U.S. Department of Health and Human Services (HHS)
Office for Human Research Protections (OHRP) Incident Report Form
Supporting Statement

INTRODUCTION

OHRP in the Office of the Assistant Secretary for Health of HHS is requesting approval from the Office of Management and Budget of OHRP's Incident Report Form. This form will facilitate prompt reporting of specific human subject protection incidents to OHRP by organizations and institutions conducting or reviewing human subjects research, and will provide a simplified standardized format for the reports. The information collected on the form will help OHRP to ensure the safety of human research subjects involved in non-exempt HHS-conducted or –supported research and to ensure that the research is conducted in accordance with the HHS Protection of Human Subjects regulations at 45 CFR part 46. This is a new information collection request.

PART A. JUSTIFICATION

1. Circumstances of Existing Information Collection in Use without an OMB Control Number

The U.S. Department of Health and Human Services (HHS) human subjects protection regulations at 45 CFR part 46 require that organizations engaged in or reviewing HHS-supported or conducted human subjects research establish and follow written procedures for ensuring prompt reporting to OHRP of the following:

- any unanticipated problems involving risks to subjects or others;
- any serious or continuing noncompliance with 45 CFR part 46 or the requirements or determinations of the institutional review board (IRB); and

- any suspension or termination of IRB approval.[1]

When these events occur in HHS-conducted or supported research, organizations must promptly report information about the incident to OHRP. Historically, OHRP has called these reports "IRPTs" (Incident Reports) and has suggested that affected organizations include the following information when communicating with OHRP:

- Information about the research study (funding source, principal investigator, title, IRB or study number)
- Information about all organizations affected by the incident
- Detailed information about the incident
- Details about a corrective action plan implemented to address the incident and to prevent similar incidents from occurring

The burden estimates for incident reporting, suspension or termination reporting requirements cited above are included in the approved information requirements in OMB No. 0990-0260, Protection of Human Subjects: Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/Informed Consent/Consent Documentation, approved through June 30, 2021.

Historically OHRP has not standardized the content required to be submitted with an IRPT nor the manner in which IRPTs must be submitted. OHRP is proposing to standardize both the content and manner in which these reports are submitted. Initially, organizations will complete a fillable, electronic version of the form and will submit the completed form to OHRP by email. In the near future, OHRP expects that the electronic version of the completed form that organizations submit will be automatically downloaded into a database, which will greatly facilitate OHRP's processing of IRPTs. .

2. Purpose and Use of the Information

While OHRP has suggested what information could be included in an incident report, the office experiences great variation in what is actually submitted. This leads to significant back-and-forth with organizations upon each submission to ensure that OHRP has the necessary information to evaluate the IRPT and the organization's response.

[1] Pre-2018 Requirements at 45 CFR 46.103(b) (5) and the 2018 Requirements at 45 CFR 46.108(a) (4).

Generally, OHRP uses the information collected through the reporting process to ensure the safety of human research subjects and that research is conducted in accordance with 45 CFR part 46. Specifically, OHRP uses the information to:

- Determine if a corrective action plan is sufficient for the organization or institution to address the incident and to prevent further incidents from occurring
- Determine if the seriousness of an incident may warrant a compliance action from OHRP against the organization or institution
- Identify common compliance issues which may require the development of guidance from OHRP, for investigators and organizations and institutions

While it is extremely rare and has not occurred in OHRP's history to our knowledge, the information could be used to:

- Recommend to appropriate HHS officials: (a) that an institution or an investigator be temporarily suspended or permanently removed from participation in specific projects, or (b) that HHS scientific peer review groups be notified of an institution's or an investigator's past noncompliance prior to review of new projects.

- Recommend to appropriate HHS officials that institutions or investigators be debarred in accordance with the procedures specified at 45 CFR part 76. Debarment is a government-wide sanction.

By standardizing the form and manner of the information collected and transmitted to OHRP, the office will be able to better ensure that we are evaluating IRPTs appropriately, as well as creating a streamlined reporting and processing mechanism for members of the regulated community and OHRP staff.

The data elements requested on this form are the minimum necessary for OHRP to establish:

- The names of all relevant parties
- The dates when incidents occurred
- Basic information about the incident

- Information about the affected organizations' response to the incident

3. Use of Improved Information Technology

OHRP is proposing to use a standardized form to collect specific information about incidents that must be reported to the office when they occur in HHS-conducted or supported research, and in research being conducted by institutions that voluntarily apply their FWA to all research conducted by their institution.. The fillable and printable form may be mailed or emailed to OHRP as an attachment.

In the near future, OHRP plans to utilize information technology to allow for electronic submission of these forms to automatically populate a database, which will eliminate the need for OHRP staff to manually enter this information into a database. The future electronic submission system will allow an additional reduction in burden, faster processing of reports, and better record keeping for organizations and OHRP.

4. Efforts to Identify Duplication

Currently, a standardized format for organizations to submit IRPTs to OHRP does not exist. Organizations submit IRPTs via email with Microsoft Word or PDF attachments, and the information that organizations provide to OHRP is not consistent.

