Reporting Incidents to OHRP (2022)

NOTE: THIS REPLACES OHRP'S June 20, 2011 GUIDANCE ENTITLED "GUIDANCE ON REPORTING INCIDENTS TO OHRP" (http://www.hhs.gov/ohrp/compliance/reports/index.html) This information has been updated to reflect current processes regarding how OHRP processes Incident Reports.

Date: September 9, 2022

Scope:
This document describes how to submit incident reports to OHRP, and how OHRP reviews and processes the reports. Incident reports include reports of unanticipated problems involving risks to subjects or others; serious or continuing noncompliance with Department of Health and Human Services (HHS) regulations at 45 CFR part 46, or the requirements or determinations of the institutional review board (IRB); and suspension or termination of IRB approval.

This document provides information on the following topics:

I. Applicability of incident reporting requirements;

II. Information to include in incident reports;

III. Time frame for reporting incidents;

IV. How OHRP processes incident reports;

V. How to submit incident reports; and

VI. Links to other relevant OHRP guidance

Target Audience: IRBs, institutional officials and institutions that may be responsible for review, oversight, or conduct of human subjects research covered by an OHRP-approved assurance.

Regulatory Background: The HHS regulations at 45 CFR part 46 require that organizations engaged in or reviewing nonexempt HHS-conducted or supported human subjects research establish and follow written procedures for ensuring prompt reporting to OHRP of the following:

(1) any unanticipated problems involving risks to subjects or others;

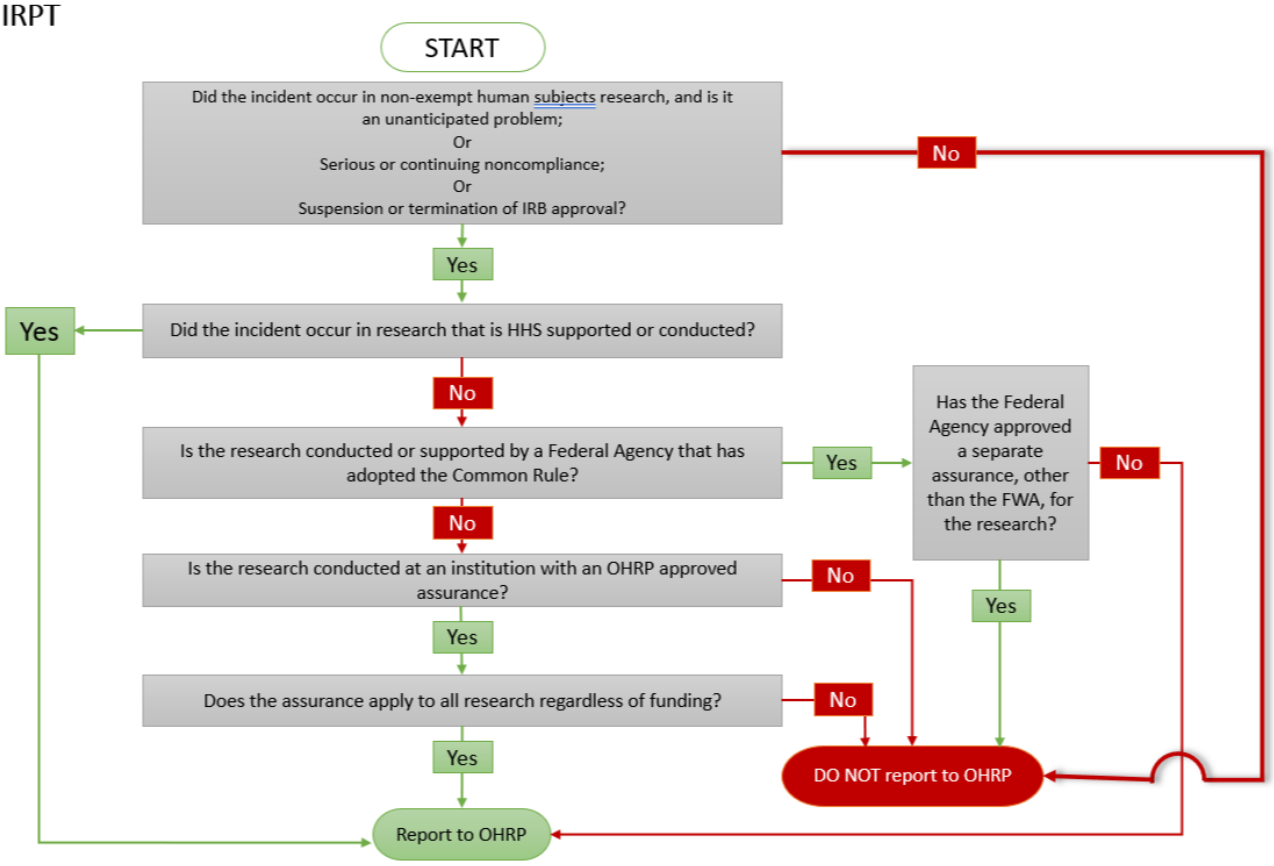
(2) any serious or continuing noncompliance with 45 CFR part 46 or the requirements or determinations of the IRB; and

