

Guidance Document	Reportable Event – Protocol Deviation
Effective Review	HSREB/NMREB
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Introduction

The primary responsibility of Western University’s Health Sciences and Non-Medical REBs is to protect the **safety and rights** of human research participants. Therefore, the REBs 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 what was previously known/recognized or as identified in the approved study protocol. The REBs must also be aware of any changes to the research that negatively impact participants’ rights.

What is a Protocol Deviation?

A protocol deviation is any change, divergence, or departure from the design or study procedures of a study protocol/research plan that has NOT been approved by the REB.

All protocol deviations should be documented in the study records. This documentation (e.g., a protocol deviation log) should include the rationale/justification for the deviation and the Principal Investigator’s sign-off. A formal report to the REB (in the form of a Reportable Event-Protocol Deviation) is only required if the deviation involves research participants or procedures *and* meets specific criteria as outlined in the **Reporting to the REB** section below.

Note: Protocol deviations that occur to protect research participants from imminent physical or psychological harm or due to publicly declared emergencies based on new information obtained during the study must be reported to the REB within a Reportable Event-Protocol Deviation Form with corresponding safety information and the Principal Investigator’s plan to update the study, as required. An Amendment Form, as applicable, should then be submitted to the REB for review and approval to revise the study protocol and related documentation to prevent similar deviations from occurring in the future.

Reporting to the REB

If a protocol deviation occurs within the jurisdiction of Western University’s REBs *and* affects any of the following criteria, it must be promptly reported to the REB in WREM (i.e., create a sub-form, choose the Reportable Event form, and select the Protocol Deviation/Violation option).

Criteria for Reporting Protocol Deviations to the REB:

- (a) jeopardizes the participant’s rights, safety and/or welfare; and/or
- (b) impacts study efficacy; and/or
- (c) impacts data integrity

Examples of protocol deviations that meet the above reporting criteria include, but are not limited to:

- Conducting study procedures that have not been approved by the REB.
- Using versions of participant-facing study documents that have not been approved by the REB.
- Sharing/handling research data in a way that was not approved by the REB.
- Obtaining informed consent in a way that was not approved by the REB (e.g., the wrong version of a letter of information/consent form was used, or a method of consent was used that was not approved, such as verbal consent instead of written consent).
- Informed consent was not obtained* (e.g., data was collected without informed consent, participants were enrolled into study procedures without informed consent).
- Over-enrolment (exceeding the target number of participants approved by the HSREB).
- Enrolling participants who do not meet the eligibility criteria.
- Study drug/intervention errors (i.e., incorrect study drug/intervention, incorrect dosage of the study drug).
- Failing to report serious adverse events (SAEs) in a timely manner (reporting to the sponsor of the study within 24 hours of learning of the event).

*This does not include projects approved with a waiver of consent.

Non-identifying supporting documents (such as a sponsor protocol deviation form), as applicable, must be uploaded to the protocol deviation form for REB review and acknowledgement.

Reportable protocol deviations that lead to Serious Adverse Events (SAEs) should be reported to the REB within 48 hours, otherwise within 10 calendar days of the event.
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NOTE:

- Research agreements may require the Principal Investigator (PI) to notify the sponsor of a research study of all or select deviations or departures from the REB approved protocol procedures. The reporting requirements for deviations dictated by a study sponsor 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 with the study sponsor and the reporting requirements of the REB. Protocol deviation forms that do not meet the REB reporting criteria outlined above may be withdrawn from REB review.
- This guidance pertains specifically to projects that have been reviewed and approved by Western University's REBs.
- Additional information regarding non-compliance more broadly can be found in the REBs Standard Operating Procedures (see SOP 901, NSOP 901 for HSREB and NMREB respectively).

- Issues related to quality assurance, research integrity, and responsible conduct of research are managed outside of the REB at an institutional level.

Resources:

1. ICH Good Clinical Practice Guidelines, Section 4.5.2-4.5.4
2. Office for Human research Protocols (OHRP) Guidelines on Reviewing and Reporting Unanticipated Problems Involving Risks to Participants or Others and Adverse Events
<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html>

Western University's Research Ethics Boards operate in compliance with the Tri-Council Policy Statement 2: Ethical Conduct of Research Involving Humans; the International Conference on Harmonization of Good Clinical Practices; Part C Division 5 of the Food and Drug Regulations of Health Canada; and the applicable laws and regulations of Ontario.