

PARTNERS HUMAN RESEARCH COMMITTEE STANDARD OPERATING PROCEDURE

PHRC Review of Reports of Problems

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to define the procedures the Partners Human Research Committees (PHRC) follow when determining whether a report of a problem or other information about the research is an unanticipated problem involving risks to subjects or others and for reporting unanticipated problems involving risks to subjects or others as required by 45 CFR 46.103(b)(5) and 45 CFR 46.108(a) and 21 CFR 56.108(b)(1).

2.0 SCOPE

Any incident, experience, information, outcome, or other problem reported to the PHRC.

3.0 DEFINITIONS

The definitions used in this SOP are derived from OHRP's Guidance on Unanticipated Problems and Adverse Events, dated January 15, 2007.

Unanticipated problem involving risks to subjects or others means any incident, experience, information, outcome, or other problem that is *unexpected* given the research procedures and that indicates that the research places subjects at increased risk of physical, psychological, economic, legal, or social harm than was previously known or recognized.

Unexpected means that the incident, experience, or outcome in terms of nature, severity or frequency is not described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document or the characteristics of the study population being studied.

4.0 PROCEDURES

Investigators relying on the PHRC for IRB review of human-subjects research and clinical investigations are required to promptly report to the PHRC any of the problems that require prompt reporting to the PHRC using the appropriate forms.

- 4.1 The Human Research Office staff is responsible for receiving the reports of problems or other information and for providing the report to the PHRC Chairperson with the protocol file containing the PHRC-approved protocol and consent form. The entire protocol file is available to the PHRC Chairperson.
- 4.2 The reviewing PHRC Chairperson is responsible for determining whether the problem is unexpected and suggests that the research places subjects or others at a greater risk of physical, psychological, economic, legal, or social harm than was previously known or recognized.
- 4.3 When the reviewing PHRC Chairperson determines that the problem is expected or does not indicate that subjects or others are at increased risk of harm, then the problem is determined not to be an unanticipated problem involving risks to subjects or others. The report is noted, and no further action is required under this Policy.
- 4.4 When the reviewing PHRC Chairperson determines that the problem is unexpected and indicates that subjects or others are at increased risk of harm, then the problem is determined to be an unanticipated problem involving risks to subjects or others. The problem is referred for review at a meeting of the convened PHRC.
- 4.5 When the reviewing PHRC Chairperson determines that changes are necessary to eliminate apparent immediate hazards to subjects or the rights and welfare of subjects, changes may be required and approved immediately prior to review by the PHRC at a convened meeting.
- 4.6 The presiding PHRC Chairperson assigns a primary and secondary reviewer with experience or expertise in the scientific discipline or area. The primary and secondary reviewers are provided with a copy of the report of the problem, the approved consent form, and, when applicable, the revised consent form, and the detailed protocol as well as any other documents or information submitted by the investigator for review of the problem, e.g., monitoring group reports.
- 4.7 Members not assigned to review the problem report are provided with a copy of the report of the problem and the approved consent form and, when applicable, the revised consent form.
- 4.8 The primary and secondary reviewers are responsible for an indepth review of the report of the problem and materials provided. All other members are responsible for review of the report of the problem and the consent forms in sufficient depth to vote at the meeting.

- 4.9 By majority vote of a quorum of the membership present at the convened meeting, the PHRC will take one or more of the following actions:
- Accept the report and approve the proposed changes, if any, with no further action required;
 - Require additional information;
 - Require modifications to the protocol and/or consent form;
 - Require that subjects currently on protocol be notified of the event;
 - Require that subjects whose participation has ended be notified of the problem;
 - Require that subjects currently on protocol be re-consented;
 - Modify the continuing review schedule;
 - Suspend the research;
 - Terminate the research;
 - Request a directed audit by the Human Research Quality Improvement Program; or
 - Any other action deemed appropriate by the PHRC.
- 4.10 The PHRC Administrative Chairperson is responsible for preparing a description of the problem and for recording the findings and actions of the PHRC and, when relevant, the discussion of controverted issues and their resolution, in the minutes of the meeting.
- 4.11 The Human Research Office staff is responsible for notifying the Principal Investigator in writing of the findings and actions of the PHRC.
- 4.12 Within thirty (30) days of the PHRC meeting, the Director and Chair of the PHRC or designee shall be responsible for submitting a report of any serious unanticipated problem involving risks to subjects or others and, when applicable, suspension or termination of the research in accordance with the policy *Reporting to Regulatory Agencies and Institutional Officials*.
- 4.13 Recordkeeping
- The records of the review by the PHRC and associated findings of fact and determinations and recommendations will be maintained in the Human Research Office with the protocol file.