(3) any suspension or termination of IRB approval (pre-2018 Requirements at 45 CFR 46.103(a) and (b)(5) and 45 CFR 46.113, and the 2018 Requirements at 45 CFR 46.108(a)(4) and 45 CFR 46.113).

I. Applicability of incident reporting requirements

In general, these reporting requirements apply to nonexempt human subjects research that is conducted or supported by HHS or covered by an Federalwide Assurance (FWA), regardless of funding source. See flowchart.

Flow Chart – IRPT



II. Information to be included in incident reports

The information required in the submission is outlined in the OHRP Incident Report Form Instructions for completing the OHRP Incident Report Online Form available on OHRP's website under compliance and reporting[1].

[1] https://www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/index.html

III. Time frame for reporting incidents

The reporting requirements found in the 2018 Common Rule at 45 CFR 46.108(a)(4) and 45 CFR 46.113 (for research conducted under the pre-2018 Common Rule at 45 CFR 46.103(b)(5) and 45 CFR 46.113) do not specify a time frame for reporting, except to say this must be done in a "prompt" manner. The regulations require that institutions must establish and follow written procedures for ensuring prompt reporting to the IRB; appropriate institutional officials; the department or agency head; and the Office for Human Research Protections, HHS, or any successor office, or the equivalent office within the appropriate Federal department or agency of the following:

- any unanticipated problems involving risks to subjects or others;
- any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and
- any suspension or termination of IRB approval.

In some instances, it may be appropriate for an institution or IRB to submit an initial report to fulfill the regulatory requirement for prompt reporting. Subsequent reports should be submitted when new information is available or as the institution's evaluation of the incident progresses.

For a more serious incident, this may mean reporting to OHRP within days. For a less serious incident, a few weeks may be sufficient. Depending on the incident it may be appropriate to send an initial report, and indicate that a follow-up or final report will follow by the earlier of:

- a specific date; or
- when an investigation has been completed or a corrective action plan has been implemented.

IV. How OHRP processes incident reports

OHRP generally performs initial review of all incident reports within two business days. OHRP reviews the report to determine if it involves risks to research subjects or others that may require immediate intervention to mitigate risks to subjects for which the institution conducting the research has not provided adequate steps to address. Reports deemed to involve these risks are forwarded by Division of Compliance Oversight (DCO) staff, to the DCO Director, and to the Deputy Director of OHRP for further assessment and action. The following describes how OHRP generally processes incident reports:

- When reports are submitted to OHRP, an initial acknowledgment of receipt is sent to the submitter.

- OHRP assesses the adequacy of the corrective actions taken or planned to address the incident.

- If the information is insufficient for OHRP to determine the adequacy of the corrective actions, additional information will be requested. This is an iterative process and continues until OHRP determines that the corrective actions taken are appropriate.

Data regarding incident reports may be used for reports generated by OHRP, including trend analyses and analytics. OHRP tracks receipt of all incidents and uses this information when evaluating complaints received about research. OHRP uses this information as part of its assessment of an institution for allegations of noncompliance.

V. How to submit incident reports

All reports must be submitted to OHRP using the OHRP Incident Report Online Form[2], unless an institution lacks the ability to do so. If an institution or IRB is unable to submit incident reports using the online form, a written explanation of why the institution or IRB is unable to use the online form to submit the report must be emailed to OHRP-DCO@hhs.gov.

VI. Other relevant OHRP guidance

Please see OHRP guidance on continuing review regarding the distinction between suspension and expiration of IRB approval and OHRP guidance on unanticipated problems.

[2] https://oash.force.com/ohrpwebforms/s/incident-web-form