

TITLE	302: HREB Meeting Administration
SCOPE	The activities of the Health Research Ethics Board (HREB) operating under the direct authority of the Health Research Ethics Authority (HREA)
APPROVAL AUTHORITY	Ethics Director
EFFECTIVE DATE	April 2024

1.0 PURPOSE

This standard operating procedure (SOP) describes the required activities for the preparation, management and documentation of Full Board meetings of the HREB.

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 RESPONSIBILITIES

All HREB members and Research Ethics Office (REO) Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 PROCEDURE

Except when a delegated review procedure is used, the HREB will review proposed research at Full Board meetings during which a quorum is present.

The HREB meeting agenda will provide the meeting content and establish a sequence of review. It will provide an overview of all items that have been previously (i.e., during the preceding time between HREB meetings) reviewed and approved 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 HREB meeting agenda provides the foundation for the HREB meeting minutes.

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

4.1 Quorum

Quorum rules will meet the minimum requirements of membership representation outlined in the HREA Act and the TCPS 2. Decisions requiring Full Board review will be adopted only when the members in attendance at that meeting have the specific expertise, relevant competence and knowledge necessary to provide an adequate research ethics review of the proposals under consideration.

Quorum rules help to ensure the soundness and integrity of the research ethics review process. To maintain quorum when HREB members are geographically dispersed or when face-to face meetings are not possible, partial or fully virtual meetings will be held.

Ad hoc advisors, observers and REO Personnel attending HREB meetings will not be counted in the quorum for an HREB, nor will they be allowed to vote on HREB decisions. Decisions without a quorum are not valid or binding.

4.1.1 A quorum consists of regular and/or their alternate members and requires:

- two members have expertise in relevant research disciplines, fields and methodologies covered by the HREB;
- one member is knowledgeable in ethics;
- one member is knowledgeable in the law related to health research involving human subjects. This person must not be legal counsel or risk manager for the institution where the research will be conducted
- one community member to represent the general public; and
- one (1) member who is primarily experienced in non-scientific disciplines

For research subject to the US Code of Federal Regulations, quorum shall also include a majority (50%+1) of voting members.

4.1.2 A quorum will be present to proceed with a Full Board meeting. Should quorum fail during a Full Board meeting (e.g., through recusal of HREB members with conflicts of interest or early departures), the HREB will not make further decisions until quorum can be restored.

4.1.3 In all cases, the HREB Chairperson will ensure that there is adequate expertise to provide appropriate ethical and scientific review of the study(ies) in question.

4.1.4 Should an HREB member not be physically present during a Full Board meeting, they may participate by teleconference or videoconference. HREB members participating by teleconference or videoconference count towards quorum.

4.1.5 Ad hoc reviewers will not be used to establish a quorum.

4.1.6 HREB members recusing themselves due to a conflict of interest will not count toward quorum.

- 4.1.7** When face-to face meetings are not possible, (e.g., during public health alerts and state of emergency), HREB meetings will be conducted via simultaneous videoconference or teleconference provided everyone has access to the review materials and quorum is met.
- 4.1.8** Only those HREB members present (i.e., in person, or via videoconference or teleconference) at the Full Board meeting will participate in the deliberation and final decision regarding approval.
- 4.1.9** Observers may be invited or permitted to attend HREB meetings, subject to the agreement of the HREB and execution of a Confidentiality of Information and Conflict of Interest Agreement. Observers will disclose any vested interest in, or scientific or management responsibility for, any applications being considered at the HREB meeting.
- 4.1.10** If requested, Researchers may (in person or via teleconference) attend the HREB meeting to present their research and respond directly to any comments or questions raised by the HREB, subject to the agreement of the HREB. Researchers must not be present during their research deliberations and/or voting.
- 4.1.11** Any individual not listed on the official HREB membership roster will not participate in the decisions of the HREB.

4.2 Agenda Preparation

- 4.2.1** Following an administrative review of each submission (e.g., new studies, amendments, continuing review applications, reportable events) by the REO Personnel and the determination of the review type by the HREB Chairperson or designee, the responsible REO Personnel will add any submissions requiring Full Board review to the next appropriate Full Board meeting agenda.
- 4.2.2** For submissions that were reviewed and approved via delegated review procedures, the HREB will be notified of these approvals at the next applicable full board meeting.
- 4.2.3** The REO Personnel will include with the agenda, any previous HREB meeting minutes for Full Board review and approval, and will add any other items for information or discussion at the HREB meeting (e.g., SOPs, educational articles, presentations, reports).
- 4.2.4** The REO Personnel, in consultation with the HREB Chairperson or designee, as necessary, will review the agenda, confirm HREB meeting attendance and assign the reviewers.
- 4.2.5** The REO Personnel, in consultation with the HREB Chairperson or designee, as necessary, will invite an appropriate alternate HREB member to the meeting when a regular HREB member is not able to attend.

4.2.6 The reviewer assignment and agenda will be issued in a timely manner prior to the HREB meeting date. The HREB members attending the HREB meeting will receive a copy of the HREB meeting agenda and all relevant study documentation.

4.2.7 Ad hoc advisors will receive copies of relevant submissions for review.

4.2.8 Any changes to the agenda will be communicated to all HREB members and REO Personnel. The REO Personnel or designee also may issue an updated agenda notice depending on the nature of the changes.

4.3 Primary and Secondary Reviewers

4.3.1 Prior to the meeting, the REO Personnel, in consultation with the HREB Chairperson or designee, as necessary, will assign a primary reviewer and may assign one or more secondary reviewer(s) for each research project. Amendments that are required to be reviewed by the Full Board in accordance with regulatory or sponsor requirements will be assigned to one primary reviewer. Annual renewals will be reviewed by the Full Board.

