

REPORTING PROTOCOL DEVIATIONS

As a Research Ethics Board, the RvH REB's primary responsibility is to protect the safety and rights of human research participants, and therefore the REB must be aware of situations that place research participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized or as identified in the approved protocol.

The term protocol deviation is not well defined by regulations or guidelines but deviations are identified as any unplanned or unforeseen change to a REB approved protocol or protocol procedures. Deviations are different from amendments in that they generally apply to a single occurrence or participant and are not intended at the time to modify the entire protocol. Amendments are changes to the protocol or protocol procedures that are planned and that are approved by the REB prior to implementation.

There have been attempts to categorize protocol deviations as major versus minor and/or to distinguish between deviations and violations; however, there is no clear guidance on these distinctions. There are, however, guidelines and requirements for reporting protocol deviations. Examples of protocol deviations that should be reported to the REB include the following:

- Implementation of additional procedures for monitoring participants;
- Suspension of enrolment of new participants;
- Suspension of research procedures in currently enrolled participants.

If an unanticipated deviation or divergence from the approved research protocol, consent document(s) or study addenda jeopardizes participant safety, study efficacy or data integrity, it must be **promptly** reported to the REB using the attached reporting form. Specific examples of reportable deviations (i.e., if they place participants at a greater risk):

- Informed consent improperly obtained or not obtained;
- Emergency deviations to the research protocol initiated by the investigator prior to obtaining REB approval to (e.g., to eliminate apparent immediate hazards to participants);
- Major, non-emergent deviations without prior approval;
- Participant enrolment without meeting the eligibility criteria and without prior sponsor approval;
- Study drug or dose not administered per protocol with increased risk of harm to participant.

If a protocol deviation meets the reportable criteria and has not otherwise been reported through an amendment to the protocol or consent form, it should be reported to the REB using the Protocol Deviation Reporting Form. Protocol Deviations that lead to an SAE should be reported within 48 hours, otherwise within 10 working days.

***Note:** Research agreements may require the PI to notify the sponsor of all unplanned deviations or departures from REB approved protocol procedures. Sponsor reporting requirements for deviations may differ from the REB's reporting requirements. It is the PI's responsibility to comply with the reporting requirements outlined in the signed contract.*

Resources:

1. Office for Human Research Protections (OHRP) Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Participants or Others and Adverse Events www.hhs.gov/ohrp/policy/AdvEventGuid.htm
2. ICH Good Clinical Practice Guidelines, Section 3.3.7 & Section 4.5.1 – 4.5.5
3. Goldfarb, Norman M. Directory of Protocol Deviation & Violation (PDV) Codes: A Lexicon for Understanding & Communicating Protocol Deviations & Violations. First Clinical Research. www.firstclinical.com/resources/codes
4. Protocol Violations: Implications for Clinical Research* Clinical Research Focus, 12(7) Oct 2001

Format For Protocol Deviation Report

Michal Rosen-Zvi



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