

<b>PARKVIEW HEALTH</b>	<b>INSTITUTIONAL REVIEW BOARD MANUAL</b>
Policy & Procedure Title: Reporting Procedure Category: IRB Review Process	

## I. Policy Statement

In accordance with the federal regulations, the PH IRB is responsible for maintaining written procedures for ensuring prompt reporting by the Investigators to the PH IRB, appropriate institutional officials, and the FDA/OHRP of:

- 1) Any unanticipated problems involving risks to human subjects or others;
- 2) Any instance of serious or continuing noncompliance with the regulations, or the requirements or determinations of the PH IRB; and
- 3) Any suspension or termination of PH IRB approval.

The PH IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the PH IRB's requirements, regulations or that has been associated with unexpected serious harm to subjects.

Key issues to consider include:

- Minimizing harm to subjects enrolled in research.
- Protecting the informant from retaliation.
- Protecting the reputations of the Investigators and research staff until a determination is made.
- Ensuring a fair process of investigation.
- Appointing appropriate individuals to conduct the investigation.
- Developing procedures for fact finding.
- Documentation of the investigation / fact finding process.
- Determination of corrective actions or sanctions.
- Referring matters of research misconduct to appropriate institutional officials.
- Reporting to federal regulatory and funding agencies.

## II. Definition of Terms

PH Institutional Official (PH IO): A high-level PH official, who has the authority to act for PH, as well as all the institutional components listed in the Federalwide Assurance (FWA), and on behalf of PH, obligates PH to the terms of the FWA. The PH IO cannot be the chair or member of any IRB designated under the FWA.

Suspension: occurs when the PH IRB orders the research to stop pending an action.

Termination: occurs when the PH IRB determines that the research activity must cease.

Origination Date: 04-2007 Revision Date(s): 04/09	Source: PH IRB Authorized by: Institutional Official
--	---

<b>PARKVIEW HEALTH</b>	<b>INSTITUTIONAL REVIEW BOARD MANUAL</b>
Policy & Procedure Title: Reporting Procedure Category: IRB Review Process	

### III. Procedure

- A. It is the responsibility of the Investigator to be aware of and comply with the PH IRB Policies and Procedures.
- B. An Investigator is required to sign a “Statement of Principles Concerning Clinical Research and Investigation Involving Human Beings” as a condition of study approval and prior to initiation of a study. This document will be provided to the Investigator by the PH IRB Office at the time of request for review of a new Protocol. A copy of the signed document will be kept on file at the PH IRB Office and will be available for review by PH IRB Members upon request.
- C. The reporting of unanticipated problems/serious adverse events is outlined in PH IRB P&P: Adverse Event Reports of this manual.
- D. The reporting of any noncompliance is outlined in the PH IRB P&P: Deviation and Noncompliance Reporting, and may include notification of the PH IRB Chairperson and/or Parkview Health Administrative staff members.
- E. The reporting of any suspension or termination of PH IRB approval is outlined in the PH IRB P&P: Continuing Review, and in PH IRB P&P: Suspension or Termination of a Protocol.
- F. In addition to the standard reporting procedure of Investigator to Sponsor to FDA or OHRP, as the case may be, and when applicable, reporting to appropriate institutional officials shall be accomplished by the inclusion of at least one Parkview Health Administrative staff member serving as a Member or attending as a regular guest of the PH IRB, and reporting in writing to the Institutional Official by the PH IRB Office.
- G. The PH IRB Institutional Official shall report to the appropriate federal agency, as may be applicable.

### IV. References

- A. [21 CFR 56.108](#)
- B. [45 CFR 46.103](#)

Origination Date: 04-2007 Revision Date(s): 04/09	Source: PH IRB Authorized by: Institutional Official
--	---