U.S. Department of Health and Human Services (HHS)

Office for Human Research Protections (OHRP)
Incident Report Form, OMB Control No. 0990-0477

Supporting Statement

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Introduction

The U.S. Department of Health and Human Services (HHS)' Office for Human Research Protections (OHRP) is requesting reinstatement of OMB No. 0990-0477, the OHRP Incident Report Form, with changes, for a three-year period. Reinstatement is necessary because prior OMB approval of the information collection on the Incident Report Form expired on May 31, 2024. This reinstatement request includes two new information elements on the Incident Report form: *IORG # for Reviewing IRB*; and, *Revising research policies and procedures* as a corrective action plan category, if it applies. Inclusion of these data elements did not affect the burden estimate.

The purpose of the Incident Report form is to facilitate organizations' or institutions' prompt reporting of specific human subject protection incidents to OHRP in a simplified standardized format. Respondents for this information collection are organizations and institutions conducting or reviewing HHS conducted or supported human subjects research in compliance with the HHS Federal Policy for the Protection of Human Subjects (the Common Rule), which is codified for HHS at 45 CFR part 46, subpart A.[1]

PART A. Justification

1. Need and Legal Basis

Section 491(a) of Pub. L. 99-158 provides that the Secretary of HHS shall by regulation require that each entity applying for HHS support (e.g., a grant, contract, or cooperative agreement) to conduct research involving human subjects submit to HHS an assurance satisfactory to the Secretary that it has established an IRB to review the research in order to protect the rights of the human subjects of such research. IRBs are boards, committees, or groups formally designated by an entity to review, approve, and conduct continuing oversight of research involving human subjects.

Section 491(b) of Pub. L. 99-158 states that: "The Secretary of HHS shall establish a process for

[1] The pre-2018 Common Rule (or "pre-2018 Requirements") was originally promulgated in 1991 and amended on June 23, 2005 (70 FR 36325). The 2018 Common Rule (or "2018 Requirements") was 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).

the prompt and appropriate response to information provided to the Director of NIH respecting incidences of violations of the rights of human subjects of research for which funds have been made available under this chapter. The process shall include procedures for the receiving of reports of such information from recipients of funds under this chapter and taking appropriate action with respect to such violations."

OHRP notes that the above statutory references to the Director of NIH are outdated because when OHRP was moved from within NIH to the now-OASH in 2000, the authority to receive such reports under the statute's implementing regulations was delegated from the Secretary to OASH and OHRP.

Pursuant to Section 491(a)(above), HHS has promulgated regulations under 45 CFR part 46. These regulations require that organizations and institutions engaged in or reviewing nonexempt 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.[2]

When these events occur in HHS nonexempt conducted or supported research, organizations must promptly report information about the incident to OHRP. Historically, OHRP called these reports "IRPTs" (Incident Reports) and 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

OHRP standardized the information organizations include with an IRPT in OMB No. 0990-0477, the OHRP Incident Report form, that was approved by OMB on May 4, 2021. Initially, organizations completed a fillable electronic version of the Incident Report form which was then submitted to OHRP by email or mail. However, since January 2, 2022, organizations must

[2] Pre-2018 Requirements at 45 CFR 46.103(b) (5) and 45 CFR 46.113, and the 2018 Requirements at 45 CFR 46.108(a) (4) and 45 CFR 46.113.

complete and submit all incident reports to OHRP using the online version of the Incident Report form, unless the institution lacks the ability to do so. In 2023, all of the incident reports that were submitted to OHRP were completed and submitted electronically.

2. Purpose and Use of the Information Collection

Generally, OHRP uses the information collected 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

Rare but possible uses of information collected are potential OHRP compliance actions including:

- 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.

The information collected on the incident report form is 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

This information collection request includes two new information elements on the Incident Report form:

1. The IRB Organization Number (IORG #) of the IRB responsible for reviewing the research study under 45 CFR part 46. While the current OMB-approved OHRP Incident Report form includes the "FWA or IORG number of reporting institution," it does not include the IORG number of the IRB responsible for reviewing the research study. The addition of this element will offer institutions an option to accurately identify the IRB responsible for reviewing the research study.

2. A new corrective action plan category entitled, "Revising research policies and procedures." The addition of this category will offer institutions a more accurate option to report corrective actions that involve revisions to their research policies and procedures.

