Research Ethics Board (REB) Meeting Administration

Sunnybrook Health Sciences Centre		SOP No:	REB-SOP-III-02.004
Title	Research Ethics Board (REB) Meeting Administration	**Original Issue Date:**	February 26, 2009
Category	Research Ethics Board	**Reviewed / Effective Date:**	February 26, 2009; May 3, 2011; November 18, 2013; January 20, 2016
Sub-Category	Section III: Function and Operations	**Revision:**	May 3, 2011; November 18, 2013; January 20, 2016
Issued By:	Human Research Protections Program (HRPP), Research Ethics Office		
Approved By:	Executive Director, Research Integrity & Clinical Research Operations; REB Chair		

The Sunnybrook REO web page version of this document is considered the most current.
Please ensure that you have reviewed all linked documents and other referenced material within this SOP.

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the required activities for the preparation, management and documentation of convened Research Ethics Board (REB) meetings.

2.0 POLICY STATEMENT

Except when a delegated review procedure is used, the REB will review proposed research at convened meetings at which a quorum is present. The REB will meet monthly, or as called by the Chair.

The REB meeting agenda provides the meeting content and provides the foundation for the REB meeting minutes. It also includes an attachment of all items that have been reviewed and approved by delegated review procedures since the last convened meeting, a list of items that are pending review by the convened REB, and assigned reviewers for each of those items.

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

3.0 DEFINITIONS

See Glossary of Terms

4.0 RESPONSIBILITY

This SOP applies to the REB Chair, Executive Director, all REB Members, REB consultants, REB meeting guests and REO staff involved in REB Meeting Administration.

5.0 PROCEDURES

Sunnybrook
HEALTH SCIENCES CENTRE

Research Ethics Board (REB) Meeting Administration

5.1 Agenda and Meeting Preparation

5.1.1 The REO Coordinator, in consultation with the REB Chair as necessary, drafts the meeting agenda according to the *REB Meeting Agenda Template*, and posts all items that require full REB review to the agenda (e.g., previous meeting's minutes, business carried, amendments, renewals, new protocol submissions);

5.1.2 The REO Coordinator attaches a report of all items that were reviewed and approved via delegated review procedures and includes any other items for information or discussion (e.g. Executive Director reports, SOPs, educational articles);

5.1.3 The REO Coordinator, in consultation with the REB Chair as necessary, reviews the agenda, assigns the reviewers for each project (one primary and 2-3 secondary reviewers), posts the reviewer assignment to the agenda and notifies the REB members of the reviewer assignment, receives declarations of conflicts with the assignment, reviews with the Manager and/or Chair, readjusts the reviewer assignment as necessary and confirms meeting attendance;

5.1.4 The REO Coordinator includes the completed meeting agenda in the REB meeting packages for distribution to the REB members;

5.1.5 The REO Coordinator distributes the meeting packages to the REB members 7-10 days prior to the REB meeting;

5.1.6 All REB members receive a standard REB review package for each project;

5.1.7 In addition to the standard REB review package, the protocol and Investigator Brochure are sent to the primary reviewer. The protocols for each meeting are uploaded into the secure REB portal accessible to all REB members;

5.1.8 The primary reviewer prepares a written summary based on an in-depth review of all the materials of the assigned research project(s) and will be prepared to lead the discussion at the convened meeting;

5.1.9 Secondary reviewers perform an in-depth review of the materials provided and are encouraged to submit comments to the primary reviewer;

5.1.10 The REO Coordinator prints a copy of the written summary for the REB file;

5.1.11 All members will review the materials provided prior to the meeting and will be prepared to participate in the discussion at the convened meeting;

5.1.12 If changes need to be made to the agenda, the REO Coordinator will modify the agenda, notify the REB Chair and members, and circulate the revised agenda.

5.2 During the REB Meeting

5.2.1 Attendance is recorded using the attendance tracking record. Time of arrival, recusal, return to meeting and departure will be noted for each member as applicable;

5.2.2 A quorum must be present to conduct a convened meeting;

5.2.3 Should quorum fail during a meeting (e.g., through recusal of members with conflicts of interest or early departures), the REB may not make further decisions until quorum can be restored;

5.2.4 Consultant(s) will not be used to establish a quorum;

5.2.5 Members recusing themselves due to conflicts of interest are not counted toward quorum;

5.2.6 Under unusual circumstances (e.g., public health alerts and quarantines) the REB Chair may, at his/her discretion, conduct an REB meeting with all members attending via simultaneous videoconference or teleconference, provided everyone has received the review materials and quorum is met;

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

5.2.8 If requested, investigators, or their designate, may attend the REB meeting to present their project and respond directly to any comments or questions raised by the REB, subject to the agreement of the REB. Investigators may not be present for REB discussions, deliberations and decisions;

5.2.9 Any individual not listed on the current REB membership list may not participate in the decisions of the REB.

5.3 Meeting Minute Preparation

5.3.1 The REO Coordinator creates the outline of the meeting minutes according to the *REB Meeting Minutes Template* and incorporates the meeting agenda;

5.3.2 The REO Coordinator records the key REB discussions;

5.3.3 The REB concerns, clarifications and recommendations to the investigator as discussed at the meeting, are included in an REB comment letter that is sent to the investigator.

5.4 Meeting Minute Approval

5.4.1 The REO Coordinator prints the minutes and includes them in the REB meeting packages for distribution to the REB members;

5.4.2 It is the responsibility of the REB members to review and recommend changes (as necessary) to the meeting minutes.

5.4.3 The REB Chair requests a motion to approve the minutes at the next convened REB meeting noting any required revisions;

5.4.4 If modifications to the minutes are required, this will be done by the REO Coordinator and presented to the REB Chair for final approval.

5.5 Documentation

5.5.1 The meeting minutes and/or attendance record include the following items:

- Time meeting commenced and adjourned;
- Names of REB members in attendance (present, teleconference, videoconference);
- Names of REB members absent;
- Presence of guests and ex-officio members;

Sunnybrook
HEALTH SCIENCES CENTRE

Research Ethics Board (REB) Meeting Administration

- Use of expert consultants and their specialty as applicable;
- Declaration of any real, potential or perceived REB Member conflicts of interest;
- A summary of key discussions and issues including the basis for requiring changes in or for rejecting research;
- The decisions taken by the REB regarding approval;
- Members recused related to conflicts of interest for each project;
- Number voting for, against or abstaining in the event of a vote.

5.5.2 Reviewer forms or a copy of the completed reviewer template are kept on file with the study.

5.5.3 Meeting agendas and minutes and completed reviewer forms are stored as per Part C Division 5 of the Food and Drug Regulations of Health Canada;

5.5.4 The agendas, meeting minutes and reviewer forms are confidential documents not released outside the REO unless required by law. They may be inspected by authorized regulatory personnel (e.g., Health Canada, FDA).

6.0 REFERENCES

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2 2014) Article 6.10; 7.3;
2. The International Conference on Harmonization Guidelines for Good Clinical Practice, Section 3;
3. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103; 46.107; 46.108, 46.109, 46.115;
4. US Food and Drug Administration (FDA) Code of Federal Regulations Title 21 Part 56.107, 56.108, 56.109, 56.115;
5. OHRP Guidance on Written IRB Procedures;
6. FDA Information Sheets;
7. OPRR Memo "*IRB Meetings Convened via Telephone Conference Call*"