IWK Research Ethics
Standard Operating Procedures

Document # **RE 4.409**	Title: **Adverse Event Reporting**	Effective Date: **November 19, 2024**
Pages**: 4**	Responsibility of: **Research Ethics Board**	Date Approved: **November 19, 2024**

POLICY

The REB will ensure that the safety monitoring plan and reporting requirements are specified in the research protocol and are appropriate to that specific research before ethical approval is granted. All adverse events and serious adverse events occurring during a study must be reported to the Sponsor, if any, and to the REB. If the event is serious and unexpected, reporting must take place within 24 hours.

Investigators must notify the REB of any new information from any source that may affect the welfare and safety of research participants.

DEFINITIONS

See Glossary of Terms

RESPONSIBILITY

This SOP applies to investigators, REB Chair, Manager, REB Members, and Research Ethics Office (REO) staff.

PROCEDURES

Reporting Requirements

Serious Adverse Events (SAE) occurring at the IWK site must be reported to REO as soon as any member of the study team becomes aware of the event, using the *IWK REB Serious Adverse Event Initial Report Form*. If the investigator considers that the circumstances demand a change in the study protocol, then an *IWK REB Amendment Submission Cover Page* and appropriate *Amendment Form* should also be submitted.

SAE reports along with those of unexpected AEs or other unanticipated problems must also be reported, where applicable, to the Sponsor in accordance with the Sponsor's requirements.

Investigator Requirements

Investigators should be aware of the reporting requirements for adverse events imposed by the REB and, where appropriate, their Sponsor. It is important that the Reporting Form be completed fully, and that the Principal Investigator (PI) attests to severity and causality before signing the Form.

Failure to report SAEs may trigger an REB investigation and possible suspension of the research approval (see REB SOP 4.407 and REB SOP 4.408).

Review of Safety Reports by the IWK REB

When a safety report is received in REO, the staff will log it and pass it to the Chair or designated reviewer. After review, the report, annotated with the reviewer's comments, is placed in the respective study file. Acknowledgement of the reviewed safety report is sent to the investigator.

Depending on the nature and circumstances of the incident, the reviewer will take one or other of the following actions:

- Request for more information
- Refer to full REB for review
- Accept; no further action required
- Accept; with minor corrections to the safety report
- Accept; requires modifications to the protocol-related documents.

A summary report of all individual safety reports received will be tabled at each monthly REB meeting.

External Adverse Event Reports

Exception to PI review/documentation of new information sent from the Sponsor

- For non-local safety reports, only non-local safety reports that require submission to IWK REB are ones that cause a change in the protocol and/or ICFs, therefore it is not necessary for the PI to record their decision to report to REB unless there is an accompanying change in protocol and/or ICFs.
- Non-local (external) SUSARs (suspected unexpected serious adverse reaction), safety reports, and line listings that do not change the protocol and/or ICFs do not require review by the PI or notification to the study team for the following reasons as described and evidenced in the CAREB AE Guidance FINAL July 2010 document (see references)

Key reasons for this exception are in the document as follows:

- As noted by the US Office for Human Research Protections (OHRP), reports of individual external adverse events often lack sufficient information to allow investigators or REBs

to make meaningful judgments about whether the adverse events are unexpected, are related to participation in the research, or suggest that the research places research participants or others at a greater risk of physical or psychological harm.

- For multi-centre studies, the sponsor and/or data and safety monitoring committee is in a better position to process and analyze adverse event information for the entire study, and to assess whether an event is an "unanticipated problem". Accordingly, investigators may rely on the sponsor's assessment and provide to the REB a periodic safety update report prepared by the sponsor. The format used for annual safety reports is acceptable. In general, the sponsor should amend the Investigator's Brochure as needed so as to keep the description of safety information updated.

The PI will review and document review as previously outlined in section 4.3.2 of safety summary reports such as annual safety report summaries, investigator brochure updates, product monograph updates, and data safety monitoring updates.

Other Safety Reports
Other safety reports received by Investigators from Sponsors and other responsible sources (DSMBs, PSRIs, and various Notices) are also to be copied to the REO and will be similarly reviewed.

Actions arising from safety reports
If the reported information is considered to affect the safety or welfare of other research participants, the Board may require that the research be modified, suspended or terminated. The Board will also consider if this new information should be communicated to research participants.

Note: US regulations will be applied as applicable.

REFERENCES
1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2), Articles 6.15; 11.9;
2. The International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, Sections 3, 4.4, 4.5, 4.10, 4.11, 4.12;
3. Health Canada Food and Drug Regulations, Division 5, C.05.014
4. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21 Part 56.108, 56.109, 56.110, 56.111, 56.115;
5. US Department of Health and Human Services (HHS) CFR Title 45 Part 46.103, 46.109, 46.110, 46.111, 46.115;
6. US Office for Human Research Protections (OHRP) Guidance “Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events”

Forms/Records:

Form #	Form/Record Name
SOP 409	Adverse Event Reporting

Revision History:

Revision	Date	Description of changes
0.0	April 1, 2017	Initial Release
1.1	November 4, 2022	Additions to comply with TCPS2-2018
1.2	February 1, 2023	Updated logo
1.3	November 19, 2024	Added note regarding compliance with US regulations where applicable