

SOP Title:	REB Meeting Administration		
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Approved By:	Dr. Elizabeth Stephenson		

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 POLICY STATEMENT

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.

3.0 DEFINITIONS

3.1 See Glossary of Terms

3.2 Quorum

Quorum is defined as the minimum number of members that must be present in order for the REB to review and make its determination regarding submitted research. Quorum rules help to ensure the soundness and integrity of the research ethics review process. To maintain quorum when REB members are geographically dispersed or in unexpected circumstances (e.g., emergencies), input from member(s) is allowed by other means, such as the use of technology.

When there is less than full attendance, decisions requiring full review should be adopted only when the members in attendance at that meeting have the specific expertise, relevant competence and knowledge necessary to provide an adequate research ethics review of the proposals under consideration.

Ad hoc advisors, observers, REO Personnel and others attending REB meetings should not be counted in the quorum for an REB meeting. Nor should they be allowed to vote on REB decisions. Decisions without a quorum are not valid or binding.

4.0 RESPONSIBILITY

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

5.0 PROCEDURES

5.1 Agenda Preparation

- 5.1.1 Following an administrative review of the application (e.g., new studies, amendments, continuing review applications, reportable events) by the REO Personnel and the determination of the review type by the REB Chair or designee, the responsible REO Personnel adds any applications requiring Full Board review to the next appropriate Full Board meeting agenda;
- 5.1.2 For applications that were reviewed and approved via delegated review procedures, the list of approved applications (i.e., new studies, amendments and renewals) is appended to the next Full Board meeting agenda;
- 5.1.3 The REO 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.);
- 5.1.4 The REO Personnel, in consultation with the REB Chair or designee as necessary, reviews the agenda, confirms REB meeting attendance and assigns the reviewers;
- 5.1.5 The REB Chair or designee invites the appropriate alternate REB member to the meeting when a regular REB member is not able to attend;
- 5.1.6 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;
- 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 REO Personnel. The REO Personnel or designee 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 REO Personnel, in consultation with the REB Chair or designee as necessary, will assign a primary reviewer and may assign one or more secondary reviewers for each new research project and at least one reviewer for each continuing review submission;

- 5.2.2 No REB member will be assigned as a reviewer on an application in which he or she is an Investigator or in which there is a declared conflict of interest;
- 5.2.3 The REO Personnel will issue the reviewer assignment. The assigned reviewers will receive notification with a copy of the meeting agenda;
- 5.2.4 If any of the 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 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 Quorum

- 5.4.1 For quorum to be met at a meeting, the SickKids REB will require that, at a minimum, five voting REB Members must be present.
- 5.4.2 Inclusive in the determination of quorum will be the requirement that the composition of the five voting REB Members include the following:
 - two members with relevant expertise in the methods or areas of research covered by the REB;
 - For drug trials, one of the scientific members must be from a medical discipline, or if regarding a dental drug, from a medical or dental discipline;
 - For clinical trials involving natural health products, one of the scientific members must be knowledgeable in complementary or alternative health care.
 - one member knowledgeable in ethics;
 - one member who is not affiliated with the institution but who is recruited from the community served by the institution;
 - one member knowledgeable in the law;
 - one member whose expertise is primarily non-scientific;
 - one member knowledgeable in privacy.
- 5.4.3 In all cases the REB Chair will ensure that there is adequate expertise to provide appropriate ethical and scientific review of the research in question.
- 5.4.4 For US Federally Funded and FDA Regulated Research: In addition to the quorum requirements in 3.2.1 and 3.2.2, there must be a majority of panel members present at the meeting in order to establish quorum, 50% + 1.

5.4.5 An alternate member may attend in the place of an absent regular member in order to meet the quorum requirements outlined above.

5.4.6 Members attending via simultaneous videoconference or teleconference count towards quorum provided they have received the review materials.

5.4.7 Members recusing themselves due to conflicts of interest are not counted towards quorum.

5.4.8 A member may not fulfill more than two representative capacities or disciplines.

5.4.9 Ad hoc reviewers will not be used to establish a quorum.

5.5 During the REB Meeting

5.5.1 Quorum must be present to proceed with a Full Board meeting;

5.5.2 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;

5.5.3 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;

5.5.4 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;

5.5.5 Ad hoc advisors will not be used to establish a quorum;

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

5.5.7 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;

5.5.8 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;

5.5.9 Observers may be invited or permitted to attend REB meetings, subject to the agreement of the REB and execution of a Confidentiality and Conflict of Interest Agreement. Observers must disclose any vested interest in, or scientific or management responsibility for, any applications being considered at the REB meeting;

5.5.10 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;

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

5.6 Voting

- 5.6.1 Members of the REB generally approve studies by consensus;
- 5.6.2 Where consensus is not achieved the decision will be made by majority vote, with the exception of those who have recused themselves in accordance with the conflict of interest policies;
- 5.6.2.1 The votes will be recorded in the minutes in the following format as an example: Total = 15; Vote: For – 14, Opposed – 0, Abstained-1.
- 5.6.3 The Chair will abstain from voting; except when the Chair is counted towards quorum; or in the event a majority vote is not rendered, the Chair shall cast the deciding vote;
- 5.6.4 A majority of members present must vote in favour of an action for that category of action to be accepted by the REB. Only regular and alternate members acting in place of absent regular members may vote;
- 5.6.5 The REB may vote on the range of decisions described in SOP IV.02.001;
- 5.6.6 No votes will be taken without a quorum;
- 5.6.7 Any member with a conflict of interest will recuse themselves from the discussion and voting;
- 5.6.8 Written comments from absent members shall be allowed to inform the consideration of an application, but only members participating in the meeting, including members participating via electronic conferencing at which the specific application is considered, shall participate in any vote or decision.

5.7 Meeting Minute Preparation

- 5.7.1 The REO Personnel will draft the REB meeting minutes including key discussions, decisions and votes;
- 5.7.2 The key REB discussions and decisions for submissions are recorded;
- 5.7.3 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;
- 5.7.4 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;
- 5.7.5 The minutes are intended to reflect what the REB decided, how it resolved controverted issues, and any determinations required by the regulations;
- 5.7.6 The draft minutes should be completed prior to the next REB meeting.

5.8 Meeting Minute Approval

- 5.8.1 The minutes are made available at the next appropriate REB meeting and are presented at the REB meeting for review and approval;
- 5.8.2 An REB member moves to approve the REB meeting minutes and another member seconds that motion.
- 5.8.3 The REB motion and votes on the previous REB meeting minutes are recorded in the current REB meeting minutes;
- 5.8.4 If the previous REB meeting minutes are approved pending revisions, the REO Personnel makes the required changes, and unless the REB requests further review of the minutes prior to approval, the REO Personnel records the minutes as "approved by the REB."

5.9 Documentation

- 5.9.1 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,
- Names of REO Personnel present at the meeting,
- Presence of any 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 application, as applicable,
- The decisions taken by the REB regarding approval for each application, as applicable,
- The basis for requiring changes or for disapproving applications,
- Number of REB members in attendance for the review of each application requiring a decision,
- REB member(s) recused related to conflicts of interest for each application requiring a decision,
- Number(s) voting for, against or abstaining in the event of a vote for each application requiring a decision,
- Reference to any attachments to the agenda;

5.9.2 All REB meeting agendas and minutes are retained in the REB records;

5.9.3 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