

Human Research Protection Program Policies & Procedures

Institutional Reporting Requirements

Version 1.0

Date Effective: 10.12.2012



Research Integrity Office
Mail code L106-RI
Portland, Oregon 97239-3098
Phone: 503-494-7887
Fax: 503-346-6808

Background

It is the responsibility of the Vice President of Research, the OHSU Research Integrity Office, and the OHSU IRB to comply with all federal reporting requirements with respect to the conduct of human subject research. Federal regulations may require reporting to the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), and other agencies in certain cases of unanticipated problems involving risks to subjects or others; serious or continuing noncompliance with federal regulations or the requirements or determinations of the IRB; and suspension or termination of IRB approval. Institutions are required to have written procedures in place to ensure appropriate reporting of these incidents.

I. Scope

This policy and procedure establishes guidelines to ensure prompt reporting according to federal regulations, institutional policy and OHSU IRB policy.

II. Responsible Parties

- A. Vice President of Research
- B. OHSU Research Integrity Office (ORIO)
- C. OHSU IRB

III. Policy

- A. The OHSU IRB will promptly report, to appropriate OHSU officials, federal regulatory agencies and sponsors, the following:
 - 1. Serious or continuing noncompliance with applicable federal regulations or with the requirements or determinations of the IRB;
 - 2. Unanticipated problems involving risks to subjects or others; and
 - 3. Suspensions or terminations of previously approved IRB research.
- B. The following elements must be included in the report, which should be kept concise and include only detail that directly supports the actions taken:
 - 1. Basic identifying information:
 - a. Name of institution
 - b. Title of research project and/or grant proposal
 - c. Name of principal investigator
 - d. IRB number and any applicable grant, contract, or cooperative agreement number for which the noncompliance occurred, or, for IRB or institutional noncompliance, the IRB or institution involved
 - 2. The nature of the event or events.
 - 3. The findings of the organization.
 - 4. Actions taken by the organization, including any IRB actions taken related to this matter.
 - 5. Specific reasons for the actions identified and a description of how these actions will prevent recurrence of the incident or similar incidents.
 - 6. Clear identification that the issue is resolved or specific plans for continued investigation or action.

7. Any supplementary information or materials having relevance to the decision.
- C. The OHSU IRB will send a letter to the principal investigator notifying him or her of any of the above determinations and the report to the applicable regulatory agencies. The IRB will send a copy of the letter to the principal investigator's departmental chair or other institutional official, as appropriate.
- D. These reporting requirements apply to all non-exempt human subjects research that is:
 1. Conducted or supported by HHS;
 2. Conducted or supported by any non-HHS federal department or agency that has adopted the Common Rule and is covered by a Federal Wide Assurance (FWA) determined to be appropriate for such research; or
 3. Subject to FDA regulation.
- E. In order to comply with the requirement to report promptly, reporting will occur as soon as practicable. The IRB Chair shall devise a reporting plan that is appropriate for the reported activity. It may include preliminary reports and follow-up.
- F. Noncompliance with federal regulations on behalf of the OHSU IRB will be reported by the Chief Integrity Officer in a manner consistent with Section (B) above.

IV. Procedure

A. Reporting to Regulatory Agencies

1. Unless reporting timelines are dictated by another policy or regulation, an IRB Chair or the Chief Integrity Officer devises a reporting timeline.
2. ORIO staff prepares a communication to the appropriate federal agency(ies). A copy is sent to the Vice President of Research and the Chief Integrity Officer. In reporting noncompliance by the IRB, the Chief Integrity Officer signs regulatory communications and sends a copy to the Vice President of Research, the IRB Chair, and the members of the ORIO Leadership Committee.
3. 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.
4. It may be necessary to telephone a federal regulatory agency in order to alert the agency to a very serious problem. Subsequent written reports should reference the date and time of the initial telephone call.
5. In the case of an urgent written or phone report, indicate the nature of the report, the investigation on the part of the institution, and a pending follow-up report with more information as it becomes known.
6. The written report is distributed to federal agencies that have oversight due to funding, conduct, or an assurance of compliance.

B. Recording Reporting

1. Electronic copies of submitted reports and supporting materials are stored in internal ORIO files.
2. When pertinent to a specific study, reports will be uploaded into the the regulatory tab of the eIRB.
3. Any responses from the regulatory agency shall also be stored electronically in ORIO files and uploaded to the eIRB when applicable.
4. Failure to report promptly should be noted in the record with a reason for the delay.

V. Authority

Federal Regulations

45 CFR 46.103(b)(5) and 21 CFR 56.108(b) require written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval.

45 CFR 46.113 states that an IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

OHRP Guidance

[Guidance on Reporting Incidents to OHRP \(May 27, 2005\)](#)

VI. Definitions

Non-compliance is defined as a failure on the part of the PI or any member of the research team to: adhere to the terms of the OHSU IRB approval and/or abide by applicable laws, regulations, or OHSU policies.

Serious non-compliance is defined as failure to adhere to the terms of the OHSU IRB approval and/or abide by applicable laws, regulations or OHSU policies when that failure increases risk to participants or adversely affects the rights and welfare of the participants. Serious non-compliance is a finding that is determined by the convened IRB. The finding of serious non-compliance must be reported to regulatory authorities and the sponsor. A single instance of non-compliance may be serious. Examples of serious non-compliance may include the following:

- Falsification of IRB documents
- Human subjects research conducted without IRB approval
- Deviation from the IRB approved protocol or consent process
- Modification of protocol without prior IRB approval
- Failure to maintain regulatory documents
- Inadequate oversight of research
- Conducting a research protocol without oversight of a functional investigator

Continuing Non-compliance is defined as a pattern of repeated non-compliance actions or omissions that, if unaddressed, may compromise the integrity of the OHSU human research protection program. The pattern may reflect a lack of knowledge on the part of the investigator or a lack of commitment by the investigator and/or research team to human subject's protection. Continuing non-compliance is a finding that is determined by the convened OHSU IRB.

Unanticipated Problems are events that are not expected given the nature of the research procedures and the subject population being studied and suggest that the research places subjects or others at a greater risk of harm or discomfort related to the research

Suspension is an action taken by the IRB or other body with such authority. It is a temporary or permanent halt to some or all research procedures short of a termination until the IRB determines whether the research may recommence (with or without modifications to the research) or whether the research must be terminated.

Termination is taking action to end a study with the guarantee that no further contact with human subjects or their individually identifiable information is planned; no subjects are or will be treated or followed; all data are gathered and analyzed; and any final

reports or publications are complete. A study may be terminated when it no longer constitutes human subject research, such as de-identifying the data. The IRB may also terminate a study for cause, therefore halting further research.

VII. Additional Resources

OHSU HRPP Policies & Procedures:

- Serious and Continuing Noncompliance
- Unanticipated Problems
- Closure, Suspension, and Termination of Studies
- Protocol Deviations