IWK Research Ethics
Standard Operating Procedures

Document # **RE 4.408**	Title: **Administrative Holds, Terminations and Suspensions of Approval**	Effective Date: **February 1, 2023**
Pages**: 4**	Responsibility of: **Research Ethics Board**	Date Approved: **February 1, 2023**

POLICY STATEMENT

The REB may require that research be modified or that recruitment of new participants be suspended, or may suspend or terminate REB approval if the risks to the research participants are determined to be unreasonably high or when there is evidence that the investigator is not conducting the research in compliance with applicable standards, regulations and guidelines.

A decision to suspend or terminate REB approval of the research must include consideration of the safety, rights and well-being of participants already enrolled in the study, specifically whether and how to continue the care of enrolled participants, and how and when the notification of research participants will take place.

The convened REB has the authority to suspend or terminate REB approval of research. The REB Chair or designee has the authority to suspend approval. Any requests to lift a suspension issued by the REB or to re-approve suspended research must be reviewed by the convened REB.

DEFINITIONS

See Glossary of Terms

RESPONSIBILITY

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

PROCEDURES

Suspension or Termination by Institution

Although only the REB has the authority to grant or withhold ethical approval of research within the Health Centre the Board/CEO of the IWK may disallow any research activities at any time within the Health Centre for its own reasons, irrespective of the REB. Further actions arising out of institutional suspension are not the responsibility of the REB.

Suspension or Termination by Investigator
An investigator may voluntarily put a study on hold, for administrative or other reasons. In this case, the Investigator should notify the Board through the REO of the circumstances including likelihood of being able to resume the study at some time.

Suspension or Terminations by the Sponsor
The sponsor of a study may suspend or terminate the research (e.g. following results of an interim analysis, interruption in product/intervention availability, in response to a DSMB recommendation, or meeting a pre-planned stopping criterion). In the event this happens:

- The investigator must immediately notify the REO
- The Manager will notify the Chair and the suspension will be added to the agenda for the next meeting of the Board
- REB may suspend or terminate REB approval, in which case the research may not be resumed until a new REB review and approval process has been completed

Suspension or Terminations by the REB
If any concerns are raised during REB oversight of a research study related to new information or the conduct of research, the REB may suspend or terminate research at any time. Examples of concerns include:

- Investigator's failure to adhere to the REB-approved protocol or REB requirements or conditions imposed by a Sponsor or regulatory authority
- The research is associated with unexpected serious harm to patients, or significant concerns about the investigational drug have arisen from any source, including safety and DSMB reports
- Other unanticipated problems involving risks to participants or others.
- Investigator's failure to submit a progress report and application for continuing approval by the end of the current approval period
- Evidence or suspicion of falsification of study records or data
- Failure to properly obtain or document consent from research participants
- Failure to limit administration of the investigational drug or device to those research participants under the investigator's supervision
- Failure to obtain prior REB review and approval of amendments or modifications to the research
- Failure to maintain accurate study records or submit required adverse event reports to the REB.

In situations of urgency the Chair, acting alone, may impose temporary suspension pending Board consideration of the matter. The Board may later continue or lift the suspension, or impose additional requirements, or proceed to termination. Factors to be taken into consideration in these decisions include, *inter alia*:

- Risk(s) to current participants
- Whether participants should be informed of the termination or suspension

- Any appropriate additional actions which may be needed to protect the safety, rights and well-being of currently enrolled participants; whether withdrawal of enrolled participants is warranted and, if so, the specific procedures required for their safe withdrawal; and their appropriate follow-up care and monitoring

Temporary suspensions may be removed after corrective actions are completed to the Board's satisfaction.

Reporting Suspensions or Terminations

The Chair will promptly report orally to the investigator any suspension or termination of REB approval, and the reasons for this decision. The Chair will also send a formal letter of suspension or termination to the Investigator, setting out the reasons for this decision and, where appropriate, listing the corrective measures the Board requires before such suspension might be removed.

In cases of drug trials or sponsored studies, the Investigator will also be required to report the suspension or termination to the study sponsor, the investigator's academic department head, and any involved and the appropriate Institutional Official and any regulatory authorities involved. Alternatively, the Chair may choose to notify these entities directly.

REFERENCES

1. The International Conference on Harmonization Good Clinical Practices, Section 4.12;
2. Tri-Council Policy Statement: Ethical conduct for Research Involving Humans, 2018:
(short name: TCPS 2), Article 11.9;
3. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103;
4. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21 Part 56.108;
5. US Department of Health and Human Services (HHS) Title 45 CFR 46.109, 46.111.
45 CFR 46.103(5)

Forms/Records:

Form #	Form/Record Name
SOP 408	Administrative Holds, Terminations and Suspensions of Approval

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