
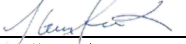
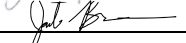



Title	REB Meeting Administration
SOP Code	302.004
Effective Date	15-May-2023

Site Approvals

Name and Title (typed or printed)	Signature	Date MM/DD/YYYY
Meera Sidhu, Research Ethics Manager		12/01/2023
Steven Smith, Deputy Vice-Principal Research		12/04/2023
Jacob Brower, Chair GREB		May 8 2024
Dean Tripp, Chair HSREB		May 7 2024

1.0 PURPOSE

This standard operating procedure (SOP) describes the required activities for preparing, managing and documenting Full Board meetings of the Research Ethics Board (REB).

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable regulations and guidelines.

3.0 RESPONSIBILITIES

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

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

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



The REB meeting agenda provides the meeting content and establishes a review sequence. It also provides an overview of all items previously (i.e., during the preceding time between REB meetings) reviewed and approved by delegated review procedures, a list of items pending review by the Full Board and assigned reviewer(s) for each. The information documented in the REB meeting agenda provides the foundation for the meeting minutes.

The REB meeting minutes document the actions that occur during an REB meeting. The minutes should enable a person who was absent from the REB meeting to determine how and with what justification the REB arrived at its decisions. They should also provide the REB itself with sufficient detail to help it reconstruct its discussions later, if necessary.

5.1 Agenda Preparation

- 5.1.1 Following an administrative review of the submission (e.g., new studies, amendments, continuing review applications, reportable events) by the REB Office Personnel and the determination of the review type by the REB Chair or designee, the responsible REB Office Personnel will add any submissions requiring Full Board review to the next appropriate Full Board meeting agenda.
- 5.1.2 For submissions that were reviewed and approved via delegated review procedures, the REB will be made aware of these approvals promptly.
- 5.1.3 The REB Office Personnel will attach to the agenda any previous REB meeting minutes for Full Board review and approval and adds any other items for information or discussion at the REB meeting (e.g., SOPs, educational articles, presentations, reports, etc.);
- 5.1.4 The REB Office Personnel, in consultation with the REB Chair or designee as necessary, will review the agenda, confirm REB meeting attendance, and assign the reviewers.
- 5.1.5 The REB Chair or designee will invite the appropriate alternate REB member to the meeting when a regular REB member cannot attend.
- 5.1.6 The reviewer assignment and the agenda will be issued in a timely manner before the REB meeting date. **HSREB and GREB will give a minimum of 1.5 weeks to review documents before the full board meeting date.** The REB members attending the REB meeting will receive a copy of the REB



meeting agenda **before the meeting date**.

- 5.1.7 Ad hoc advisors will receive copies of relevant submissions.
- 5.1.8 Any changes to the agenda are communicated to all REB members and REB Office Personnel. The REB Office Personnel or designee may also issue an updated agenda notice depending on the nature of the changes.

5.2 Primary and Secondary Reviewers

- 5.2.1 Before the meeting, the REB Office Personnel, in consultation with the REB Chair or designee as necessary, will assign a primary and may assign one or more secondary reviewers for each new research **ethics application project** and at least one reviewer for each amendment.
- 5.2.2 No REB member will be assigned as a reviewer on a submission in which they are a Researcher or co-Researcher or in which there is a declared conflict of interest.
- 5.2.3 The REB Office Personnel will issue the reviewer assignment. The assigned reviewers will receive a notification with a copy of the meeting agenda.
- 5.2.4 If any assigned reviewers declare a conflict, the submission is reassigned to another reviewer.

5.3 Prior to the REB Meeting

- 5.3.1 The primary and secondary reviewers (if applicable) will conduct in-depth reviews of their assigned submissions and **must** submit reviewer comments prior to the REB meeting. The primary reviewer should be prepared to lead the discussion at the Full Board meeting.
- 5.3.2 All REB members are expected to conduct a review of each agenda item prior to the Full Board meeting, including previous REB meeting minutes on the agenda and any attachments to the agenda for review or discussion.
- 5.3.3 REB members who are not assigned as primary or secondary reviewers **are asked to** submit their individual comments for each **submission research ethics application** prior to the meeting. Each member will have an opportunity to provide or add to, or reshape comments during the meeting.



