

<b>PARKVIEW HEALTH</b>	<b>INSTITUTIONAL REVIEW BOARD MANUAL</b>
Policy & Procedure Title: Reportable Events Category: IRB Review P&P	

## I. Policy Statement

The PH IRB responsibilities include reviewing reports of Adverse Events and Unanticipated Problems involving risks to subjects or others to ensure the continued safety and welfare of subjects. Information in these reports may impact the risk-benefit assessment of the Protocol and should be promptly reported to PH IRB.

## II. Definition of Terms

**Adverse Event (AE):** An undesirable, unintended but not necessarily unexpected result of therapy or other intervention (e.g. a headache following a spinal tap or intestinal bleeding associated with aspirin therapy).

**Serious Adverse Event (SAE):** An Adverse Event that results in any of the following:

1. Death;
2. A life threatening experience;
3. Inpatient hospitalization or prolongation of existing hospitalization;
4. A persistent or significant disability/incapacity;
5. Congenital birth defect or anomaly, or any other experience that may require medical or surgical intervention to prevent one of the serious outcomes.

**Unanticipated Problem (UP):** Any unplanned occurrence that may affect the risks and/or potential benefits involved in the research study. In general, this includes any incident, experience, or outcome that meets **all** of the following criteria:

1. Unexpected (in terms of nature, severity, or frequency) given
  - a. the research procedures that are described in the PH IRB-approved Protocol or related documents, such as Informed Consent document or Investigator Brochure; and
  - b. the characteristics of the subject population being studied.
2. Related or Possibly Related to participation in the research; and
3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

**Unanticipated Adverse Device Effect (UADE):** Any serious adverse effect on health or safety, or any life threatening event, or death caused by or associated with a device, if that effect, problem or death was not previously identified in nature, severity or degree of incidence in the PH IRB-approved Protocol or related documents; or any other unanticipated serious problem associated with a device that relates to the rights, safety or welfare of subjects.

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**Related or Possibly Related:** Means that, in the opinion of the Investigator, there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures, drug or device involved in the research.

**Internal Event:** An adverse event occurring at a site over which PH IRB has jurisdiction.

**External Event:** An adverse event occurring a non-local site over which PH IRB has no jurisdiction, such as IND Safety Reports.

### III. Procedure

- A. It is the responsibility of the Investigator to report to PH IRB all internal and external Serious, Related or Possibly Related, and Unanticipated SAE, UADE, and UP, including UP that are not necessarily AE (Reportable Events).
- B. The Investigator must also report as a Reportable Event any Event required by the Sponsor to be reported, including external adverse events, such as IND Safety Reports.
- C. Internal Reportable Events must be reported to PH IRB as soon as possible and never later than 10 business days (**day one is the first day after being notified of the event**) utilizing the PH IRB Serious Adverse Event/Unanticipated Adverse Device Effect/Unanticipated Problem Form (SAE/UADE/UP Form).
- D. External Reportable Events must be reported to PH IRB promptly utilizing the PH IRB IND Safety Report / MedWatch Form (IND SR Form).
- E. Any "Follow-Up" reports should be reported to PH IRB as soon as possible after additional information becomes available utilizing the PH IRB SAE/UADE/UP Form or IND SR Form.
- F. PH IRB's review is based upon the information submitted in the PH IRB SAE/UADE/UP Form and IND SR Form.
- G. Based upon this information, PH IRB may determine the need to:
  1. Reconsider its approval of the study,
  2. Request modifications to the study,
  3. Request revisions to the Informed Consent Form,
  4. Revise the Continuing Review time period,
  5. Request further information from the Investigator, and/or

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6. Other actions as deemed necessary by PH IRB.
- H. Reportable Events will be listed on the PH IRB Meeting Agenda and Members will review and acknowledge the report.
  - I. Following the PH IRB Meeting, the Investigator and when appropriate, the Institution, will be notified in writing of the Reportable Event acknowledgment and if further action is required.
  - J. Additionally, PH IRB is responsible for ensuring any Unanticipated Problems involving risks to human subjects or others is reported to the appropriate regulatory authority. Generally, this is reported through the standard reporting procedure of Investigator to Sponsor to FDA or OHRP. The PH IRB SAE/UADE/UP Form verifies the initiation of this procedure by requesting the date the Sponsor was notified of the event.

#### IV. References

- A. [21 CFR 56.108](#)
- B. [45 CFR 46.103](#)
- C. OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events (01-15-07) at: <http://www.hhs.gov/ohrp/policy/AdvEvtGuid.htm>
- D. FDA Guidance for Clinical Investigators, Sponsors, and IRBs: Adverse Event Reporting — Improving Human Subject Protection (01-14-09) at: <http://www.fda.gov/cber/gdlns/advreport.pdf>

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