
- b. Total annual responses 4,644
 - 1. Percentage of these responses collected electronically 100%
- c. Total annual hours requested 2,322
- d. Current OMB inventory 0
- e. Difference 2,322
- 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) \$95,666
- c. Total annualized cost requested \$95,666
- d. Current OMB inventory 0
- e. Difference \$95,666
- 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 scheduled for publication on November 18, 2015, with an effective date of December 18, 2015. 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.”