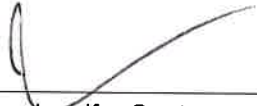

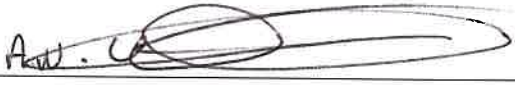


<b>Section 300:</b>	<b>Functions and Operations</b>
<b>Title:</b>	<b>HSREB Meeting Administration</b>
<b>SOP Code:</b>	<b>302.002</b>
<b>Effective Date:</b>	<b>2019APR24</b>

## Site Approvals

<b>Signature of Responsible Individual:</b>		
Manager, Research Ethics Compliance		2019APR24 Date
	Name: Jennifer Couture	
<b>Approval Authority:</b>		
Chair, HSREB		2019 APR 24 Date
	Name: Dr. Albert Clark	
<b>Approval Authority:</b>		
Director, Research Ethics Compliance		2019 APR 24 Date
	Name: Dr. Andrew Winterborn	

## 1.0 PURPOSE

This SOP describes the required activities for the preparation, management and documentation of Full Board meetings of the HSREB.

## 2.0 SCOPE

This SOP pertains to the HSREB that reviews human participant research in compliance with applicable regulations and 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.

## 4.0 DEFINITIONS

See Glossary of Terms.

## 5.0 PROCEDURES

Except when a delegated review procedure is used, the HSREB must review proposed research at Full Board meetings at which a quorum is present. A quorum is defined as having as a majority of members present (50% + 1), including at least five members, both men and women, of whom:

- At least two members who have expertise in relevant research disciplines, field and methodologies covered by the HSREB (for biomedical clinical trials, this will include at least one member who practices medicine or dentistry and who is in good standing with their regulatory body),
- At least one member who is primarily experienced in non-scientific disciplines,
- At least one member who is knowledgeable in ethics,
- At least one member who is knowledgeable in the relevant law,
- At least one community member who has no affiliation with the Queen's University and Affiliated Teaching Hospitals or the sponsor, and who is not part of the immediate family of a person who is affiliated with Queen's University and Affiliated Teaching Hospitals,
- At least one member knowledgeable in considering privacy issues,
- For research subject to the US CFR (Titles 21/45), the quorum must include the minimum composition requirements and a majority of members (50% + 1);

The HSREB meeting agenda provides the meeting content and establishes a sequence of review. It also provides an overview of all items that have been previously (i.e. during the preceding time between HSREB meetings) reviewed and ethically cleared by delegated review procedures, a list of items that are pending review by the Full Board, and assigned reviewer(s) for each of those items. Information documented in the HSREB meeting agenda provides the foundation for the HSREB meeting minutes.

The HSREB meeting minutes document the actions that occur during a HSREB meeting. The minutes should enable a reader who was not present at the HSREB meeting to determine how and with what justification the HSREB arrived at its decisions. They should also provide the HSREB itself with sufficient detail to help it reconstruct its discussions at a later date, if necessary.

## **5.1 Agenda Preparation**

- 5.1.1 Following an administrative review of the submission (e.g., new studies, amendments, renewal of applications, reportable events) by the HSREB Ethics Coordinator or designee and the determination of the review type by the HSREB Chair or designee, the HSREB Ethics Coordinator or designee adds any submissions requiring Full Board review to the next appropriate Full Board meeting agenda;

