Purpose

This document outlines the policy and procedures for ensuring prompt reporting of those determinations made by the Institutional Review Board, to the appropriate institutional officials, Federal Department or Agency head, and OHRP, as required.

Regulatory Background

HHS regulations for the protection of human subjects at 45 CFR 46.103(a) and (b)(5) require that institutions have written procedures to ensure that the following incidents are promptly reported to OHRP:

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

Scope

This applies to all investigators under the jurisdiction of Princeton University, including faculty, staff and students conducting research involving human research participants.

Responsibilities

Investigators: Investigators and research staff are responsible for promptly reporting any unanticipated problems involving risks to subjects, complaints or possible allegations of noncompliance to the IRB.

RIA Administrator(s): RIA Administrators may conduct preliminary review and inquiry, write reports, and/or make determination of the appropriate subject matter expert and level of review for unanticipated problems, complaints, possible reports of noncompliance.

IRB Member(s): Conducts expedited review or presents summary including findings of unanticipated problems, possible reports of noncompliance or complaints or other events that may heighten risks to subjects at convened meetings and votes to make the determination as to the final disposition of the submission.

Institutional Official (IO): The IO is responsible for ensuring that the Human Research
Protection Program (HRPP) functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO represents Princeton and is named in the Federalwide Assurance (FWA).

Definitions

Please see Policies and Procedures on Unanticipated Problems, Noncompliance, Suspensions and Terminations for relevant definitions.

Policy

HHS regulations for the protection of human subjects 45 CFR 46.103(a) and (b)(5), require prompt reporting to appropriate institutional officials, OHRP and department or agency head of (i) any unanticipated problems involving risks to subjects or others, any serious or continuing noncompliance with HRPP policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval. Princeton's Human Research Protection Program, which includes the IRB will comply with this requirement. When research is exempt or not federally funded or conducted, reports of these determinations are made to investigators, the IRBs, the Institutional Official and other institutions, as appropriate.

Procedure

IRB Determinations, Actions and Report Content

Reports of IRB determinations and actions are initially drafted by RIA administrators with input from the General Counsel's Office, as needed. Each report will promptly be submitted to the federal agencies, as appropriate. The IRB Chair, director and assistant director or RIA and the Institutional Official may review the document and modify the letter/report if needed. The Institutional Official is the signatory for all correspondence from Princeton.

The procedures below will be initiated by IRB administrators, once the IRB takes any of the following actions:

1. Determines that an event is considered an unanticipated problem involving risks to human subjects or others
2. Determines that noncompliance was serious or continuing
3. Suspends or terminates approval of research

Institutional Reporting Requirements

Each report includes but is not limited to the following:

1. The nature of the event (Unanticipated problem involving risks to participants or
others, serious or continuing noncompliance, suspension or termination of approval of research

2. Name of the institution conducting the research

3. Title of the research project and/or grant proposal in which the problem occurred

4. Name of the principal investigator on the protocol

5. Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement)

6. A detailed description of the problem including the findings and the reasons for the IRB's decision

7. Actions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.)

8. Plans, if any, to send a follow-up or final report by the earlier of
   a. A specific date
   b. When an investigation has been completed or a corrective action plan has been implemented

A copy of the report will be sent to:

1. The IRB, by including the letter in the next agenda as an information item

2. The Institutional Official

3. The following federal agencies, when applicable:
   a. OHRP, if the study is subject to DHHS regulations or subject to a DHHS Federalwide assurance
   b. FDA, if the study is subject to FDA regulations
   c. If the study is conducted or funded by any Federal Agency other than DHHS that is subject to “The Common Rule”, the report is sent to OHRP or the head of the agency as required by the agency
   d. Reporting to a regulatory agency is not required if the event occurred at a site that was not subject to the direct oversight of Princeton, and the agency has
been notified of the event by the investigator, sponsor, another organization, or other mechanisms

4. Principal investigator
5. Sponsor, if the study is sponsored
6. Contract research organization, if the study is overseen by a contract research organization
7. Chairman or supervisor of the principal investigator
8. Director of Research Integrity and Assurance
9. The Privacy Officer of a covered entity, if the event involved unauthorized use, loss, or disclosure of individually-identifiable patient information from that covered entity
10. The Information Security Officer of an organization if the event involved violations of information security requirements of that organization
11. Others as deemed appropriate by the Institutional Official

References

Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events

- [http://www.hhs.gov/ohrp/compliance/reports/](http://www.hhs.gov/ohrp/compliance/reports/)

Guidance on Reporting Incidents to OHRP

- [http://www.hhs.gov/ohrp/compliance/reports/](http://www.hhs.gov/ohrp/compliance/reports/)

Version History

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