RESEARCH ETHICS BOARD STANDARD OPERATING PROCEDURES SOP Number REB Meeting Administration Date of Issue Date of Revision 2005 12 28 2010 08 17 2018 03 30 2022 07 13

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) and meeting procedures to ensure they are conducted and documented in a consistent manner in order to meet regulatory and institutional requirements.

Directives: Fraser Health Policy "The Ethical Conduct of Research and Other Studies Involving Human Participants"

References: 2019 10 08 CAREB SOP 302.003

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

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 sequence of review. It also provides an overview of all items that have been previously (i.e., during the preceding time between REB meetings) reviewed and approved by delegated review procedures, a list of items that are pending review by the Full Board. 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.

1.0 Assignment of Studies to REB members

- 1.1 All studies are assigned to all REB members for review with the expectation that each member reviews according to their expertise and board role;
- 1.2 Reviewers who are also the Principal Investigator or co-investigator are not assigned their own studies for review;
- 1.3 The protocol may also be assigned to an additional expert (external review) who is not a member of the REB if the nature of the protocol warrants the need for additional expertise.

2.0 Agenda Preparation

- 2.1 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 adds any submissions requiring Full Board review to the next appropriate Full Board meeting agenda;
- 2.2 For submissions that were reviewed and approved via delegated review procedures, the REB will be made aware of these approvals in a timely manner;
- 2.3 The REB Office Personnel 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.);
- 2.4 The REB Office Personnel, in consultation with the REB Chair or designee as necessary, reviews the agenda and confirms REB meeting attendance;
- 2.5 The REB Chair or designee invites the appropriate alternate REB member to the meeting when a regular REB member is not able to attend;
- 2.6 Ad hoc advisors will receive copies of relevant submissions;
- 2.7 The agenda 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;
- 2.8 Any changes to the agenda are communicated to all REB members and REB Office Personnel. The REB Office Personnel or designee also may issue an updated agenda notice depending on the nature of the changes.

3.0 Prior to the REB Meeting

3.1 The REB Members will conduct in-depth reviews of their assigned submissions and may submit reviewer comments prior to the REB meeting;

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

4.0 During the REB Meeting

- 4.1 A quorum must be present to proceed with a Full Board meeting;
- 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;
- 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;
- 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;
- 4.5 Ad hoc advisors will not be used to establish a quorum;
- 4.6 REB members recusing themselves due to a conflict of interest are not counted toward quorum;
- 4.7 The REB Chair 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;
- 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;
- 4.9 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;
- 4.10If 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;

4.11Any individual not listed on the official REB membership roster may not participate in the decisions of the REB.

5.0 Meeting Minutes Preparation

- 5.1 The REB Office Personnel will draft the REB meeting minutes including key discussions, decisions and votes;
- 5.2 The key REB discussions and decisions for submissions are recorded;
- 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;
- 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:
- 5.5 The minutes are intended to reflect what the REB decided, how it resolved controverted issues, and any determinations required by the regulations;
- 5.6 The draft minutes should be completed prior to the next REB meeting.

6.0 Meeting Minutes Approval

- 6.1 The minutes are made available at the next appropriate REB meeting and are presented at the REB meeting for review and approval;
- 6.2 The REB motion and votes on the previous REB meeting minutes are recorded in the current REB meeting minutes;
- 6.3 If the previous REB minutes are approved pending revisions, the REB Office Personnel makes the required changes, and unless the REB requests further review of the minutes prior to approval, the REB Office Personnel records the minutes as "approved by the REB."

7.0 Documentation

- 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 or abstaining in the event of a vote for each submission requiring a decision,
- Reference to any attachments to the agenda;
- 7.2 All REB meeting agendas and minutes are retained in the REB records;
- 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.