

SOP #: 001 – 13-14

Title: Issuing a Halting Order, a Suspension, or Termination of REB Approval

## 1.0 PURPOSE

This standard operating procedure (SOP) describes the procedures associated with initiating a halting order, suspension, or termination of a research protocol previously approved by the Research Ethics Board (REB).

## 2.0 POLICY STATEMENT

Circumstances may arise that make it necessary to halt, suspend or terminate REB approval of an active research program, especially in cases where it has become apparent that research activity exposes participants to unanticipated and undue risk. Approval may also be suspended or terminated where it is found that research is not being conducted in accordance with an REB approved protocol, the TCPS, or other applicable regulations.

In order to protect research participants, the Chair has the authority to order an immediate halt to research activity pending review by the REB. Where such a halting order has been issued, the Chair will convene a meeting of the REB within 15 days to review the decision. The REB will then decide whether to lift the halting order, formally suspend its approval of the protocol, or terminate the protocol. The researcher will be provided the opportunity to meet with the REB and provide reasons why the research should not be suspended or terminated.

Changes to a researcher's employment circumstances (e.g. termination, suspension) may necessitate suspension of any REB-approved research program for which the researcher is Principal Investigator. Suspension in such cases does not require consultation with the REB. However, the disposition of research programs that have been suspended under such circumstances will be subject to REB review, particularly in cases where a new Principal Investigator might be appointed through amendment to the protocol.

Any decision to lift a suspension of REB approval or terminate a research program must be taken by the REB.

## 3.0 DEFINITIONS

**Chair:** The REB Chair or designee

**Halting Order:** An immediate stop to research activities involving human participants issued by the REB Chair pending REB review

**Principal Investigator:** The Principal Investigator of record as identified by REB-approved protocol

**Suspension:** Temporary withdrawal of REB approval

**Termination:** Permanent withdrawal of REB approval

#### **4.0 RESPONSIBILITY**

This SOP applies to the REB Chair, Vice-Chair, REB members, and Research Ethics Officer(s), and Research Ethics Office (REO) staff.

The Chair is responsible for determining whether any information received during the course of the research warrants the protocol being issued a halting order.

The REB is responsible for issuing suspensions or terminations to REB approved protocols.

Only the REB can lift a suspension. Terminated projects cannot be reinstated.

#### **5.0 PROCEDURES**

##### **5.1 Suspension or Termination by the Sponsor**

5.1.1 The sponsor of a study may suspend or terminate a research protocol.

5.1.2 The researcher must immediately notify the REB and the institution of any suspension or termination by the sponsor and the reasons for the action.

5.1.3 Reports of suspensions or terminations by the sponsor will be reviewed by the REB.

##### **5.2 Halting, Suspension, or Termination by the REB**

5.2.1 The REB may suspend or terminate the research based on concerns that include:

- failure to conduct research in accordance with the REB-approved protocol or REB requirements;
- indication of unexpected serious harm to participants;
- unanticipated problems involving risks to subjects or others;
- failure to submit an application for renewal by the end of the approval period
- falsification of study records or data;
- failure to comply with prior conditions imposed by the REB (i.e. under a suspension or approval with modification);
- failure to obtain informed consent from research participants;
- failure to comply with conditions placed on the study by the REB, sponsor, or regulatory agencies;
- failure to obtain prior REB review and approval of amendments or modifications to the research;
- failure to maintain accurate study records or submit required reports to the REB.
- non-compliance with the TCPS2

5.2.2 The Chair has the authority to issue a halting order pending REB review and the REB has the authority to suspend or terminate REB approval of active protocols.

5.2.3 Prior to suspending or terminating REB approval the REB must consider:

- risk to current participants;
- rights of current participants;
- whether participants should be informed of the termination or suspension
- corrective measures, and the time frame in which the corrective measures are to be implemented

5.2.4 Where research has been halted or suspended, a letter of notification will be sent to the researcher explaining the reason(s) for the REB's decision. The letter will advise the researcher that he/she has the right to attend any REB meeting in which consideration of the status of his/her research is on the Agenda (except in cases of employment suspension). The researcher may submit relevant documentation/evidence for the REB's consideration.

5.2.5 The REB will determine the conditions under which suspension will be lifted. Only the REB has the authority to lift a suspension.

5.2.6 Suspensions or terminations will be reported to the Board of Governors through the Office of the President. Such reports will be limited to a general characterization of the reason for the suspension or termination (e.g. "failure to meet TCPS provisions for informed consent").

## 6.0 REFERENCES

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2), Article 6.3

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REB Chair: \_\_\_R. Maundrell\_\_\_\_\_

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