4.3.2 HREB members will not be assigned to review a submission in which they are a Researcher or co-Researcher or in which there is a declared conflict of interest.

4.3.3 The REO Personnel will issue the reviewer assignment. The assigned reviewers will receive notification with a copy of the meeting agenda.

4.3.4 If studies are assigned to HREB members with a conflict of interest, the HREB member will notify REO Personnel and the study will be reassigned to another reviewer.

4.4 Prior to the HREB Meeting

4.4.1 HREB members will receive the review materials one (1) week before the scheduled HREB meeting. The documentation will be sent electronically via the Researcher Portal online system. HREB members will receive an e-mail notifying them that the material has been assigned.

4.4.2 The primary and secondary reviewers (if applicable) will conduct in-depth reviews of their assigned submissions and may submit reviewer comments prior to the HREB meeting. The primary reviewer will be prepared to lead the discussion at the Full Board meeting.

4.4.3 All HREB members will conduct a review of each agenda item prior to the Full Board meeting, including previous HREB meeting minutes on the agenda and any attachments to the agenda for review or discussion.

4.4.4 HREB members who are not assigned as primary or secondary reviewers may submit their individual comments for each submission prior to the meeting.

4.4.5 All HREB members will be prepared to present their comments and participate in the discussion at the Full Board meeting.

4.5 Meeting Minute Preparation

4.5.1 The REO Personnel, using the applicable template, will draft the HREB meeting minutes including key discussions, decisions and votes.

4.5.2 The key HREB discussions and decisions for submissions will be recorded in the minutes.

4.5.3 The HREB's concerns, clarifications and recommendations to the Researcher as discussed at the HREB meeting will be included in the HREB review letter that is sent to the Researcher. The minutes will only be viewed by REO Personnel and HREB members.

4.5.4 The meeting may be audio and/or video recorded (on an encrypted device) for reference purposes and to provide additional reference information for the generation of the final draft of the minutes.

4.5.5 The minutes will reflect what the HREB decided, how it resolved controversial issues, and any determinations required by the regulations.

4.5.6 The draft minutes will be completed prior to the next HREB meeting.

4.6 Meeting Minute Approval

4.6.1 The minutes will be available at the next appropriate HREB meeting and will be presented at the HREB meeting for review and approval.

4.6.2 The HREB motion and votes on the previous HREB meeting minutes will be recorded in the current HREB meeting minutes.

4.6.3 If the previous HREB meeting minutes are approved pending revisions, the REO Personnel will make the required changes, and unless the HREB requests further review of the minutes prior to approval, the REO Personnel will record the minutes as "approved by the HREB."

4.7 Documentation

4.7.1 The HREB meeting minutes will include the following items:

- date, place, and time the HREB meeting commenced and adjourned;
- names of HREB members in attendance (including tele/videoconference);

- names of REO 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 HREB to address them (as applicable) or a note that none were declared;
- a summary of key discussions and controverted issues and their resolution for each submission, as applicable;
- the decisions taken by the HREB regarding approval for each submission, as applicable;
- the basis for requiring changes or for refusing to approve submissions,
- the number of HREB members in attendance for the review of each submission requiring a decision;
- HREB 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; and
- reference to any attachments to the agenda.

The minutes will not include reviewer comments submitted on the Researcher Portal online system that were not discussed at the meeting.

4.7.2 All HREB meeting agendas and minutes will be retained in the HREB records.

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

4.8 HREB Decisions

- **4.8.1** HREB decisions are made either by consensus or a majority vote of the HREB members present at a Full Board meeting, with the exception of those who have recused themselves in accordance with the conflict of interest policies.
- When the decision is made by majority vote (e.g. U.S. regulated studies), the minutes will reflect the number of HREB members present at the time of approval, as well as the number of members voting for, against and abstaining.

4.9 Distribution Prior to HREB Meetings

4.9.1 All HREB meeting agendas and minutes will be retained in the HREB records.

4.9.2 Application materials described in SOP 301 will be made available to all HREB members, one

week prior to the scheduled meeting.

4.9.3 HREB members will have access all relevant documentation via the Researcher Portal online system, except those studies where they are in a position of conflict of interest.

4.9.4 Ad hoc reviewers will receive material via the Researcher Portal online system or e-mail. Late submissions (add-ons) may be permitted at the discretion of the HREB Chairperson.

4.10 Confidentiality

4.10.1 All material received by the HREB is considered confidential. Materials accessed by HREB members will be for the purpose of review only. The Researcher Portal is a secure online system which can only be accessed by individuals with the appropriate log-in credentials. HREB members will be provided with access appropriate to their Board requirements. HREB members will not store any application material on personal devices.

4.10.2 REO Personnel will be provided with expanded access to allow them to complete their additional duties in relation to managing the workflow of applications.

4.10.3 All ad hoc reviewers and observers of HREB meetings will be required to sign a Confidentiality of Information and Conflict of Interest Agreement. HREB members must execute the Member Declaration concerning Confidentiality and Conflict of Interest.

4.11 Destruction of Copies

4.11.1 Any miscellaneous hard copies of confidential meeting materials will be destroyed in a secure manner by individual HREB members or REO Personnel as soon as the materials are no longer needed, which is generally understood to be immediately subsequent to the HREB meeting at which the materials were reviewed.

4.11.2 Any HREB members without access to secure disposal must return HREB materials to the REO for confidential waste disposal.

5.0 REFERENCES

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 6:
<https://ethics.gc.ca/eng/documents/tcps2-2022-en.pdf>

Health Research Ethics Authority Act: An Act to Establish A Health Research Ethics Authority For The Province (2011). Retrieved from: [SNL2006 CHAPTER H-1.2 - HEALTH RESEARCH ETHICS AUTHORITY ACT \(assembly.nl.ca\)](#)