



# Research Ethics Board

## Standard Operating Procedure

<b>Document Number</b>	<b>REB.SOP.407</b>
<b>Title</b>	Suspension or Termination of REB Clearance
<b>Effective Date</b>	September 23, 2021
<b>Next Review</b>	2026
<b>Next Administrative Review</b>	2023

### 1. Purpose

This standard operating procedure (SOP) describes the procedures to be undertaken in determining and executing the suspension or termination of the Research Ethics Board's (REB) clearance of research.

### 2. Definitions

See the MSVU **REB Glossary of Terms (REB.INFO.001)**

### 3. Scope

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

### 4. Responsibilities

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

The REB is responsible for determining whether any information received throughout the course of the research requires the suspension or termination of REB clearance for the research being considered.

The Researcher is responsible for notifying the REB and the organization of any suspensions or terminations of the research and for providing a detailed explanation for the action.

The REB Chair or designee is not authorized to terminate REB clearance; however, the REB Chair or designee is authorized to suspend REB clearance, which must be reported to the REB at its next Full Board meeting. The REB is authorized to terminate REB clearance by majority vote following its review at a Full Board meeting.

The REB Chair or designee is responsible for notifying the Researcher, and the Organizational Official(s), of any suspension or termination of REB clearance of the research.

## 5. Procedures and/or Specific Policies

As a result of ongoing review activities, the REB may require that research be modified, or may suspend or terminate REB clearance if the risks to the research participants are determined to be unreasonably high; or when there is evidence that the Researcher is not conducting the research in compliance with applicable policies and guidelines. The REB also has the authority to suspend recruitment while additional information is requested.

The REB has the authority to suspend or to terminate the REB's clearance of the research. The REB Chair or designee has the authority to suspend ethics clearance.

Any requests to lift a suspension or to re-approve the research must be reviewed by the Full Board.

A Researcher may decide to voluntarily suspend or terminate some or all research activities; however, this is not considered a suspension or termination of REB clearance.

### 5.1. Suspension or Terminations of Research Activities

- 5.1.1. Research may be suspended or terminated by the REB or by the researcher for a variety of reasons, e.g., following results of interim analyses, in response to a safety or privacy concern, due to pre-planned stopping criteria, etc.;
- 5.1.2. The Researcher must immediately notify the REB of any suspensions or terminations of the research and the reasons for the action;
- 5.1.3. Reports of suspensions or terminations will be forwarded to the REB Chair or designee for review;

### 5.2. Suspension or Termination of REB Clearance

- 5.2.1. If any concerns are raised during the REB's oversight of the research that are related to new information or to the conduct of the research, the REB may suspend or terminate its clearance of the research as appropriate. These concerns may include but are not limited to:
  - The research not being conducted in accordance with the REB-approved protocol or REB requirements,
  - The research is associated with unexpected serious harm to participants (i.e., as may be determined following REB review of reportable events),
  - Failure to comply with prior conditions imposed by the REB (i.e., under a suspension or clearance with modifications),
  - Repeated or deliberate failure to properly obtain or document consent from research participants,
  - Repeated or deliberate failure to obtain prior REB review and clearance of amendments or modifications to the research, or
  - Repeated or deliberate failure to maintain accurate research records or submit required reportable event reports to the REB;
  - In accordance with an ongoing allegation or finding of a breach of responsible conduct of research, as determined through the Organization's policy and procedures.
- 5.2.2. The REB Chair or designee is authorized to suspend REB clearance of research. If the Chair or designee suspends clearance of the research, they

- must notify the REB at its next Full Board meeting;
- 5.2.3. The REB is authorized to terminate its clearance of the research following a review at a Full Board meeting;
- 5.2.4. Prior to suspending or terminating REB clearance, the REB must consider:
- Risks to current participants,
  - Actions to protect the safety, rights and well-being of currently enrolled participants,
  - Whether participants should be informed of the termination or suspension,
  - Whether adverse events or outcomes should be reported to the REB,
  - Identification of a time frame in which the corrective measures are to be implemented;
- 5.2.5. The REB Chair or designee will notify the Researcher of any suspensions or terminations of REB clearance, and the reasons for the decision;
- 5.2.6. Unless otherwise stated by the REB, when the REB Chair or designee suspends or terminates ethics clearance of the research, no further activities can take place other than the submission of an amendment or reportable events;
- 5.2.7. If the research is suspended or terminated, the REB Chair or designee will issue a formal letter to the Researcher with the reason(s) for the REB action and the corrective measures proposed by the REB (if any);
- 5.2.8. Suspensions may be lifted after corrective actions are completed to the REB's satisfaction.

### 5.3. Reporting Suspensions or Terminations

The REB Chair or designee will report any suspension or termination of REB clearance to the appropriate Organizational Official(s).

## 6. References

See References listed (if applicable)

## 7. Acknowledgements

The development of this document has benefited directly from similar documents made public by the Tri-Council, as well as several Canadian universities. In some instances, specific formulations drawn from these sources have been incorporated into this document. Specific iterations were drawn from the following:

- Standard Operating Procedures for Observational Health and Non-Clinical Trial Research Ethics Boards - [N2/CAREB-ACCER REB SOPs – Canadian Association of Research Ethics Boards](#) (retrieved July 2021)
- N2/CAREB-ACCER REB SOPs - N2 Network of Networks - [Resources - N2 Canada](#) (retrieved July 2021)

## 8. SOP History

SOP Number	Key Changes	Effective Date
REB.SOP.407	Original Version	September 2021

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