

TITLE	302: HREB Meeting Administration
SCOPE	The activities of the Human Research Ethics Board operating under the direct authority of Trinity Western University
RESPONSIBILITIES	The Vice-Provost, Research & Graduate Studies, all Human Research Ethics Board (HREB) members, including the Chair(s) and Coordinator
APPROVAL AUTHORITY	The Vice-Provost, Research & Graduate Studies
EFFECTIVE DATE	November 14, 2019
Supersedes documents dated	N/A

1.0 PURPOSE

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

2.0 DEFINITIONS

See Glossary of Terms.

3.0 PROCEDURE

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

The HREB shall meet monthly during the semester, with the exception of December and April, and will hold additional meetings during the summer as necessary in order to review all projects that involve greater than minimal risk.

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

3.1 Agenda Preparation

- 3.1.1 Following an administrative review of the submission (e.g., new studies, amendments, continuing review applications, reportable events) by the HREB Office Personnel and the determination of the review type by the HREB Chair or designee, the responsible HREB Office Personnel adds any submissions requiring Full Board review to the next appropriate Full Board meeting agenda;
- 3.1.2 For submissions that were reviewed and approved via delegated review procedures, the HREB will be made aware of these approvals in a timely manner ;
- 3.1.3 The HREB Office Personnel attaches to the agenda any previous HREB meeting minutes for Full Board review and approval, and adds any other items for information or discussion at the HREB meeting (e.g., SOPs, educational articles, presentations, reports, etc.);
- 3.1.4 The HREB Office Personnel, in consultation with the HREB Chair or designee as necessary, reviews the agenda, confirms HREB meeting attendance and assigns the reviewers;
- 3.1.5 The HREB Chair or designee invites the appropriate alternate HREB member to the meeting when a regular HREB member is not able to attend;
- 3.1.6 The reviewer assignment and the agenda are 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;
- 3.1.7 Ad hoc advisors will receive copies of relevant submissions;
- 3.1.8 Any changes to the agenda are communicated to all HREB members and HREB Office Personnel. The HREB Office Personnel or designee also may issue an updated agenda notice depending on the nature of the changes.

3.2 Primary and Secondary Reviewers

- 3.2.1 Prior to the meeting, the HREB Office Personnel, in consultation with the HREB Chair or designee as necessary, will assign a primary and may assign one or more secondary reviewers for each new research project and at least one reviewer for each amendment;
- 3.2.2 No HREB 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;
- 3.2.3 The HREB Office Personnel will issue the reviewer assignment. The assigned reviewers will receive notification with a copy of the meeting agenda;

- 3.2.4 If any of the assigned reviewers declare a conflict, the submission is reassigned to another reviewer.
- 3.3 Prior to the HREB Meeting
 - 3.3.1 The primary and secondary reviewers (if applicable) will conduct in-depth reviews of their assigned submissions and may submit reviewer comments prior to the HREB meeting. The primary reviewer should be prepared to lead the discussion at the Full Board meeting;
 - 3.3.2 All HREB members are expected to 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;
 - 3.3.3 HREB members who are not assigned as primary or secondary reviewers may submit their individual comments for each submission prior to the meeting;
 - 3.3.4 All HREB members should be prepared to present their comments and participate in the discussion at the Full Board meeting.
- 3.4 During the HREB Meeting
 - 3.4.1 A quorum must be present to proceed with a Full Board meeting;
 - 3.4.2 Quorum is defined as two-thirds of the HREB membership, where the members present include representation per TCPS2 (2018) Article 6.4: *Research Ethics Board Composition—basic REB membership requirements*. In exceptional circumstances, meetings shall be deemed to meet quorum where absent members have, prior to the meeting, provided their feedback regarding any decisions to be made in the meeting;¹
 - 3.4.3 Should quorum fail during a Full Board meeting (e.g., through recusal of HREB members with conflicts of interest or early departures), the HREB may not make further decisions unless quorum can be restored;
 - 3.4.4 An alternate HREB member may attend in the place of a regular HREB member to meet quorum requirements. When a HREB member and his/her alternate both attend the HREB meeting, only one is allowed to participate in the deliberations and final decisions regarding approval;
 - 3.4.5 Should a HREB member not be physically present during a Full Board meeting, he/she may participate via videoconference or teleconference. HREB members participating by videoconference or teleconference count towards quorum;
 - 3.4.6 Ad hoc advisors will not be used to establish a quorum;

¹ See SOPs 402.4.1 and 201 for details regarding full-board review procedures and membership representation, respectively.

- 3.4.7 HREB members recusing themselves due to a conflict of interest are not counted toward quorum;
 - 3.4.8 Under unusual circumstances (e.g., public health alerts and quarantines) the HREB Chair or designee may, at his/her discretion, conduct an HREB meeting with all HREB members attending via simultaneous videoconference or teleconference, provided everyone has access to the review materials and quorum is met;
 - 3.4.9 Only those HREB 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;
 - 3.4.10 Observers may be invited or permitted to attend HREB meetings, subject to the agreement of the HREB 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 HREB meeting;
 - 3.4.11 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;
 - 3.4.12 Any individual not listed on the official HREB membership roster may not participate in the decisions of the HREB.
- 3.5 Meeting Minute Preparation
- 3.5.1 The HREB Office Personnel will draft the HREB meeting minutes including key discussions, decisions and votes;
 - 3.5.2 The key HREB discussions and decisions for submissions are recorded;
 - 3.5.3 The HREB's concerns, clarifications and recommendations to the Researcher as discussed at the HREB meeting are included in the HREB review letter that is sent to the Researcher. The information documented in the letter is included in the HREB meeting minutes;
 - 3.5.4 The meeting may be audio tape recorded (on an encrypted device) for reference purposes and to provide additional reference information for the generation of the final draft of the minutes;
 - 3.5.5 The minutes are intended to reflect what the HREB decided, how it resolved controverted issues, and any determinations required by the regulations;
 - 3.5.6 The draft minutes should be completed prior to the next HREB meeting.
- 3.6 Meeting Minute Approval
- 3.6.1 The minutes are made available at the next appropriate HREB meeting and are presented at the HREB meeting for review and approval;

- 3.6.2 The HREB motion and votes on the previous HREB meeting minutes are recorded in the current HREB meeting minutes;
- 3.6.3 If the previous HREB meeting minutes are approved pending revisions, the HREB Office Personnel makes the required changes, and unless the HREB requests further review of the minutes prior to approval, the HREB Office Personnel records the minutes as “approved by the HREB.”

3.7 Documentation

- 3.7.1 The HREB meeting minutes include the following items:
- Date, place, and time the HREB meeting commenced and adjourned,
 - Names of HREB members in attendance (present, teleconference, videoconference),
 - Names of HREB members absent,
 - Names of HREB 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 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 disapproving submissions,
 - 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,
 - Reference to any attachments to the agenda;
- 3.7.2 All HREB meeting agendas and minutes are retained in the HREB records;
- 3.7.3 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.

4.0 REFERENCES

See References.

5.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 302	November 14, 2019	Original version