WOMEN'S COLLEGE RESEARCH INSTITUTE
Health care for women | REVOLUTIONIZED

Research Ethics Board Standard Operating Procedures

Suspension or Termination of REB Approval

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ISSUED BY:	Research Ethics Office		
APPROVED BY	Vice President, Research		

The WCH Research Ethics Office (REO) webpage version of this document is considered the most current.

Please ensure that you have reviewed all linked documents and other reference material within this SOP

1.0 POLICY STATEMENT:

The purpose of this Standard Operating Procedure (SOP) is to describe the procedures associated with suspension or termination of research previously approved by the Women's College Hospital (WCH) Research Ethics Board (REB).

The WCH REB may require that research be modified or may suspend or terminate WCH REB approval if the risks to the research participants are determined to be unreasonably high. The WCH REB also has the authority to suspend new enrolment while additional information from the investigator is requested.

A decision to suspend or terminate WCH 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 WCH REB Chair or delegate is responsible for determining whether any information received throughout the course of the research requires consideration of suspension or termination of WCH REB approval for the research. The WCH REB Chair alone is not authorized to terminate research. However, the WCH REB Chair or delegate is authorized to suspend research and is responsible for reporting any suspensions to the next available convened WCH REB meeting. The WCH REB is authorized to terminate research at a convened WCH REB meeting. Any requests to lift a suspension or reapprove research must be reviewed by the convened WCH REB.

2.0 DEFINITION(S):

See Glossary of Terms

3.0 RESPONSIBILITY:

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

The REB or the REB Chair or designee is responsible for determining whether any information received throughout the course of the study requires consideration of suspension or termination of REB approval for the research. The REB Chair alone is not authorized to terminate research; however, the REB Chair or designee is authorized to suspend research and is responsible for reporting any suspensions to the convened REB at the next available meeting. The REB is authorized to terminate research following review at a convened REB meeting.

WOMEN'S COLLEGE RESEARCH INSTITUTE
Health care for women | REVOLUTIONIZED

Research Ethics Board Standard Operating Procedures
Suspension or Termination of REB Approval

The investigator is responsible for notifying the REB and the institution of any suspensions or termination of research and providing a detailed explanation for the action.

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

4.0 PROCEDURES:

4.1 Suspension or Termination by the Sponsor

4.1.1 The sponsor of a study may place research activities on hold or terminate the research (e.g. following results of an interim analyses; inadequate drug availability; in response to a DSMB recommendation; or a pre-planned stopping criteria).

4.1.2 The investigator must immediately notify the WCH REB and WCH of any suspensions or terminations and the reasons for the action.

4.1.3 Reports of suspensions or terminations by the sponsor will be forwarded for review by the convened WCH REB.

4.1.4 The WCH REB has the authority to suspend or terminate WCH REB approval, which will require WCH REB review and approval prior to resuming the research following the sponsor's lifting of a suspension.

4.2 Suspension or Termination by the WCH REB

4.2.1 If any concerns are raised during WCH REB oversight of a research study related to new information on the conduct of research, the WCH REB may suspend or terminate research at any time. These concerns include, but are not limited to, the following:

- the research is not being conducted in accordance with the WCH REB-approved protocol or WCH REB requirements;
- the research is associated with unexpected serious harms to patients;
- safety reports that indicate potential serious harms;
- unanticipated problems involving risks to subjects or others,
- DSMB reports with recommendations to discontinue a research study;
- failure to submit a progress report and application for continuing approval by the end of the approval period;
- falsification of study records data;
- failure to comply with prior conditions imposed by the WCH REB (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 limit administration of the investigational drug or device to those research participants under the investigator's supervision;
- repeated or deliberate failure to comply with conditions placed on the study by the WCH REB, sponsor, or regulatory authorities;
- repeated or deliberate failure to obtain prior WCH REB review and approval of amendments or medications to the research; or
- repeated or deliberate failure to maintain accurate study records or submit required adverse event reports to the WCH REB.

4.2.2 The WCH REB Chair or delegate has the authority to suspend approval and the WCH REB has the authority to suspend or terminate WCH REB approval of research.

4.2.3 Prior to suspending or terminating WCH REB approval, the WCH REB, or the WCH REB Chair or delegate must consider:

- risk(s) to current participants;
- actions to protect the safety, rights, and well-being of currently enrolled participants;
- 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 WCH REB;
- corrective measure time frame within which the corrective measures are to be implemented.

4.2.4 If the WCH REB Chair or delegate suspends the research, he/she must notify the WCH REB at the next convened WCH REB meeting.

4.2.5 Research Ethics Office (REO) staff draft a formal letter to the investigator with the reason(s) for the WCH REB action and the corrective measures proposed by the WCH REB. The letter is reviewed, revised as necessary and signed by the WCH REB Chair or delegate and sent to the principal investigator (PI).

4.2.6 Once the PI has responded to the letter and demonstrated that the corrective actions are completed, the study and PI response will be reviewed at the next convened WCH REB meeting.

4.2.7 Approval may be reinstated after corrective actions are completed to the WCH REB's satisfaction. The WCH REB may also require further follow up actions, or may decide to terminate WCH REB approval.

WOMEN'S COLLEGE RESEARCH INSTITUTE
Health care for women | REVOLUTIONIZED

Research Ethics Board Standard Operating Procedures
Suspension or Termination of REB Approval

4.2.8 The WCH REB decision will be communicated formally in a letter to the PI within one week of the convened WCH REB meeting. This letter will be signed by the WCH REB Chair or delegate.

4.3 Reporting Suspensions or Terminations

4.3.1 The WCH REB Chair or delegate will promptly report orally to the investigator any suspension or termination of WCH REB approval, and the reasons for the decision. The decision will follow in writing.

4.3.2 The WCH REB Chair or delegate will request that the investigator report any suspension or termination or WCH REB approval of research to the study sponsor and the appropriate Institutional Official and regulatory authorities. In addition, the WCH REB Chair may choose to notify the Institutional Official and regulatory authorities directly.

5.0 REFERENCES:

1. The International Conference on Harmonization Good Clinical Practices, Section 4.12;
2. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2), 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), Tile 21, Part 56, 108
5. ISO 14155 Clinical investigation of medical devices for human subjects – Good Clinical Practice
6. Sunnybrook Health Sciences Centre Research Ethics Board Standard Operating Procedure– *Suspension or Termination of REB Approval* (REB-SOP-IV-06.003)