

Supporting Justification Statement for OMB Control Number 0990-0431
HHSAR 370.301

1. Circumstances Making the Collection of Information Necessary

The Department of Health and Human Services (HHS), Office of the Assistant Secretary for Financial Resources, Office of Acquisitions is requesting the Office of Management and Budget (OMB) grant an extension on a previously approved information collection request, OMB control number 0990-0431, Acquisitions Involving Human Subjects.

Performance of HHS mission requires the support of contractors in programs involving human subjects. Before awarding a contract to any contractor that will need to use human subjects, the Contracting Officer is required to verify that the contractor holds a valid Federal Wide Assurance (FWA) approved by the NIH Office for Human Research Protections (OHRP). Under the provisions of 45 CFR part 46, and as prescribed in HHS Acquisition Regulation (HHSAR) Subpart 370.3—Acquisitions Involving Human Subjects, the provisions are implemented via contract clauses found at HHSAR 352.270-4a (Notice to Offerors, Protection of Human Subjects), the clause at HHSAR 352.270-4b (Protection of Human Subjects), the provision at HHSAR 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 HHSAR 352.270-11 (Protection of Human Subjects—Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required).

The Agency is requesting a 3-year extension to collect this information from public or private businesses.

2. Purpose and Use of Information Collection

The information is used to determine that a contractor has a valid FWA. Before a contract is awarded contractors must show that they obtained an FWA or are in the process of obtaining an FWA. The NIH OHRP issues FWA's for all relevant contractors with the requirements of 45 CFR part 46.103. Each FWA is initiated by an application process from the contractor.

3. Use of Improved Information Technology and Burden Reduction

All data submitted by contractors (100 percent) is requested to be submitted electronically. We use improved information technology to the maximum extent practicable. Where contractors are capable of electronic interchange, the contractors may submit this information collection requirement electronically. Nothing in the HHSAR precludes the use of electronic interchange where the requirement is for written documents. The information is necessary for the purposes of determining whether the contractor holds a valid FWA at the time of proposal submittal or has provided documentation for acquiring the FWA approval. When the FWA has not been approved, the contracting officer shall designate a time period in which the FWA must be approved.

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. Once an FWA is approved, it may be used for multiple contracts. The contractor shall certify annually that the FWA is current and has been reviewed and approved by the Institutional Review Board (IRB). 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 contractor 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 Part 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 with proposal submission. In most cases contractors will have minimum of 30 days to prepare a proposal submission. With contracting officer approval, the contractor may submit an FWA within a specified time frame after proposal submission.
- 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 specify record retention requirements for contracts.
- 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. The information collected does not include statistical 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.

- The request fully complies with the regulation.

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

A 60-day Federal Register Notice was published in the *Federal Register* on August 16, 2021, vol. 86, No. 155; pp: 45740-45742 (see attachment 0990-0431-resources.docx). No public comments related to data collection were received.

9. Explanation of any Payment/Gift to Respondents

There will be no payments or gifts offered to the respondents for this collection of information. This collection of information will be part of the requirements of an HHS RFP response or the award of an HHS contract.

10. Assurance of Confidentiality Provided to Respondents

Data will be kept private to the extent allowed by law. This information collection does not include personally identifiable information. Information provided to HHS by a contractor is subject to being requested by third parties under the Freedom of Information Act (FOIA), as amended (5 U.S.C. 552), but business proprietary information is generally exempt from public disclosure under the FOIA. FWA application information is about contractor entities so does not constitute Privacy Act records. The information in this supporting statement has been reviewed by HHS privacy personnel.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Hour and Cost Burden

12.A. Estimated Annualized Burden Hours

| Type of Respondent | No. of Respondents | No. Responses per Respondent | Average Burden per Response (in hours) | Total Burden Hours |
|-----------------------|--------------------|------------------------------|--|--------------------|
| Business (contractor) | 90 | 4 | 5 | 1800 |
| Total | 90 | 4 | 5 | 1800 |

12.B. Estimated Annualized Burden Costs

| Type of Respondent | Total Burden Hours | Hourly Wage Rate | Total Cost to the Respondents |
|-----------------------|--------------------|------------------|-------------------------------|
| Business (contractor) | 1800 | \$63.78 | \$114,804.00 |

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 equipment or overhead costs. Government FTEs and contractors, however, are being used to support the data collection. The cost to the federal government would be the cost of the salaries of the HHS staff that collects and disseminates the data and the cost of the contractor staff that supports the analysis and submission of the data.

The total estimated annualized cost to the federal government is \$7,761.00. Table A-14 describes how this cost estimate was calculated and the roles.

Table A-14: Estimated Annualized Cost to the Federal Government

| Organization | Role | Rate | Hours | Cost |
|--------------|--------------------------|----------|-------|------------|
| OS/ASFR/OA | Federal SME | \$82.65 | 40 | \$3,306.00 |
| Contractor | Contractor Analyst | \$104.00 | 30 | \$3,120.00 |
| Contractor | Contractor Staff Support | \$89.00 | 15 | \$1,335.00 |
| Total | | | 85 | \$7,761.00 |

15. Explanation for Program Changes or Adjustments

This is an extension of the current collection effort. There was no change to the current OMB inventory burden hours of 1800 hours.

16. Plans for Tabulation and Publication and Project Time Schedule

Approval is requested by February 16, 2022 to allow for continued use of the HHSAR clauses.

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

There is no request to not display the OMB Expiration Date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

SECTION B STATISTICAL METHODOLOGY

This does not require any statistical or other analysis.