

HSREB Guidance for Protocol Deviation Reporting

A protocol deviation is an unanticipated or unintentional divergence or departure from the expected conduct of an ethically cleared research project. Protocol deviations in general, can be a result of changes necessary to ensure participant safety, be inadvertent in nature, or may be minor logistical/administrative changes. Deviations are different from amendments, as they generally only apply to a single occurrence or participant and are not intended at the time to modify the entire research protocol.

Some general examples of protocol deviations are noted below:

- Changes in procedures initiated to eliminate immediate hazards to participants;
- Enrollment of participants that do not meet inclusion/exclusion criteria (i.e. randomization of ineligible participants), regardless of sponsor approval;
- Medication/intervention errors for those interventions administered by the research team;
- Inadvertent deviations from the study timing (missed/late study visit) or procedures (missed lab test, EKG, etc.) on part of the research team;
- Deviations with the consent process on part of the research team.

1. Minor Protocol Deviations

Deviations that do not impact participant safety, compromise the integrity of the data, or affect the participant's willingness to participate in the research project. Minor deviations can be reported to the HSREB on a **quarterly basis (every three months)**.

Some examples are noted below:

- Isolated case(s) of study procedure(s) being done outside of the protocol timeline, on part of the research team, that do not increase/create risk;
- Isolated case(s) of missed or late lab tests, on part of the research team, that do not increase/create risk;
- Isolated case(s) of missed/late treatment(s), where the treatment is being administered by the research team, that do not increase/create risk.

2. Major, Planned, Non-Emergent Deviations (Amendments)

Any planned changes that will be made to the ethically cleared research must be reviewed and cleared by the HSREB, in the form of an amendment, prior to implementation. For more information, refer to SOP 404 Amendment Reporting.

Some general examples are noted below:

- Modifications to the research protocol;
- Modifications to the consent form, participant material (e.g., patient diary, handouts), to the Investigator Brochure (IB) or product monograph (PM);
- Changes in participant materials (e.g., wallet cards, diary cards, recruitment materials);
- Changes in the recruitment process;
- Changes in the research team roster.

3. Major, Unplanned Non-Emergent Protocol Deviations

Deviations that have an impact on participant safety, the integrity of the data, or that affect the participant's willingness to participate in the research project. The Researcher must submit a Protocol Deviation Report to the HSREB within **five business days** of becoming aware of any major, unplanned protocol deviation.

Some general examples are noted below:

- Enrollment of an ineligible patient;
- Deviation(s) in the consent process (wrong consent form version used, missing signatures, original consent form not located at research site);
- Performance of a study procedure or test that was not included in the initially cleared research project that may impact patient safety or the integrity of the data;
- Failure to perform a study procedure that may impact patient safety or the integrity of the data;
- Study procedures performed outside of protocol timelines that may impact the safety or integrity of the data;
- Dosing errors/intervention errors that may impact patient safety or the integrity of the data.

4. Emergency Protocol Deviations

Deviations from the protocol to eliminate immediate hazard(s) to participant(s) without prior HSREB clearance. The Researcher must submit a Protocol Deviation Report to the HSREB within **five business days** of becoming aware of the Emergency Protocol Deviation.

Some general examples are noted below:

- A change in procedures to eliminate an immediate hazard to participants;
- A change in treatment/intervention to eliminate an immediate hazard to participants.

5. Confidentiality/Privacy Breaches

The Researcher must report to the HSREB the unauthorized collection, use, and/or disclosure of personal information within **1 business day** of becoming aware of the privacy breach.

Some general examples are noted below:

- Failure to remove participant identifiers from consent forms or data collection forms prior to sending off-site (i.e., sponsor, central data repository);
- Failure to de-identify participant information prior to uploading data into an electronic data base;
- Collection of personal/confidential information without prior ethics clearance;
- Unauthorized access to personal/confidential information.