

<b>Title</b>	<b>Suspension or Termination of REB Approval</b>
<b>SOP Code</b>	409.01
<b>Effective Date</b>	September 2023

**Site Approvals**

<b>Name and Title (typed or printed)</b>	<b>Signature</b>	<b>Date</b>
Dr. Craig Kuziemsky Associate Vice-President, Research	<i>Original signed</i>	October 2020
Dr. Craig Kuziemsky, AVPR	<i>Original signed</i>	September 2023

**1.0 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) approval of research.

**2.0 SCOPE**

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

**3.0 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 approval for the research being considered.

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

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

## **4.0 DEFINITIONS**

See Glossary of Terms.

## **5.0 PROCEDURE**

As a result of ongoing review activities, the REB may require that research be modified, 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 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 approval of the research. The REB Chair or designee has the authority to suspend ethics approval. 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 approval.

### **5.1 Suspension or Termination of REB Approval**

5.1.1 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 approval of the research as appropriate. These concerns may include:

- 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 approval 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 approval 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;

5.1.2 The REB Chair or designee is authorized to suspend REB approval of research. If the Chair or designee suspends approval of the research, they must notify the REB as per applicable requirements;

- 5.1.3 The REB is authorized to terminate its approval of the research following a review at a Full Board meeting;
- 5.1.4 Prior to suspending or terminating REB approval, 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;
- 5.1.5 The REB Chair or designee will notify the Researcher of any suspensions or terminations of REB approval, and the reasons for the decision;
- 5.1.6 Unless otherwise stated by the REB, when the REB Chair or designee suspends or terminates ethics approval of the research, no further activities can take place other than the submission of an amendment or reportable events;
- 5.1.7 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);
- 5.1.8 If REB approval of a research or if the conduct of the research has been suspended, the suspension may be lifted after corrective actions are completed to the REB's satisfaction.

## **5.2 Reporting Suspensions or Terminations**

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

## **6.0 REFERENCES**

See References.

## 7.0 REVISION HISTORY

<b>SOP Code</b>	<b>Effective Date</b>	<b>Summary of Changes</b>
409.00	October 8 2020	Original version
409.01	September 2023	Reviewed, no revisions needed