5. Involvement of 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 IRPT form minimizes burden for small businesses by providing a simplified standardized format for reporting incidents. The information collection will not have a significant economic impact on small entities.

6. Consequences if Information is Collected Less Frequently

Not applicable; 45 CFR part 46 mandates that organizations engaged in or reviewing nonexempt HHS supported or conducted human

subjects research must *promptly* report information about certain activities (outlined in number 1 above) to OHRP.

We intend for respondents to use this form on an incident-by-incident reporting basis to OHRP. A system whereby organizations report incidents on a periodic basis (such as quarterly or annually) would not satisfy the requirement that entities conducting human subjects research report certain incidents promptly to OHRP and thus would cause those entities to be out of compliance with 45 CFR part 46.

7. Special Circumstances

There are no special circumstances.

8. Consultation Outside of Agency

Comments were requested related to this information collection during a 60-day period in the Federal Register issue that was published on September 22, 2020 (85 FR, No. 184, p 59537). No public comments were submitted during the comment period..

9. Payment of Gifts

Payments or gifts to respondents are not provided.

10. Assurance of Confidentiality

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 Incident Report Form will not collect information that will be 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 the incidents appropriately. As explained in 2, all OHRP actions in response to reports have, to date, been directed at the affected organization or institution. Certain actions against an organization's or institution's investigator are also authorized, but OHRP has taken no such actions to date. Although the "names of

relevant parties" information described in A.2. will identify the particular individuals involved in each incident reported, the forms (as intended to be used by OHRP, based on past history) will be about organizations and institutions, not individuals. A form would be about an individual and would be subject to the Privacy Act only in the unlikely event that OHRP, in the future, takes an action directed at an investigator and retrieves the form by the investigator's name or other personal identifier. To date, OHRP has not retrieved the forms by personal identifier for the purpose of conducting the Human Research Protections program. OHRP has, on occasion, searched by the name of an individual to try to locate records for purposes of responding to a request from a Freedom of Information Act (FOIA) requester or to answer a question from a reporter or other requester, when the requester provided the name of an individual without the name of the associated organization or institution.

11. Questions of a Sensitive Nature

The form does not contain questions of a sensitive nature.

12. Estimates of Annualized Hour Burden

As of May 7, 2020, there are 5,145 active IRB organizations with 6,005 IRBs registered with OHRP. In 2018, IRBs or IRB organizations sent an estimated 1,200 incident reports to OHRP.

The estimated annualized burden for the incident report form is presented in Table 1. We estimate that 800 organizations will submit incidents reports to OHRP annually. Of those 800 organizations, 500 will submit one report, 200 will submit two reports, and 100 will submit three reports. We estimate the total annualized burden hours to be 600 hours. We estimate that each respondent will take an average of 30 minutes to complete the form and that respondents will be administrative staff persons (to include IRB Administrators) within organizations. We estimate the hourly wage to be $41.25 and the total burden cost is estimated to be $24,750.

The burden estimates for incident reporting, suspension and termination reporting requirements cited above are included in the approved information requirements under OMB No. 0990-0260, approved through June 30, 2021. In addition, the burden estimates for organization and IRB registration are included under OMB No. 0990-0279 approved through February 28, 2022

Table A.1: Estimates of Annualized Hour Burden

Form Name	Number of Respondents	Responses per Respondent	Total Number of Responses	Burden Hours per Response	Total Burden Hours	Hourly Wage	Total Burden in Dollars
Incident Report	**500**	**1**	**500**	**0.5**	**250**	**$41.25**	**$10,312.50**
Incident Report	**200**	**2**	**400**	**0.5**	**200**	**$41.25**	**$8,250.00**
Incident Report	**100**	**3**	**300**	**0.5**	**150**	**$41.25**	**$6,187.50**
Total					**600**		**$24,750.00**

13. Estimates of Annualized Cost Burden to Respondents

Total capital and start-up costs: $0
Total operation, maintenance, and purchase of services: $0

14. Estimates of Annualized Cost to the Government

As described in section 12 above, OHRP receives approximately 1,200 incident reports per year.

- The average OHRP hourly rate of personnel processing incident reports is $42.27.
- Currently, OHRP personnel spend approximately 1 hour 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 IRPTs per year, OHRP determines that additional investigation is needed. OHRP personnel spend on average 10 hours conducting additional investigation on each of these cases.

Estimated costs to government

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

15. Explanation for Program Changes or Adjustments

This is a new collection.

16. Plans for Analysis and Publication of Information

A 3-year clearance is being requested for this recurring data collection as required by 45 CFR part 46. No complex analytical techniques will be used to analyze the information. OHRP may publish the number of IRPTs received on a quarterly basis on the OHRP website.

17. Display of Expiration Date

The expiration date will be displayed.

18. Exception to Certification statement

This collection of information involves no exceptions to the Certification for Paperwork Reduction Act Submissions.