

PARKVIEW HEALTH	INSTITUTIONAL REVIEW BOARD MANUAL
Policy & Procedure Title: Deviation and Noncompliance Reporting Category: IRB Review Process	

I. Policy Statement

It is the policy of PH IRB and required by federal regulations that the Principal Investigator or designee report to PH IRB any Deviations and Noncompliance.

This reporting is required even for Emergency Protocol Deviations.

II. Definition of Terms

Deviation: A failure, whether intended or unintended, to follow the PH IRB approved Protocol.

Examples of Deviations include, but are not limited to:

1. Failure to obtain informed consent from the subject;
2. Informed consent obtained after subject has already started study procedures;
3. Enrolling a subject who does not meet the inclusion and exclusion criteria;
4. Failure to perform a required laboratory test or procedure;
5. Drug dispensing or dosing error;
6. Incorrect storage of study medications;
7. Use of prohibited concomitant medication;
8. Study visits outside the Protocol-prescribed visit window;
9. Subject-specific waivers from Sponsors.

Emergency Protocol Deviation: A Deviation that is necessary to eliminate apparent immediate hazards to the subject as determined by the Investigator or Sponsor.

Examples of Emergency Protocol Deviations include but are not limited to:

1. Immediate reduction in the study drug dose or Study Closure due to new safety information or serious side effects;
2. Administration of a prohibited medication.

Noncompliance: A failure, whether intended or unintended, to follow federal regulations, or the requirements and determinations or policies and procedures of PH IRB.

Examples of Noncompliance include but are not limited to:

1. Use of outdated or otherwise unapproved consent form;
2. Inappropriate consent process documentation (dated by someone other than the subject, missing signature of person obtaining consent, incorrect date on consent);
3. Continuing unauthorized research activities after PH IRB approval has expired;

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4. Enrolling more subjects than was proposed and approved by PH IRB;
5. Enrollment of a subject from a Vulnerable Population (i.e. children, pregnant women, prisoners, etc.) without prior PH IRB approval;
6. Use of recruitment procedures that have not been approved by PH IRB;
7. Submitting a Serious Adverse Event Report outside the required 10 business day reporting timeframe;
8. Failure of the subject to return study medication.

III. Procedure

- A. **Emergency Protocol Deviations:** Should be reported to PH IRB as soon as possible after they occur, but in no event later than **five (5) business days** after the emergency occurred using the PH IRB Deviation and Noncompliance Report Form.
- B. All other **Deviations and Noncompliance** should be reported to PH IRB within **ten (10) business days** of the Investigator's knowledge of the Deviation or Noncompliance using the PH IRB Deviation and Noncompliance Report Form.
- C. Information in the report of a Deviation or Noncompliance should include the facts of the case, including the date of Deviation or Noncompliance, any impact on the subject's safety, remedial action taken, and plan for preventing the Deviation in the future (if applicable). These reports will be added to the agenda for the next convened PH IRB meeting.
- E. Should PH IRB require additional information regarding any Deviation or Noncompliance, a written request will be sent to the Investigator and study staff.
- D. PH IRB will determine if additional actions or follow-up need to be taken. Additional actions might include but are not limited to:
 1. Seeking additional information from the Sponsor or Investigator;
 2. Discussion of Protocol compliance with the Investigator and/or study staff;
 3. Increasing the frequency of Continuing Review for the study;
 4. Suspension or termination of the study. (See PH IRB P&P: Suspension or Termination of IRB Approval of Research)
 5. Other oversight as might be deemed appropriate.

IV. References

- A. [21 CFR 56.103](#); [21 CFR 56.108\(a\)\(3\)\(4\)](#); [21 CFR 56.108\(b\)](#); [21 CFR 312.66](#); [21 CFR 812.35](#); [21 CFR 812.150\(a\)\(4\)](#).
- B. [45 CFR 46.103\(b\)\(4\)\(iii\)](#); [45 CFR 46.103\(b\)\(5\)](#); [45 CFR 46.109](#).

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- C. [FDA DRAFT-Guidance for Clinical Investigators, Sponsors and IRBs, Adverse Event Reporting - Improving Human Subject Protection](#) (April 2007).

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