SOP Title	HSREB Meeting Administration
Number.Version	302.007
Effective Date	October 1, 2021

Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics and Compliance		Oct 1, 2021
Dr. Philip Jones Chair Health Sciences Research Ethics Board		Oct 1, 2021

1. PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the required activities for the preparation, management and documentation of convened Health Sciences Research Ethics Board (HSREB) meetings.

2. GENERAL POLICY STATEMENT

Except when a delegated review procedure is used, the HSREB will review proposed research at convened meetings at which a Quorum is present. The HSREB will meet twice monthly, or at the call of the Chair.

The HSREB meeting agenda provides the meeting content and provides the foundation for the HSREB meeting minutes. It also includes an attachment of all items (initial approvals for Delegated level 1 and Delegted Level 2, amendments, Updated Approvals, etc.) that have been reviewed and approved by delegated review procedures since the last convened meeting, a list of items that are pending review by the convened HSREB, and assigned reviewers for each of those items.

The HSREB meeting minutes document the actions that occur during an HSREB meeting and should provide the HSREB itself with sufficient detail to help it reconstruct its discussions at a later date, if necessary.

3. RESPONSIBILITY

This SOP applies to the HSREB Chair, Vice Chair(s), all HSREB Members, HSREB consultants, HSREB meeting guests and Office of Human Research Ethics (OHRE) office staff involved in HSREB Meeting Administration.

4. DEFINITIONS

See Glossary of Terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. Agenda and Meeting Preparation

5.1.1. The Ethics Officer (EO), in consultation with the HSREB Chair as necessary, drafts the meeting agenda according to the *HSREB Agenda Template*, and posts all items that require

full HSREB review to the agenda (e.g. previous meeting's minutes, business carried, new business, updated approvals, FDA reports, Amendments, new protocol submissions, new approvals by delegated review, educational items and other pertinent items.);

5.1.2. The EO, in consultation with the HSREB Chair as necessary, reviews the agenda, assigns the reviewers for each project (one primary reviewer), posts the reviewer assignment to the agenda;

5.1.3. The EO includes the completed meeting agenda in the HSREB meeting packages for distribution to the HSREB members;

5.1.4. The OHRE staff distributes the meeting packages to the HSREB members, electronically, 7 days prior to the HSREB meeting;

5.2. **Primary Reviewer**

5.2.1. No HSREB member will be assigned as a reviewer on a submission in which he or she is a principal or a co-Investigator or in which there is a declared conflict of interest;

5.2.2. Once the HSREB members receive the meeting package the primary reviewer can declare, to the ORE, any conflicts with their assigned protocol(s). If there is a conflict the EO in consultation with the HSREB Chair as necessary will reassign the submission to another HSREB member;

5.3. **Prior to the HSREB Meeting**

5.3.1. All HSREB members will review the materials provided prior to the meeting and will be prepared to participate in the discussion at the convened meeting.

5.3.2. The primary reviewer prepares a written summary based on an in-depth review of all the materials of the assigned research project(s) and prepares to lead the discussion at the convened meeting. They should also posts their comments in the online system;

5.3.3. Prior to the HSREB meeting, HSREB members who are not the primary reviewer are expected to log their individual comments online for each submission;

5.3.4. All reviewer comments are accessible in the online system to all HSREB members and ORE staff;

5.3.5. If changes need to be made to the agenda, the EO will modify the agenda, notify the HSREB Chair and HSREB members, and circulate the revised agenda;

5.4. **During the REB Meeting**

5.4.1. A Quorum must be present to conduct a convened meeting, the meeting will not begin until Quorum is met;

5.4.2. Attendance is recorded using the attendance tracking record. Time of arrival, recusal, return to meeting and departure will be noted for each member as applicable;

5.4.3. Should Quorum fail during a meeting (e.g., through recusal of members with conflicts of interest or early departures), the HSREB may not make further decisions until Quorum can be restored;

5.4.4. An alternate member may attend in the place of a regular member to meet quorum requirements.

5.4.5. Should a member not be physically present during a convened meeting, he/she may participate via videoconference or teleconference. Members participating by videoconference or teleconference count towards quorum;

5.4.6. Ad hoc advisors will not be used to establish a quorum;

5.4.7. Members recusing themselves due to conflicts of interest are not counted toward quorum;

5.4.8. Under unusual circumstances (e.g., public health alerts and quarantines) the HSREB Chair may, at his/her discretion, conduct an HSREB meeting with all members attending via simultaneous videoconference or teleconference, provided everyone has received the review materials and quorum is met;

