Humber River Health
Research Ethics Board Protocol Deviation Guidelines

Title:	**Protocol Deviations**
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Revised:	
Approved By:	REB Chair

1.0 PURPOSE

The purpose of this guideline is to describe how Protocol deviations are submitted to and reviewed by the REB.

2.0 POLICY STATEMENT

The Principal Investigator is responsible for conducting the study in compliance with the protocol that was approved by the REB. Should an unanticipated or unintentional deviation from the expected conduct of an approved study occur, the PI may be required to report it to the REB. The REB recognizes that deviations from the protocol can be both minor and major, and distinguishes between those that must be reported to the REB and those that should not. All deviations that were implemented to eliminate immediate hazard(s) to a study participant(s) and/or that impacted the safety, welfare, comfort or rights of study participant(s), *whether they were intentional or unintentional*, are considered major and must be reported to the REB. Protocol deviations that involve only logistical or administrative aspects of the study are considered minor and should not be reported to the REB (e.g., study participant missed appointment, change in appointment date).

3.0 PROCEDURES

3.1 Submitting Protocol Deviations

All available information about the deviation must be provided to the REB as soon as the deviation occurs by using the HRH Protocol Deviation Report Form. The HRH Protocol Deviation Report Form directs the Principal Investigator to provide recommendations on:

- whether the protocol deviation affects the safety/increases the risk(s) to study participants(s)
- whether corrective measures have been made to ensure that similar deviations do not occur
- whether the deviation affects the integrity of the study data

- whether a protocol amendment will be submitted to the REB for review and approval as a result of the deviation

The REB will not accept Protocol Deviation reports without an original signature from the PI. This signature attests that the PI is aware of the deviation and its safety implications and has assessed the impact of the deviation on the study procedures.

3.2 Review Process

The REB office will assess protocol deviations and will contact the PI when further information is needed. The REB may make recommendations to amend the protocol in order to eliminate such occurrences in future.

The REB will not acknowledge receipt of the protocol deviation report form and will generally not contact the PI unless further action is required.

3.3 Protocol Deviations That Lead to Study Amendments

A protocol deviation may result in the need for an amendment to the study. In the event that a protocol deviation results in the need for an amendment, the deviation must be reported to the REB *and* an amendment must be submitted to the REB for review and approval. If the amendment has already been implemented to eliminate an immediate hazard, indicate this by answering 'Yes' to the question that asks this on the amendment form. The deviation and amendment must be submitted to the REB together to facilitate the review process.

3.4 Protocol Deviations That Are Also Serious Adverse Event(s)/Unanticipated Problem

If a protocol deviation resulted in an internal adverse event/unanticipated problem, the Internal Serious Adverse Event/Unanticipated Problem Reporting Form must be submitted together with the deviation report to the HRH REB.

4.0 REFERENCES

1. ICH Harmonized Tripartite Guideline E6: Guideline for Good Clinical Practice, 1997.
2. Tri Council Policy Statement 2, 2022.