
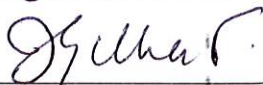


<b>SOP Title</b>	Study suspension and termination
<b>Number.Version</b>	408.004
<b>Version Date</b>	06/15/ 2016

### Approvals

<b>Name and Title of Signatories</b>	<b>Signature</b>	<b>Date mm/dd/yyyy</b>
Erika Basile Director, Research Ethics		06/15/2016
Dr. Joseph Gilbert Chair, Health Sciences Research Ethics Board		06-16-2016

### 1. PURPOSE

This standard operating procedure (SOP) describes the procedures associated with suspension or termination of research previously approved by the Health Sciences Research Ethics Board (HSREB).

### 2. GENERAL POLICY STATEMENT

As a result of ongoing review activities, the HSREB may require that research be modified or may suspend or terminate HSREB 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 HSREB also has the authority to suspend new enrolment while additional information from the investigator is requested.

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

### 3. RESPONSIBILITY

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

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

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

The HSREB Chair is responsible for requesting that the Investigator report any suspension or termination or HSREB approval of research to the study sponsor, the appropriate Institutional Official and Department Head, and regulatory authorities. Alternatively, the HSREB 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; inadequate drug availability; in response to a DSMB recommendation; or a pre-planned stopping criteria);
- 5.1.2. The investigator must immediately notify the HSREB 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 HSREB Chair or designee for review;
- 5.1.4. If the HSREB Chair or designee decides to suspend HSREB approval of the research, he/she must notify the HSREB at its next Full Board meeting;
- 5.1.5. If the HSREB approval is suspended, a subsequent review must be conducted and the HSREB suspension must be lifted prior to resumption of the research following the Sponsor's lifting of a suspension.

##### **5.2. Suspension or Terminations of HSREB Approval**

- 5.2.1. If any concerns are raised during HSREB oversight of a research study related to new information of the conduct of research, the HSREB may suspend or terminate research at any time. These concerns include:
  - the research is not being conducted in accordance with the HSREB-approved protocol or HSREB requirements,
  - the research is associated with unexpected serious harm to patients,
  - safety reports,
  - unanticipated problems involving risks to participants or others,
  - DSMB reports,

- 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 HSREB (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 HSREB, sponsor, or regulatory agencies,
- repeated or deliberate failure to obtain prior HSREB 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 HSREB;

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

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

5.2.4. Prior to suspending or terminating HSREB approval the HSREB, or the HSREB 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 HSREB,
- corrective measures time frame in which the corrective measures are to be implemented;

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

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

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

### 5.3. Reporting Suspensions or Terminations

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

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

## 6. REFERENCES

- 6.1. The International Conference on Harmonization Good Clinical Practices, Section 4.12;
- 6.2. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2), Article 11.9;
- 6.3. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103;
- 6.4. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21 Part 56.108;
- 6.5. ISO 14155 Clinical investigation of medical devices for human subjects – Good Clinical Practice.

## 7. SOP HISTORY

<b>SOP Number.Version</b>	<b>Key Changes</b>	<b>Effective Date mm/dd/yyyy</b>
408.001	Original	05/29/2014
408.002	Minor administrative changes for clarification	07/29/2014
408.003	Minor administrative corrections for clarity	05/10/2016
408.004	5.1.3: revised to clarify that reports of suspensions or terminations by the sponsor may will be forwarded to the HSREB Chair or designee for review; Added 5.1.4: If the HSREB Chair or designee decides to suspend HSREB approval of the research, he/she must notify the HSREB at its next Full Board meeting; 5.1.5: administrative corrections for clarity 5.2.3: revised to clarify that the HSREB has the authority to suspend or terminate HSREB approval following a review at a Full Board meeting; 5.2.6: Revise to clarify that if the research is suspended or terminated, the HSREB Chair or designee will issue a formal letter to the Investigator.	06/15/2016