3. Use of Improved Information Technology and Burden Reduction

OHRP's utilization of information technology to allow for electronic completion and submission of the incident report form information to OHRP eliminated the need for institutions to manually complete a fillable electronic version of the incident report form and submit it to OHRP via email or mail. In addition, OHRP staff no longer had to manually enter the collected information into a database.

4. Efforts to Identify Duplication and Use of Similar Information

The incident report form information does not duplicate any other information collected by OHRP.

5. Impact on Small Businesses or 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 incident report form information minimizes burden for small businesses by providing a simplified standardized electronic process for reporting incidents. The information collection will not have a significant economic impact on small entities.

6. Consequences or Collecting the Information Less Frequently

The HHS Protection of Human Subjects regulations, 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 the incident report 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 Relating o the Guidelines of 5 CFR 1320.5

The information collection request fully complies with regulation 5 CFR 1320.5.

8. *Federal Register* Notice /Outside Consultation

Public comments were solicited for a 60-day period in the *Federal Register* published on April 25, 2024 (89 FR 31759). No comments were submitted.

9. Explanation of Any Payment/Gifts to Respondents

No payments or gifts will be provided to the respondents.

10. Assurance of Confidentiality Provided to Respondents

The information on the incident report 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. All OHRP actions in response to incident 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" will identify the particular individuals involved in each incident reported, the forms (as intended to be used by OHRP) 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. Justification for Sensitive Questions

The incident report form does not contain questions of a sensitive nature.

12. Estimates of Annualized Hour and Cost Burden

As of January 20, 2024, there are 4,958 active IRB organizations with 5,812 active IRBs registered with OHRP. In 2023, two hundred thirty-three IRBs or IRB organizations sent 1,033 incident reports to OHRP.

The estimated annualized burden for the incident report form is presented in Table 1. We estimate that 250 IRBs or IRB organizations will submit an estimated 1,100 incident reports to OHRP annually. Of those 250 organizations, 25 will submit one report, 25 will submit three reports and 200 will submit five reports. We estimate the total annualized burden hours to be 550 hours.

Table A.1 Estimates of Annualized Hour and Cost Burden

Type of Respondent	**Form Name**	**Number of Respondents**	**Number of Responses per Respondent**	**Total Number of Responses**	**Average Burden Hours per Response**	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
IRBs/IRB Organizations	Incident Report	25	1	25	0.5	12.5	$82.00	$1,025.00
IRBs/IRB Organizations	Incident Report	25	3	75	0.5	37.5	$82.00	$3,075.00
IRBs/IRB Organizations	Incident Report	200	5	1,000	0.5	500	$82.00	$41,000.00
	Total			**1,100**		**550**		**$45,100.00**

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. Using 2022 wage data from the Bureau of Labor Statistics (U.S. Department of Labor, Bureau of Labor Statistics, May 2022 National Occupational Employment and Wage Estimates, United States, https://www.bls.gov/oes/current/oes_nat.htm), we estimate $82 per hour (mean salary of mid-level IRB staff, plus overhead and personnel benefits) for preparing and submitting the incident report information. We estimate the information collection costs respondents an average of $45,100 annually.

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

There are no capital costs, or operating and maintenance costs, associated with the information collection.

14. Annualized Cost to the Federal Government

OHRP will receive approximately 1,100 incident reports per year

- OHRP personnel will spend approximately 30 minutes per report to ensure that the incident report information is appropriately entered into the federal database (1100 reports times 0.5 hours equals 550 hours).
- For approximately 50 of the incident reports, OHRP will determine that additional investigation is needed. OHRP personnel spend on average 10 hours conducting additional investigation on each of these cases (50 reports times 10 hours equals 500 hours).
- The average OHRP hourly rate of personnel processing incident reports is $53.87 ($53.87 times 1050 total staff hours equals $56,563.50).

The annual for operating, managing and hosting the incident reports database is $200,000.

The total annualized Federal Government cost is $256,563.50.

15. Explanation for Program Changes or Adjustments

The annual burden estimates changed compared to the current burden estimates. The changes are due to agency adjustments. The total annual burden in the current OMB-approved information collection, 600 hours and $24,750.00, respectively, is projected to be 550 hours and $45,100.00, respectively, in this information collection request.

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16. Plans for Tabulation and Publication and Project Time Schedule

A three-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 on its website, on a quarterly basis, the number of incident reports it received.

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

OHRP will display the OMB control number and expiration date, as required.

18. Exception to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.