

Procedures: Human Research Ethics**SOP 302 REB Meeting Administration****Associated Policy**

Human Research Ethics Policy AR-03

Procedure Holder

Associate Vice President Research

Executive Lead

Research Services

Approval Authority

President

Original Date

Replaces AR-03 procedures (May 2009, Oct. 2014)

Effective Date

July 2022

1.0 PURPOSE

This standard operating procedure (SOP) describes the required activities for the preparation, management and documentation of 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

The REB Co-Chairs and the Research Ethics Coordinator 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 quorum is present and maintained.

The REB meeting agenda provides structure and order for meeting. Agenda items normally include review and approval of minutes from the previous meeting, declarations of conflict of interest, an overview of all items that have been reviewed and approved through the delegated review procedure, new information pertinent to REB review such as new policies or guidelines, a list of items that are pending review by the Full Board, and assigned reviewer(s) for each of those items (if required).

Information documented in the REB meeting agenda provides the foundation for the REB meeting minutes.

The REB meeting minutes document the actions that occur during an REB meeting. The minutes

should enable a reader who was not present at 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 at a later date, if necessary.

5.1 Agenda Preparation

- 5.1.1 Following a document review of the submission (e.g., new studies, amendments, continuing review applications, reportable events) by the Research Ethics Coordinator and the determination of the review type by the REB Co-Chairs or designee, the Research Ethics Coordinator adds 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 list of approvals is appended to the next Full Board meeting agenda;
- 5.1.3 The Research Ethics Coordinator attaches 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 Research Ethics Coordinator, in consultation with the REB Chair or designee as necessary, reviews the agenda, confirms REB meeting attendance and assigns reviewers if required;
- 5.1.5 The REB Co-Chairs or designee invites the appropriate alternate REB member to the meeting when a regular REB member is not able to attend;
- 5.1.6 The agenda (and reviewer assignment if required) is issued in a timely manner prior to the REB meeting date. The REB members attending the REB meeting will receive a copy of the REB meeting agenda;
- 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 the Research Ethics Coordinator. The Research 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 Research Ethics Coordinator, in consultation with the REB Co-Chairs or designee as necessary, may assign a primary and one or more secondary reviewers for each new research project as required, and one or more reviewers 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 Supervisor or in which there is a declared conflict of interest;
- 5.2.3 The Research Ethics Coordinator will issue the reviewer assignment if applicable. The assigned reviewers will receive notification with a copy of the meeting agenda;
- 5.2.4 If any of the assigned reviewers declares 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 may 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 may submit their individual comments for each submission prior to 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 their 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,

they may participate via videoconference or teleconference. REB 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 REB members recusing themselves due to a conflict of interest are not counted toward quorum;
- 5.4.7 REB Office Personnel serving as REB members are not counted toward quorum.
- 5.4.8 Under unusual circumstances (e.g., public health alerts and quarantines) the REB Co-Chairs or designee may, at their 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;
- 5.4.9 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;
- 5.4.10 Observers may be invited or permitted to attend REB meetings, 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 being considered at the REB meeting;
- 5.4.11 If requested, Researchers may (in person or via videoconference or 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;
- 5.4.12 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 Research Ethics Coordinator will draft the REB meeting minutes including key discussions, decisions and votes;
- 5.5.2 The key REB discussions and decisions for submissions are recorded;
- 5.5.3 The REB's concerns, clarifications and recommendations to the Researcher as discussed at the REB meeting are included in the REB review letter that is sent to

the Researcher. The information documented is included in the REB meeting minutes;

- 5.5.4 The meeting may be audio recorded (on an encrypted device or secure platform) for reference purposes for the generation of the final draft of the minutes;
- 5.5.5 The minutes are intended to reflect what the REB discussed, how it resolved controverted issues, and the decisions made;
- 5.5.6 The draft minutes should be completed prior to the next REB meeting.

5.6 Meeting Minute Approval

- 5.6.1 The minutes are made available at the next appropriate REB meeting and are presented at the REB meeting for review and approval;
- 5.6.2 The REB motion and votes on the previous REB meeting minutes are recorded in the current REB meeting minutes;
- 5.6.3 If the previous REB meeting minutes are approved pending revisions, the Research Ethics Coordinator makes the required changes, and unless the REB requests further review of the minutes prior to approval, the Research Ethics Coordinator records the minutes as “approved by the REB”.

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 members absent,
 - Name of the Research Ethics Coordinator 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 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 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
SOP 302	July 2022	YukonU version adapted from N2/CAREB SOP 302.003 (October 8, 2019) and CAREB 2021 updates