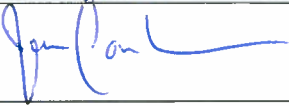




<b>Section 200:</b>	<b>HSREB Organization</b>
<b>Title:</b>	<b>Duties of HSREB Members</b>
<b>SOP Code:</b>	<b>203.001</b>
<b>Effective Date:</b>	<b>2015MAY25</b>

### Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		2015 MAY 22
	Name: Jennifer Couture	Date
Approval Authority:		
Chair, HSREB		May 22, 2015
	Name: Dr. Albert Clark	Date
Approval Authority:		
Director, Research Ethics Compliance		May 22, 2015
	Name: Dr. Andrew Winterborn	Date

## 1.0 PURPOSE

This SOP describes the duties of the members of the HSREB.

## 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 Chair is responsible for clearly articulating all required duties associated with membership to the HSREB to potential and current HSREB members.

HSREB members and alternates are responsible for fulfilling their duties as specified in this SOP.

## **4.0 DEFINITIONS**

See Glossary of Terms.

## **5.0 PROCEDURES**

Each HSREB member's primary duty is to protect the rights and welfare of human research participants.

In order to fulfill his or her duties, HSREB members must be well versed in regulations governing human participants' protection and biomedical research ethics, and policies germane to human research participant protection. The HSREB will function impartially and provide a fair hearing to all research proposals.

### **5.1 Attendance**

- 5.1.1 Regular HSREB members are expected to attend the regularly scheduled HSREB meetings. HSREB Members may be asked to step down if they consistently miss more than 25 percent of the scheduled HSREB meetings;
- 5.1.2 HSREB members must notify the HSREB office if they will be absent for an HSREB meeting to ensure that quorum can still be met and/or so that an appropriate alternate may attend in his/her place;
- 5.1.3 Alternate HSREB members are expected to attend the identified HSREB meetings for which they have confirmed their availability to replace a regular HSREB member, and/or a minimum of two HSREB meetings per year;
- 5.1.4 HSREB members are expected to be available for the entire HSREB meeting, not just the sections for which they have been assigned as reviewers.

### **5.2 Terms of Duty**

- 5.2.1 All members of the HSREB, including the HSREB Chair and Vice-Chair, will be appointed for a term as specified in the HSREB

Terms of Appointment which is outlined in SOP 202 Management of HSREB Membership.

### 5.3 Duty

- 5.3.1 All HSREB members attending a HSREB meeting are expected to review the relevant materials submitted for each item under review or consideration by the HSREB, to submit comments in advance of the HSREB meeting, and to be prepared to discuss each agenda item and provide input at the Full Board meeting;
- 5.3.2 Each HSREB member is expected to fulfill specific duties based on the role as outlined below. More than one HSREB member may fulfill each role;
- 5.3.3 **Non-scientific members** are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. Non-scientific members should advise the HSREB if additional experience in a non-scientific area is required to assess whether the research adequately protects the rights and welfare of participants and to comment on the comprehension of the consent document;
- 5.3.4 **Community member(s)** are expected to provide input regarding their knowledge about the local community and be able to discuss issues and research from that perspective;
- 5.3.5 **Member(s) knowledgeable in relevant law** are expected to alert the HSREB to legal issues and their implications, but not to provide formal legal opinions nor to serve as legal counsel to the HSREB;
- 5.3.6 **Member(s) knowledgeable in ethics** are expected to guide the HSREB in identifying and addressing ethical issues related to the research under review;
- 5.3.7 **Ad hoc advisors:** individuals with competence in special areas may be required to provide input on issues that require expertise beyond or in addition to that available on the HSREB. The ad hoc advisor may be required to submit a written report and to participate via teleconference or to attend the HSREB meeting to lend his/her expertise to the discussions;
- 5.3.8 **HSREB Chair:** The HSREB Chair or designee provides overall leadership to the HSREB:
  - The HSREB Chair is responsible for ensuring that the HSREB review process is compliant with all applicable local