- 5.1.2 For submissions that were reviewed and granted ethics clearance via delegated review procedures, the list of cleared delegated reviews is appended to the next Full Board meeting agenda;
- 5.1.3 The HSREB Ethics Coordinator or designee attaches to the agenda any previous HSREB meeting minutes for Full Board review and any comments/clarifications relevant to the ethical clearance of a Full Board application;
- 5.1.4 The Ethics Coordinator or designee adds any other items for information or discussion at the HSREB meeting (e.g., SOPs, educational articles, presentations, reports, etc.);
- 5.1.5 The HSREB Ethics Coordinator or designee, in consultation with the HSREB Chair or designee as necessary, reviews the agenda, confirms HSREB meeting attendance and assigns the reviewers;
- 5.1.6 The HSREB Chair or designee invites the appropriate alternate HSREB member to the meeting when a regular HSREB member is not able to attend;
- 5.1.7 The reviewer assignment and the agenda are issued in a timely manner prior to the HSREB meeting date. The HSREB members attending the HSREB meeting will receive a copy of the HSREB meeting agenda;
- 5.1.8 Ad hoc advisors will receive copies of relevant submissions;
- 5.1.9 Any changes to the agenda, including convening unscheduled meetings to deal with contingencies, are communicated to all HSREB members and HSREB Office Personnel. The HSREB Ethics Coordinator or designee also may issue an updated agenda notice depending on the nature of the changes.

## **5.2 Primary and Secondary Reviewers**

- 5.2.1 Prior to the meeting, the HSREB Ethics Coordinator or designee, in consultation with the HSREB Chair or designee, will assign a primary and secondary reviewer for each new application and one reviewer for each renewal and amendment (if applicable);
- 5.2.2 No HSREB member will be assigned as a reviewer on a submission in which he or she is a Researcher or Co-Researcher or in which there is a declared conflict of interest;
- 5.2.3 The HSREB Ethics Coordinator or designee will issue the reviewer assignment. The assigned reviewers will receive notification and a copy of the meeting agenda;
- 5.2.4 If any of the assigned reviewers declare a conflict, the submission is reassigned to another reviewer.

## **5.3 Prior to the HSREB Meeting**

- 5.3.1 The primary and secondary reviewers (if applicable) will conduct in-depth reviews of their assigned submissions and should submit reviewer comments prior to the HSREB meeting. The primary

reviewer should be prepared to lead the discussion at the Full Board meeting;

- 5.3.2 All HSREB members are expected to conduct a review of each agenda item prior to the Full Board meeting, including previous HSREB meeting minutes on the agenda and any attachments to the agenda for review or discussion;
- 5.3.3 HSREB members who are not assigned as primary or secondary reviewers may submit their individual comments for each submission prior to the meeting;
- 5.3.4 All HSREB members should be prepared to present their comments and participate in the discussion at the Full Board meeting.

#### **5.4 During the HSREB Meeting**

- 5.4.1 A quorum must be present to proceed with a Full Board meeting;
- 5.4.2 Should quorum fail during a Full Board meeting (e.g., through recusal of HSREB members with conflicts of interest or early departures), the HSREB may not make further decisions unless quorum can be restored;
- 5.4.3 An alternate HSREB member may attend in the place of a regular HSREB member to meet quorum requirements. When a HSREB member and their alternate both attend the HSREB meeting, only one is allowed to participate in the deliberations and final decisions regarding ethical clearance;
- 5.4.4 Should a HSREB member not be physically present during a Full Board meeting, they may participate via videoconference or teleconference. HSREB members participating by videoconference or teleconference count towards quorum;
- 5.4.5 Ad hoc advisors will not be used to establish a quorum;
- 5.4.6 HSREB members recusing themselves due to a conflict of interest are not counted toward quorum;
- 5.4.7 Under unusual circumstances (e.g., public health alerts and quarantines) the HSREB Chair or designee may, at their discretion, conduct an HSREB meeting with all HSREB members attending via simultaneous videoconference or teleconference, provided everyone has access to the review materials and quorum is met;
- 5.4.8 Only those HSREB members present (i.e. in person, or via videoconference or teleconference) at the Full Board meeting may participate in the deliberation and final decision regarding ethical clearance; however written comments from absent members can be submitted for review for consideration of an application;
- 5.4.9 When there is less than full attendance at a Full Board Meeting, decisions should be adopted only when the members in attendance

have the specific expertise, relevant competence and knowledge necessary to provide an adequate review;

