U. S. Department of Health and Human Services (HHS)
Office for Human Research Protections
Research Complaint Form

Supporting Statement

Background

The Office of the Assistant Secretary for Health, Office for Human Research Protections (OHRP) is requesting a new approval from the Office of Management and Budget of OHRP's Research Complaint Form. This form will provide a simplified standardized format for submitting to OHRP allegations of noncompliance involving human subject research projects conducted or supported by HHS. The information collected will help OHRP ensure the rights of human subjects involved in such research and that assured institutions are complying with the HHS Protection of Human Subjects regulations. This is a new information collection request.

A. Justification

1. Need and Legal Basis

Section 289 of the Public Health Service Act authorizes OHRP, on behalf of HHS, to establish a compliance oversight process regarding violations of the rights of human subjects of research conducted or supported by HHS. Pursuant to that authority, OHRP may receive reports of violations and take appropriate action. OHRP also derives compliance authority from the HHS Protection of Human Subjects regulations at 45 CFR 46[1] (hereafter referred to as "HHS regulations"). HHS regulations at 45 CFR 46.103(a) require each institution engaged in non-exempt human subjects research conducted or supported by HHS to provide assurance that it will comply with the requirements of the HHS regulations. The Federalwide Assurance (FWA) is the only type of assurance currently accepted and approved by OHRP. An OHRP-

[1] The pre-2018 HHS Protection of Human Subjects Regulations (or pre-2018 Requirements), codified at subpart A, 45 CFR part 46 (as amended), were originally promulgated in 1991 (56 FR 28012, 28022) and amended on June 23, 2005 (70 FR 36325). The 2018 HHS Protection of Human Subjects Regulations (or 2018 Requirements), codified at subpart A, 45 CFR part 46 (as amended), were originally published on January 19, 2017 (82 FR 7149), and amended on January 22, 2018 (83 FR 2885) and June 19, 2018 (83 FR 28497).

approved FWA commits an assured institution to full compliance with the HHS regulations whenever the institution is engaged in HHS-conducted or -supported human subjects research.

Sources of allegations or indications of noncompliance with the HHS regulations, include, but are not limited to, research subjects and their family members, individuals involved in the conduct of research (e.g., investigators), and institutional officials.

In carrying out its responsibility for oversight of compliance with the HHS regulations, OHRP reviews allegations of noncompliance involving human subject research conducted or supported by HHS or that are otherwise subject to the regulations, and determines whether to conduct a for-cause compliance evaluation. For details, see OHRP guidance, titled, "Compliance Oversight Procedures for Evaluating Institutions."

2. Purpose and Use of Information Collection

Historically OHRP has not standardized the content of the information that is submitted in allegations of noncompliance with the HHS regulations (hereafter referred to as "complaint(s)"). Currently, such complaints are submitted to OHRP via a dedicated email address (complaints.ohrp@hhs.gov) and OHRP staff manually enter the complaint information into a database. This information collection request proposes to standardize both the content of submitted complaint information and the manner in which the collected information is submitted to OHRP, which should in turn reduce the burden for complainants. Respondents would complete and submit an electronic version of the proposed research complaint form, eliminating the need for OHRP staff to manually enter the collected information into a database.

OHRP use the collected information to determine whether it has jurisdiction to evaluate the possible noncompliance, and if so, whether OHRP will conduct a for-cause evaluation.

3. Improved Information Technology and Burden Reduction

OHRP will use information technology to allow for electronic completion and submission of the collected information that is automatically transferred to a database. The current need for OHRP to manually enter complaint information into a database would be eliminated.

4. Efforts to Identify Duplication and Use of Similar Information

   There is no duplication of efforts or use of similar information.

5. Impact on Small Businesses or Other Small Entities

   The small businesses that are most likely to be affected are for-profit, independent IRB companies and small companies that conduct HHS-supported research involving human subjects. The proposed research complaint form minimizes burden for small businesses by providing a simplified standardized format for reporting complaints. The information collection will not have a significant impact on small entities.

6. Consequences of Collecting the Information Less Frequently

   Not applicable.

7. Special Circumstances Relating to the Guidelines of 5 C.F.R. 1320.5

   There are no special circumstances for this information collection.

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

   Comments are being requested from the public for a 60-day period.

9. Explanation of any Payment/Gift to Respondents

   No payment or gifts are provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

    The information on the form will not be affirmatively made public due to policy considerations; it will only be made public to the extent required by the Freedom of Information Act (FOIA) in response to a FOIA request.

The Research Complaint Form will not collect information that is subject to the Privacy Act; all information collected is intended to be about organizations or institutions and to be used by OHRP to ensure that those entities address allegations appropriately.

11. Justification for Sensitive Questions

No sensitive information is being collected.

12. Estimates of Annualized Burden Hours and Costs

There are over 14,000 organizations with active assurances with OHRP. In 2022 OHRP received approximately 1000 complaints related to research conducted in the United States. On average, we estimate that approximately 1000 complaints will be submitted to OHRP annually. Of those 1000 complainants, 500 complainants will submit one report, 400 will submit two reports, and 100 will submit an average of three reports. We estimate the total annualized burden hours to be 800 hours. We estimate that each respondent will take an average of 30 minutes to complete the form.

12a. Estimated Annualized Burden Hours

Form Name	Number of Respondents		Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Research Complaint Form	500		1	30/60	250
Research Complaint Form	400		2	30/60	400
Research Complaint Form	100		3	30/60	150

Total					**800**

We expect that respondents will be research staff persons (to include IRB members, IRB administrators, research coordinators) within organizations or the general public. We estimate the hourly wage to be an average $41.25 and the total burden cost is estimated to be $33,000.

12b. Estimated Burden Costs

Form Name	Number of Respondents	Burden Hours	Hourly Wage	Total Respondent Costs
Research Complaint Form	500	250	$41.25	$10,312.50
Research Complaint Form	400	400	$41.25	$16,500
Research Complaint Form	100	150	$41.25	$6,187.50
Total				**$33,000**

13. Estimates of Annualized Cost Burden to Respondents

There are no direct costs to respondents other than their time to complete the form.

14. Estimates of Annualized Cost to the Government

As described in section 12 above, OHRP receives approximately 1,000 complaint emails per year. The average OHRP

hourly rate of personnel processing complaints is $42.27. Currently, OHRP personnel spend approximately 2 hours per report to manually input information into federal databases.

- With the use of the proposed form and streamlined submission system, we estimate that OHRP personnel will spend approximately 30 minutes per report to ensure that information is appropriately entered into federal databases.
- OHRP personnel spend an additional 30 minutes per report to assess the adequacy of the submitted information to determine if follow-up is needed.
- For approximately 50 complaints per year, OHRP determines that additional investigation is needed. OHRP personnel spend on average 10 hours conducting additional investigation on each of the complaints.

Estimated costs to government

Description (support staff)	Total Hours	Hourly Cost	Total cost of processing complaints/yr
OHRP input into database, Conduct additional investigation	2300	42.27	$97,221.00

- 1000 respondents, 2-5 frequency of response, 1664 hours/year. Currently, OHRP has a GS12 equivalent FTE that spends approximately 80% of their time reviewing and processing complaints about research sent to OHRP annually.
- Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.

15. Explanation for Program Changes or Adjustments

This is a new collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Information related to results of the collected information may be published on the OHRP website.

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

    The OMB expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

    No certification exception is requested.

List of ATTACHMENTS

Attachment 1 – Legal Authorities

a. 42 U.S.C Section 289
b. 45 CFR 46 (pre-2018 Requirements
c. 45 CFR 56 (2018 Requirements)

Attachment 2 – Research Complaint Form