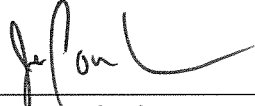
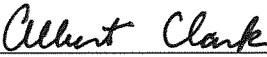



Section 400:	Review of Research
Title:	Suspension or Termination of HSREB Ethics Clearance
SOP Code:	407.004
Effective Date:	2016SEP12

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016 Sep 14
	Name: Jennifer Couture	
Approval Authority:		
Chair, HSREB		Date: Sept 14, 2016
	Name: Dr. Albert Clark	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016 Sep 15
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This standard operating procedure (SOP) describes the processes associated with the suspension or termination of HSREB ethics clearance.

2.0 SCOPE

This SOP pertains to the HSREB that reviews human participant research in compliance with applicable regulations, guidelines and current and emerging best practices.

3.0 RESPONSIBILITIES

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

The HSREB, the HSREB Chair and/or designee and/or other Ethics Office Personnel or designee are responsible for determining whether the research requires the suspension or termination of HSREB ethics clearance.

The Researcher is responsible for notifying the HSREB and Queen's University and Affiliated Teaching Hospital Official(s), as applicable, of any suspensions or terminations to the research.

The HSREB Chair or designee is authorized to suspend and terminate HSREB ethics clearance when a research study has allowed its annual renewal to lapse. When the HSREB Chair or designee terminates (or closes) a research study, it must be reported to the HSREB. The HSREB may overturn HSREB Chair's or designee's decision following a review at a Full Board meeting.

The HSREB Chair or designee shall notify the Researcher, and if applicable, Queen's University and Affiliated Teaching Hospital Official(s), of any suspension or termination of HSREB ethics clearance, and has the authority to notify the regulatory authorities and the Sponsor, as applicable. The HSREB may delegate regulatory authority reporting.

4.0 DEFINITIONS

Suspension is defined as a temporary or permanent halt to all research activities pending future action by the HSREB, the HSREB Chair or designee, by the sponsor and/or by the Researcher.

Termination is defined as a permanent halt by the HSREB, HSREB Chair or designee, by the sponsor and/or by the Researcher to all or some research activities.

5.0 PROCEDURES

As a result of ongoing review activities, the HSREB may require that research be modified, or may suspend or terminate HSREB ethics 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 regulations and guidelines. The HSREB Chair or designee also has the authority to suspend new enrollment while additional information is requested.

A decision to suspend or to terminate HSREB ethics clearance must include consideration of the safety, rights and well-being of the participants already enrolled in the research; specifically, how to continue the care of enrolled participants, and how and when the notification to participants of the suspension or termination of the research will take place.

The HSREB Chair or designee has the authority to suspend or to terminate HSREB ethics clearance. The HSREB Chair or designee must report all suspensions and terminations to the Full Board. Any requests to lift a suspension or termination may require a Full Board review.

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

5.1 Suspension or Termination of Research by the Sponsor

- 5.1.1 The sponsor of the research may suspend or terminate the research (e.g., following results of interim analyses, due to inadequate drug availability, in response to a Data and Safety Monitoring Board (DSMB) recommendation, due to pre-planned stopping criteria, etc.);
- 5.1.2 The Researcher must immediately notify the HSREB if the research is abandoned, or for any suspensions or terminations of the research and the reasons for the action;
- 5.1.3 Reports of suspensions or terminations of the research 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 ethics clearance, Full Board review may be required to lift the suspension;
- 5.1.5 HSREB ethics clearance suspension must be lifted prior to resumption of the research following the sponsor's lifting of a suspension.

5.2 Suspension or Termination of HSREB Ethical Clearance

- 5.2.1 If any concerns are raised during the HSREB's oversight of the research that are related to new information or to the conduct of the research, the HSREB may suspend or terminate ethics clearance of the research. These concerns may include:
 - The research not being conducted in accordance with the HSREB cleared protocol or HSREB requirements,
 - The research is associated with unexpected serious harm to participants (i.e., as may be determined following HSREB review of reportable events or DSMB reports),
 - Falsification of research records or data,
 - Failure to comply with prior conditions imposed by the HSREB (i.e., under a suspension or ethics clearance with modifications),
 - 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 Researcher's supervision,
 - Repeated or deliberate failure to comply with conditions placed on the research by the HSREB, by the sponsor, or by regulatory agencies,
 - Repeated or deliberate failure to obtain prior HSREB review and ethics clearance of amendments or modifications to the research, or

- Repeated or deliberate failure to maintain accurate research records or submit required reportable event reports or renewal reports to the HSREB;
- 5.2.2 The HSREB Chair or designee is authorized to suspend and/or terminate HSREB ethics clearance of research;
- 5.2.3 All suspensions and terminations must be reported at a Full Board meeting;
- 5.2.4 The HSREB has the authority to accept the suspension or termination decision or overturn the decision;
- 5.2.5 Prior to suspending or terminating HSREB ethics clearance, the HSREB must consider:
 - Risks to current participants,
 - Actions to protect the safety, rights and well-being of currently enrolled participants,
 - The appropriate care and monitoring of research participants,
 - 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,
 - Identification of a time frame in which the corrective measures are to be implemented;
- 5.2.6 The HSREB Chair or designee will notify the Researcher of any suspensions or terminations of HSREB ethics clearance, and the reasons for the decision;
- 5.2.7 Unless otherwise stated by the HSREB, when the HSREB Chair or designee suspends or terminates ethics clearance of the research, no further activities can take place other than the submission of an amendment, renewal, or reportable events;
- 5.2.8 If the research is suspended or terminated, the HSREB Chair or designee or other Ethics Office Personnel will issue a formal letter to the Researcher, on behalf of the HSREB Chair, with the reason(s) for the HSREB action and the corrective measures proposed by the HSREB;
- 5.2.9 If HSREB ethics clearance of a research study or if the conduct of the research has been suspended or terminated, the suspension or termination may be lifted once corrective actions are outlined and/or implemented to the HSREB's satisfaction.

5.3 Reporting Suspensions or Terminations

- 5.3.1 The HSREB Chair or designee or other Ethics Office Personnel will report any suspension or termination of HSREB ethics clearance to appropriate Official(s) at Queen's University and/or Affiliated Teaching Hospitals as applicable;
- 5.3.2 The HSREB Chair or designee and/or other Ethics Office Personnel have the authority to notify the regulatory authorities (as applicable), and the sponsor. The HSREB may delegate regulatory authority reporting as applicable.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Suspension or Termination of HSREB Ethical Clearance	v.407.001 2015MAY25	Original: Adoption of standardized SOPs developed by CAREB/N2 with an effective date of 2014SEP15. Minor modifications were made to the CAREB/N2 SOPs to reflect institutional policies.
Suspension or Termination of HSREB Ethical Clearance	v.407.002 2015OCT22	Revised to correct process for dealing with backlog of lapsed renewals.
Suspension or Termination of HSREB Ethical Clearance	v.407.003 2016APR04	Revised to clarify language and reporting process for suspended and terminated applications.
Suspension or Termination of HSREB Ethics Clearance	v.407.004 2016SEP12	<ol style="list-style-type: none"> 1. Title changed to 'Suspension or Termination of HSREB Ethics Clearance'. 2. Minor revisions to purpose, scope and procedures. 3. 5.2.7: Added renewal submissions 4. Minor updates made to sections 5.2.8 – 5.3.2 to add references to other Ethics Office Personnel.