SOP Title	Study suspension and termination
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Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Office of Human Research Ethics	Erika Basile	Mar 3, 2025
Dr. Isha DeCoito Chair, Non-Medical Research Ethics Board	Isha DeCoito	Mar 4, 2025

1. PURPOSE

This standard operating procedure (SOP) describes the procedures associated with suspension or termination of research previously approved by the Non-Medical Research Ethics Board (NMREB).

2. GENERAL POLICY STATEMENT

As a result of ongoing review activities, the NMREB may require that research be modified or may suspend or terminate NMREB approval if the risks to the research participants are determined to be unreasonably high, for example, in cases in which there are high numbers of unexpected serious adverse events, or when there is evidence that the Investigator is not conducting the research in compliance with applicable regulations and guidelines. The NMREB also has the authority to suspend new enrolment while additional information from the investigator is requested.

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

3. RESPONSIBILITY

This SOP applies to the NMREB Chair, Vice-Chair(s), NMREB members, and the Office of Human Research Ethics (OHRE) staff.

The NMREB or the NMREB Chair or designee is responsible for determining whether any information received throughout the course of the research requires consideration of suspension or termination of NMREB approval for the research. The NMREB Chair alone is not authorized to terminate research; however, the NMREB Chair or designee is authorized to suspend research

and is responsible for reporting any suspensions to the convened NMREB at the next Full Board meeting.

The Investigator is responsible for notifying the NMREB and the institution of any suspensions or terminations of research and providing a detailed explanation for the action.

The NMREB Chair is responsible for requesting that the Investigator report any suspension or termination or NMREB approval of research to the study sponsor, the appropriate Institutional Official and Department Head, and regulatory authorities. Alternatively, the NMREB Chair may choose to notify the Institutional Official and Department Head, and regulatory authorities directly.

4. DEFINITIONS

See glossary of terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. Suspension or Terminations by the Sponsor

5.1.1. The Sponsor of a study may place research activities on hold or terminate the research (e.g. following results of an interim analyses; or a pre-planned stopping criteria);

5.1.2. The Investigator must immediately notify the NMREB and institution of any suspensions or terminations and the reasons for the action;

5.1.3. Reports of suspensions or terminations by the sponsor will be forwarded to the NMREB Chair or designee for review;

5.1.4. If the NMREB Chair or designee decides to suspend NMREB approval of the research, they must notify the NMREB at its next Full Board meeting;

5.1.5. If the NMREB approval is suspended, a subsequent review must be conducted and the NMREB suspension must be lifted prior to resumption of the research following the Sponsor's lifting of a suspension.

5.2. Suspension or Terminations of NMREB Approval

5.2.1. If any concerns are raised during NMREB oversight of a research study related to new information of the conduct of research, the NMREB may suspend or terminate research at any time. These concerns include:

- the research is not being conducted in accordance with the NMREB-approved protocol or NMREB requirements,
- the research is associated with unexpected serious harm to participants,
- unanticipated problems involving risks to participants or others,
- failure to submit a Continuing Ethics Review (CER) form and application for continuing approval annually,

- falsification of study records or data,
- failure to comply with prior conditions imposed by the NMREB (i.e. under a suspension or approval with modification),
- repeated or deliberate failure to properly obtain or document consent from research participants,
- repeated or deliberate failure to comply with conditions placed on the study by the NMREB or regulatory agencies,
- repeated or deliberate failure to obtain prior NMREB review and approval of amendments or modifications to the research, or
- repeated or deliberate failure to maintain accurate study records or submit required reportable events to the NMREB;

5.2.2. The NMREB Chair or designee has the authority to suspend approval;

5.2.3. The NMREB has the authority to suspend or terminate NMREB approval following a review at a Full Board meeting;

5.2.4. Prior to suspending or terminating NMREB approval the NMREB, or the NMREB Chair or designee must consider:

- risk(s) to current participants;
- actions to protect the safety, rights and well-being of currently enrolled participants,
- the appropriate follow-up care and monitoring,
- whether withdrawal of enrolled participants is warranted and the specific procedures for their safe withdrawal,
- whether participants should be informed of the termination or suspension,
- whether adverse events or outcomes should be reported to the NMREB,
- corrective measures time frame in which the corrective measures are to be implemented;

5.2.5. If the NMREB Chair or designee suspends the research, he/she will notify the NMREB at the next convened NMREB Full Board meeting;

5.2.6. If the research is suspended or terminated, the NMREB Chair or designee will issue a formal letter to the Investigator with the reason(s) for the NMREB action and the corrective measures proposed by the NMREB. The letter is reviewed, revised as necessary and signed by the NMREB Chair or designee and sent to the Investigator;

5.2.7. Approval may be reinstated after corrective actions are completed to the NMREB's satisfaction.

5.3. **Reporting Suspensions or Terminations**

5.3.1. The NMREB Chair or designee will promptly report either orally or by formal letter to the Investigator any suspensions or terminations of NMREB approval, and the reasons for the decision. The decision will follow in writing;

5.3.2. The NMREB Chair or designee will request that the Investigator report any suspension or termination or NMREB approval of research to the study sponsor and the appropriate Institutional Official and regulatory authorities. Alternatively, the NMREB Chair may choose to notify the Institutional Official and regulatory authorities directly.

6. REFERENCES

6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2), Article 11.9;

6.2. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103.

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
N408.001	Original	07/07/2016
N408.002	Administrative Corrections	09/10/2018
N408.003	Update Chair and Addition of section 5.1: Suspension or Terminations by the Sponsor	02/24/2025