5.3.4 All REB members should be prepared to present their comments and participate in the discussion at the Full Board meeting.

5.4 During the REB 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 REB members with conflicts of interest or early departures), the REB may not make further decisions unless quorum can be restored.

5.4.3 An alternate REB member may attend in the place of a regular REB member to meet quorum requirements. When a REB member and his/her alternate both attend the REB meeting, only one is allowed to participate in the deliberations and final decisions regarding approval.

5.4.4 Should a REB member not be physically present during a Full Board meeting, he/she may participate via videoconference or teleconference. REB members participating by videoconference or teleconference count towards quorum.

5.4.5 Ad hoc advisors/**affiliate members and/or research ethics coordinators/manager** will not be used to establish a quorum.

5.4.6 REB 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 REB Chair or designee may, at his/her discretion, conduct an REB meeting with all REB members attending via simultaneous videoconference or teleconference, provided everyone has access to the review materials and quorum is met.

5.4.8 Only those REB 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 approval.

5.4.9 Observers may be invited or permitted to attend REB meetings by the Chair of their designate, subject to the agreement of the REB and execution of a *Confidentiality Agreement*. Observers must disclose any vested interest in, or scientific or management responsibility for, any applications considered at the REB meeting.



5.4.10 If requested, Researchers may (in person or via teleconference) attend the REB meeting to present their research and respond directly to any comments or questions raised by the REB, subject to the agreement of the REB.

5.4.11 Any individual not listed on the official REB membership roster may not participate in the decisions of the REB.

5.5 Meeting Minute Preparation

5.5.1 The REB Office Personnel will draft meeting minutes, including key discussions, decisions and votes.

5.5.2 The key REB discussions and decisions for submissions are recorded.

5.5.3 As discussed at the REB meeting, the REB's concerns, clarifications, and recommendations to the Researcher are included in the REB review letter sent to the Researcher. **These letters are accessible to all REB members through an online system. The information documented in the letter will be reflective of the comments submitted before the REB meeting, as well as a reflection of the discussion at the meeting itself.**

5.5.4 The meeting may be audio tape recorded (on an encrypted device) for reference purposes and to provide additional reference information to generate the final draft of the minutes. **Records will be deleted within 10 business days or when the initial response to applicant has been sent following a full board meeting.**

5.5.5 The minutes are intended to reflect what the REB decided, how it resolved controversial issues, and any determinations required by the regulations.

5.5.6 The draft minutes should be completed before the next REB meeting.

5.6 Meeting Minutes

5.6.1 The minutes will be available at the next appropriate REB meeting, and members are requested to review the minutes and note any errors for correction.

5.7 Documentation

5.7.1 The REB meeting minutes include the following items:

- Date, place, and time the REB meeting commenced and adjourned,
- Names of REB members in attendance (present, teleconference, videoconference),
- Names of REB 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 REB 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 REB regarding approval for each submission, as applicable,
- The basis for requiring changes or for disapproving submissions,
- Number of REB members in attendance for the review of each submission requiring a decision,
- REB member(s) recused related to conflicts of interest for each submission requiring a decision,
- Number(s) voting for, against and abstaining in the event of a vote for each submission requiring a decision,
- Reference to any attachments to the agenda.

5.7.2 All REB meeting agendas and minutes are retained in the REB records.

5.7.3 The agendas, REB 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 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP302.001	15-Sept-2014	Original version



SOP302.002	08-Mar-2016	5.1.2: revision to the reporting criteria and notification of the REB for all delegated reviews.
SOP302.003	08-Oct-2019	5.5.3: deletion of last sentence, "The information documented in the letter is included in the REB meeting minutes"; 5.7.1: deletion of 'Names of REB members absent'
SOP302.004	15-May-2023	5.6: deletion of approval 5.6.1 : deletion of 'are presented at the meeting for REB approval'; inclusion of 'members are requested to review the minutes and to note any errors for correction' 5.6.2 : deletion 5.6.3 : deletion 5.7.1 : deletion of 'or' replaced by 'and'; 'Number(s) voting for, against and abstaining. ,
SOP302.004	1-Dec-2023	Queen's Specific Revisions/Clarifications added to the N2 SOPs with modifications in bolded text