policies, national and international regulations and guidelines,

- The HSREB Chair can delegate any of his/her responsibilities, as appropriate, to a Vice-Chair or other qualified individual(s),
- Any responsibilities that are delegated by the HSREB Chair must be documented,
- The HSREB Chair or designee facilitates the review process based on the HSREB and Queen's University policies and procedures, SOPs and applicable regulations and guidelines,
- The HSREB Chair or designee determines the level of risk of each research project,
- The HSREB Chair or designee monitors the HSREB's decisions for consistency and ensures that decisions are recorded accurately and communicated to Researchers in writing in a timely fashion,
- The HSREB Chair or designee ensures that all HSREB members are free to participate in discussions during the HSREB meetings,
- The HSREB Chair or designee can ask a substitute HSREB member to attend an HSREB meeting in order to draw his/her expertise in an area that may be relevant to the HSREB's review and deliberations of the research,
- The HSREB Chair or designee determines the appropriateness of a Full Board or delegated review of the research,
- The HSREB Chair or designee performs or delegates authority to (an) HSREB member(s) to perform a delegated review,
- The HSREB Chair or designee signs off on all HSREB decisions in writing,
- For HSREB ethical clearance of clinical trials approved by Health Canada, the HSREB clearance letter which includes the HSREB attestation, is signed by the HSREB Chair or designee,

- The HSREB Chair or designee can suspend the conduct of any research project deemed to place participants at unacceptable risk pending discussion by the Full Board. The HSREB Chair or designee can suspend the conduct of the research if he/she determines that a Researcher is not adhering to the HSREB ethically cleared protocol or to the HSREB's policies and procedures,
- The HSREB Chair or designee in conjunction with the Director of Research Ethics Compliance will report on the activities of the HSREB to Queen's University through the Vice Principal (Research) and the Joint Liaison Committee on an annual basis, which is based on the fiscal year (May 1<sup>st</sup> – April 30<sup>th</sup>),
- The HSREB Chair or designee, in conjunction with the Ethics Compliance Advisor and Director of Research Ethics Compliance, and other Queen's University and Affiliated Teaching Hospital Official(s) as applicable, ensures the HSREB members are informed of all new legislation, regulations, policies and guidelines pertaining to human participant research, and shall advise the HSREB on policies and procedures related to research conduct,
- The HSREB chair, in conjunction with the HSREB Ethics Compliance Advisor and Director of Research Ethics Compliance, shall assess the educational and training needs of the HSREB members and Office Personnel, and will address any gaps identified,
- The HSREB Chair or designee reviews and approves HSREB policies and procedures annually, to ensure the HSREB SOPs meet all current standards.

5.3.9 **HSREB Vice-Chair:** The HSREB Vice-Chair or equivalent is responsible for performing the duties of the HSREB Chair when the HSREB Chair is unable to do so:

- The HSREB Vice-Chair performs all responsibilities assigned by the HSREB Chair,
- The HSREB Vice-Chair assists with the overall operation of the HSREB.

## **5.4 Primary and Secondary Reviewers**

5.4.1 HSREB members will act as primary and/or secondary reviewers for assigned research projects at Full Board meetings. The primary and secondary reviewers present their findings resulting from review of the HSREB submission materials, provide an assessment of the soundness and safety of the research, and recommend specific action to the HSREB. They lead the discussion of the research project during the HSREB meeting. The primary and secondary reviewers review additional material(s) as requested by the HSREB for the purpose of ethical clearance of the research.

## **5.5 Training and Education**

5.5.1 HSREB members are expected to follow training and education procedures outlined in SOP 103 Training and Education.

## **5.6 Conflict of Interest**

5.6.1 HSREB members are expected to follow conflict of interest procedures outlined in SOPs 105A-C Conflict of Interest.

## **6.0 REFERENCES**

See References.

## **7.0 APPENDICES**

None.

## **8.0 REVISION HISTORY**

<b>SOP Title</b>	<b>Version</b>	<b>Updates</b>
Duties of HSREB Members	v.203.001 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.