Ontario Shores
Centre for Mental Health Sciences

REB STANDARD OPERATING PROCEDURES MANUAL

Name of SOP: REB Meeting Administration
REB SOP # 020

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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).

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

Description:
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, and assigned reviewer(s) for each of those items. 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.
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Procedure:

1) Meeting Agenda Preparation:

- 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

- For submissions that were reviewed and approved via delegated review procedures, the list of approvals is appended to the next Full Board meeting agenda

- 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.)

- The REB Office Personnel, in consultation with the REB Chair or designee as necessary, reviews the agenda, confirms REB meeting attendance and assigns the reviewers

- The REB Chair or designee invites the appropriate alternate REB member to the meeting when a regular REB member is not able to attend

- The reviewer assignment and the agenda are 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

- Ad hoc advisors will receive copies of relevant submissions

- 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

2) Primary and Secondary Reviewers:

- Prior to the meeting, the REB Office Personnel, in consultation with the REB Chair or designee as necessary, will assign a primary and a secondary reviewer for each new research project and at least one reviewer for each amendment

- No REB member will be assigned as a reviewer on a submission in which he or she is a Investigator or co-Investigator or in which there is a declared conflict of interest

- The REB Office Personnel will issue the reviewer assignment. The assigned reviewers will receive notification with a copy of the meeting agenda

- If any of the assigned reviewers declare a conflict, the submission is reassigned to another reviewer

3) Prior to the REB Meeting:

- 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

- 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

- REB members who are not assigned as primary or secondary reviewers may submit their individual comments for each submission prior to or during the meeting

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

4) During the REB Meeting:

- A quorum must be present to proceed with a Full Board meeting. A quorum is defined as five regular REB members present at the meeting

- 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

- 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

- 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

- Ad hoc advisors will not be used to establish a quorum

- REB members recusing themselves due to a conflict of interest are not counted toward quorum

- 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 video or teleconference, provided everyone has access to the review materials and quorum is met

- Only those REB members present (i.e., in person, or via video or teleconference) at the Full Board meeting may participate in the deliberation and final decision regarding approval

- 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

- If requested, Investigator(s) 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

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

5) Meeting Minute Preparation:

- The REB Office Personnel will draft the REB meeting minutes including key discussions, decisions and votes

- The key REB discussions and decisions for submissions are recorded

- The REB's concerns, clarifications and recommendations to the Investigator as discussed at the REB meeting are included in the REB review letter that is sent to the Investigator. The information documented in the letter is included in the REB meeting minutes

- With the permission of the board, 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;

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

- The draft minutes should be completed prior to the next REB meeting

6) Meeting Minute Approval:

- The minutes are made available at the next appropriate REB meeting and are presented at the REB meeting for review and approval

- The REB motion and votes on the previous REB meeting minutes are recorded in the current REB meeting minutes

- If the previous REB meeting 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) Documentation:

- 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
- Names of REB Office Personnel present at the meeting
- Presence of observers, if any
- 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

- All REB meeting agendas and minutes are retained in the REB records

- 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

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

References:

1) N2 CAREB REB SOPs v1 *SOP 302.001* (September 2014) https://oicronca.box.com/s/95k7ydj574579ajvbe06

2) Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical conduct for Research Involving Humans, December 2010: (short name: TCPS 2) http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

3) ICH: E6 - Guidance for industry: Good Clinical Practices (GCP): (April 1996) http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf

4) U.S. Department of Health and Human Services (HHS): Code of Federal Regulations (CFR), Title 45 Part 46.103, Part 46.108 http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

5) U.S. Department of Health and Human Services (HHS): Office for Human Research Protections (OHRP) Policy & Guidance Library http://www.hhs.gov/ohrp/policy/index.html

6) Ontario Shores Research Ethics Board Terms of Reference, Functions and Responsibilities (2009)