5.4.9. Only those HSREB members present (i.e., in person or via videoconference or teleconference) at the convened meeting may participate in the deliberation and final decision regarding approval;

5.4.10. Guests may be invited or permitted to attend HSREB meetings, subject to the agreement of the HSREB Chair and execution of a *Confidentiality and Conflict of Interest Agreement*. Guests must disclose any vested interest in, or scientific or management responsibility for any applications being considered at the meeting;

5.4.11. If requested, Investigators, or their designate, may attend the HSREB meeting to present their project and respond directly to any comments or questions raised by the HSREB, subject to the agreement of the HSREB. Investigators may not be present for HSREB discussions, deliberations and decisions;

5.4.12. Any individual not listed on the current HSREB membership list may not participate in the decisions of the HSREB.

5.5. **Meeting Minute Preparation**

5.5.1. The EO creates the outline of the meeting minutes according to the HS*REB Meeting Minutes Template* and incorporates the meeting agenda;

5.5.2. The EO records the key HSREB discussions, the Boards motion and votes within the minutes document;

5.5.3. The HSREB concerns, clarifications and recommendations to the Investigator as discussed at the meeting are not included in the minutes but in a separate *HSREB Recommendations* form which is sent to the Investigator;

5.5.4. The draft minutes should be completed prior to the next meeting.

5.6. **Meeting Minute Approval**

5.6.1. The designated EO includes the minutes from the previous HSREB meeting in the upcoming HSREB meeting packages for distribution to the HSREB members;

5.6.2. It is the responsibility of the HSREB members to review and recommend changes (as necessary) to the meeting minutes;

5.6.3. The HSREB Chair requests a motion to approve the minutes at the next convened HSREB meeting noting any required revisions;

5.6.4. If modifications to the minutes are required, this will be done by the EO and presented to the HSREB Chair or designee for final approval. Any modifications to the minutes will be noted in the succeeding meeting minutes.

5.7. **Recommendations**

5.7.1. The EO compiles all HSREB recommendations from the online system and from the meeting notes. The recommendations are then entered into the *HSREB Recommendations Form*;

5.7.2. The HSREB Chair or designee reviews the recommendations for completeness and accuracy and signs off on these recommendations;

5.7.3. The *HSREB Recommendations Form* is sent to the Investigator via the online system within 3 days of the HSREB meeting.

5.8. **Documentation**

5.8.1. The meeting minutes and/or attendance record include the following items:

- Time meeting commenced and adjourned;
- Names of HSREB members and ORE staff in attendance (present, teleconference, videoconference);
- Names of HSREB members who have sent regrets when scheduled for a meeting
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- Presence of guests and ex-officio members;
- Use of expert consultants and their specialty as applicable;
- Declaration of any real, potential or perceived REB Member conflicts of interest;
- A summary of key discussions and issues including the basis for requiring changes in or for rejecting research;
- The decisions taken by the REB regarding approval;
- Members recused related to conflicts of interest for each project;
- Number voting for, against or abstaining in the event of a vote.

5.8.2. Reviewer comments entered in the online system are kept on file in the online system. Reviewer comments discussed at the HSREB meeting are compiled and kept on file with the study.

5.8.3. Meeting agendas and minutes and completed reviews are stored as per Part C Division 5 of the Food and Drug Regulations of Health Canada;

5.8.4. The agendas, meeting minutes and reviews are confidential documents not released outside the Office of Research Ethics unless required by law. They may be inspected by authorized regulatory personnel (e.g., Health Canada, FDA).

6. REFERENCES

6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2) Article 6.10; 7.4;
6.2. The International Conference on Harmonization Guidelines for Good Clinical Practice, Section 3;
6.3. U.S. Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103;
6.4. U.S. Food and Drug Administration (FDA) Code of Federal Regulations Title 21 Part 56.107, 56.108, 56.109;
6.5. FDA Information Sheets;
6.6. OHRP Guidance on Written IRB Procedures.

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
302.001	Original	01/21/2014
302.002	Sections 5.2-5.7 revised for clarification and completeness	05/22/2014
302.003	Revisions throughout for clarification	07/29/2014
302.004	Minor Administrative Changes	05/11/2016
302.005	Minor Administrative Changes	09/06/2018
302.006	Minor Administrative Changes	02/21/2020
302.007	Minor Administrative Change	10/01/2021