- 5.4.10 The HSREB may be required to convene unscheduled meetings due to exigencies (i.e. publically declared emergencies);
- 5.4.11 Observers may be invited or permitted to attend HSREB meetings, subject to the agreement of the HSREB and execution of a Confidentiality Agreement. Observers must disclose any vested interest in, or scientific or management responsibility for, any applications being considered at the HSREB meeting;
- 5.4.12 If requested, Researchers may (in person or via teleconference) attend the HSREB meeting to present their research and respond directly to any comments or questions raised by the HSREB, subject to the agreement of the HSREB; however they cannot participate in deliberations or votes;
- 5.4.13 Any individual not listed on the official HSREB membership roster may not participate in the decisions of the HSREB.

## **5.5 Meeting Minute Preparation**

- 5.5.1 The HSREB Ethics Coordinator or designee will draft the HSREB meeting minutes including attendance, key discussions, decisions and votes;
- 5.5.2 The key HSREB discussions and decisions for submissions are recorded;
- 5.5.3 The HSREB's concerns, clarifications and recommendations to the Researcher as discussed at the HSREB meeting are documented in the meeting minutes and sent back to the Researcher;
- 5.5.4 The meeting may be audio tape recorded for reference purposes and to provide additional reference information for the generation of the final draft of the minutes;
- 5.5.5 The minutes are intended to reflect what the HSREB decided, how it resolved controverted issues, and any determinations required by the regulations;
- 5.5.6 The draft minutes should be completed prior to the next HSREB meeting.

## **5.6 Meeting Minute Approval**

- 5.6.1 The minutes are made available at the next appropriate HSREB meeting and are presented at the HSREB meeting for review and approval in draft format;
- 5.6.2 The HSREB motion and votes on the previous HSREB meeting minutes are recorded in the current HSREB meeting minutes;
- 5.6.3 If the previous HSREB meeting minutes are approved pending revisions, the HSREB Ethics Coordinator or designee makes the required changes, and unless the HSREB requests further review of the minutes prior to approval, the HSREB Ethics Coordinator or

designee records the minutes as approved. If no changes are necessary, a final version of the minutes will be marked as approved.

## **5.7 Documentation**

5.7.1 The HSREB meeting minutes include the following items:

- Date, place, and time the HSREB meeting commenced and adjourned,
- Names of HSREB members in attendance (present, teleconference, videoconference),
- Names of HSREB members absent,
- Names of HSREB Office Personnel present at the meeting,
- Presence of observers,
- Use of ad hoc advisors and their specialty,
- List of declared conflicts of interest, a summary of any discussions, and the decision taken by the HSREB to address them (as applicable),
- A summary of key discussions and controverted issues and their resolution for each submission, as applicable,
- The decisions taken by the HSREB regarding ethical clearance for each submission, as applicable,
- The basis for requiring changes or for not granting ethics clearance for submissions,
- Number of HSREB members in attendance for the review of each submission requiring a decision,
- HSREB member(s) recused related to conflicts of interest for each submission requiring a decision,
- Number(s) voting for, against or abstaining in the event of a vote for each submission requiring a decision,
- Reference to any attachments to the agenda;

5.7.2 All HSREB meeting agendas and minutes are retained in the HSREB records;

5.7.3 The agendas, HSREB meeting minutes and review documents are confidential and will not be released or made available unless required for inspection or auditing purposes.

## **6.0 REFERENCES**

See References.

## **7.0 APPENDICIES**

None.

## 8.0 REVISION HISTORY

SOP Title	Version	Updates
HSREB Meeting Administration	v.302.001 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.
HSREB Meeting Administration	v.302.002 2019APR22	<ol style="list-style-type: none"><li>1. Section 5.4: Updated to gender neutral terminology.</li><li>2. Section 5.5: References to ROMEO removed as no longer relevant.</li><li>3. Section 5.5: Process for draft and final minutes updates.</li><li>4. Section 5.5: Reference to encrypted audio recorder removed.</li></ol>

