IWK Research Ethics
Standard Operating Procedures

Document # **RE 4.405**	Title: **Protocol Deviations**	Effective Date: **November 19, 2024**
Pages**: 3**	Responsibility of: **Research Ethics Board**	Date Approved: **November 19, 2024**

POLICY STATEMENT
An investigator who deviates from the REB-approved protocol either inadvertently or to eliminate an immediate hazard(s) to participants or others without prior REB approval must notify the REB using appropriate procedures.

A protocol deviation is an unanticipated or unintentional divergence or departure from the expected conduct of an approved study that is not consistent with the current research protocol, consent document or study addenda. Examples of protocol deviations include:

- Changes in procedures initiated to eliminate immediate hazards to study subjects
- Enrolment of subjects outside protocol inclusion/exclusion criteria, whether agreed to or not by the sponsor
- Medication/intervention errors (i.e. incorrect drug/intervention, incorrect dosage of the drug)
- Inadvertent deviation in specific research intervention procedures or timing of the research intervention which could impact upon the safety or efficacy of the study-related intervention or upon the experimental design (i.e. this would not include appointment deviations usually)
- Breach of confidentiality or privacy whereby confidential information about a subject is revealed in inappropriate settings, or to persons without a need to know, or by data exposure (computer security breach, documents left unsecured)
- Significant deviation from the consenting process

DEFINITIONS
See Glossary of Terms

RESPONSIBILITY
This SOP applies to Investigators, REB Chair, REO Manager, REB members, and Research Ethics Office (REO) staff.

PROCEDURES

Investigator's Responsibilities

The Investigator should not implement any deviation from, or changes of the protocol without prior REB approval, except where necessary to eliminate an immediate hazard(s) to participants, or when the change(s) involves only logistical or administrative aspects of the research (e.g. change of telephone number(s).

An investigator who deviates from the protocol either inadvertently or to eliminate an immediate hazard(s) to participants without prior REB approval must submit, as soon as reasonably possible thereafter, a report notifying the REB of the implemented deviation or change, the reasons for it, and, if appropriate, an accompanying proposed protocol amendment for review and approval, using the online electronic *IWK Safety Related Event Reporting (External SAEs, Minor Protocol Deviations, PSUr, DSMB, Safety Alerts)* Event.

Reporting Timeline

Protocol deviations affecting patient's safety or the integrity / outcome of the study should be reported promptly.

Protocol deviations that lead to a serious adverse event (SAE) must be reported within 24 hours.

REB Review of Protocol Deviations

The REB co-chair will review the report. If further information is required then the investigator will be contacted.

If there are no concerns, then the PI will receive acknowledgement and no further action will be taken.

If the deviation is an unanticipated risk to research participants, or a result of serious or continuing noncompliance then further action is required and it will be on the agenda for the next REB meeting for discussion.

Immediate action may occur at the REB Chair's discretion. Justification for this will be documented.

Note: US regulations will be applied as applicable.

REFERENCES

1. ICH Good Clinical Practice Guidelines, Section 3.3.7 & Section 4.5.1 – 4.5.5.
2. Health Canada: Summery report of the inspections of clinical trials conducted in 2003 / 2004

Forms/Records:

Form #	Form/Record Name
SOP 405	Protocol Deviations

Revision History:

Revision	Date	Description of changes
0.0	April 1, 2017	Initial Release
1.0	September 9, 2022	Additions to comply with TCPS2-2018
1.1	February 1, 2023	Updated logo
1.2	November 19, 2024	Added note regarding compliance with US regulations where applicable