WOMEN'S COLLEGE RESEARCH INSTITUTE
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Research Ethics Board Standard Operating Procedures

REB Meeting Administration

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CATEGORY	Research Ethics Board	**Reviewed/Effective Date:**	January 5, 2017
SUB-CATEGORY	Section III: REB Operations	**Original Issue Date:**	December 21, 2012
ISSUED BY:	Research Ethics Office		
APPROVED BY	Vice President, Research		

The WCH Research Ethics Office (REO) webpage version of this document is considered the most current.

Please ensure that you have reviewed all linked documents and other reference material within this SOP

1.0 POLICY STATEMENT:

The purpose of this Standard Operating Procedure (SOP) is to describe the required activities for the preparation, management, and documentation of convened Women's College Hospital (WCH) Research Ethics Board (REB) meetings.

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

The REB meeting agenda provides meeting content, establishes a sequence of review, 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 REB 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.

2.0 DEFINITION(S):

See Glossary of Terms

3.0 RESPONSIBILITY:

This SOP applies to the WCH REB Chair, Vice-Chair, all REB Members, External Reviewers, REB meeting guests, and REO staff involved in REB meeting administration.

4.0 PROCEDURES:

4.1 Agenda and Meeting Preparation:

4.1.1 The WCH REB Coordinator, in consultation with the WCH REB Chair as necessary, drafts the REB meeting agenda according to the *REB Agenda Template*, and posts all items that require full board review to the agenda.

4.1.2 The WCH Research Ethics Coordinator attaches a report of all the items that were reviewed and approved via delegated and full board review procedures and includes any other items for information or discussion (e.g. research operations updates, SOPs, educational articles).

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4.1.3 The WCH Research Ethics Coordinator, in consultation with the WCH REB Chair as necessary, reviews the agenda, assigns reviewers for each project (one primary and one secondary), posts the reviewer assignments to the agenda and notifies REB members of the reviewer assignments, requests declarations of conflicts of interest and confirms meeting attendance.

4.1.4 The agenda should be completed 7--14 calendar days prior to the REB meeting date.

4.1.5 The WCH Research Ethics Coordinator includes the agenda in the electronic REB meeting package for distribution to the REB members.

4.1.6 The WCH Research Ethics Coordinator distributes the meeting packages via email to the REB members 10-14 days prior to the REB meeting. If any REB member prefers to receive a hard copy package, they must specify this to the WCH Research Ethics Coordinator, who will prepare and send them a hard copy of the REB package.

4.1.7 All REB members receive a standard REB review package for each project.

4.1.8 In addition to the standard REB review package, the protocol and Investigator Brochure (IB)/ Product Monograph (PM) are sent to the primary/secondary reviewer.

4.1.9 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 REB meeting.

4.1.10 The secondary reviewer performs an in-depth review of the material provided and is encouraged to submit comments to the primary reviewer.

4.1.11 The WCH REB Coordinator prints a copy of the written summary for the REB file.

4.1.12 All members will review the materials provided prior to the REB meeting and will be prepared to participate in the discussion at the convened meeting.

4.1.13 If changes need to be made to the agenda, the WCH REB Coordinator will modify the agenda, notify the WCH REB Chair and members, and provide copies of the revised agenda.

4.2 During the Meeting

4.2.1 The WCH REB Coordinator or Assistant takes attendance. Time of arrival, recusal, return to meeting, and departure will be noted for each REB member.

4.2.2 A quorum must be present to conduct a convened REB meeting;

4.2.3 Should quorum fail during an REB 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.

4.2.4 External reviewers and/or non-voting members will not be used to establish a quorum.

4.2.5 REB members recusing themselves due to conflicts of interest are not counted toward quorum.

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

4.2.7 Guests may be invited or permitted to attend REB meetings, subject to execution of a Confidentiality and Conflicts of Interest Agreement. Guests must disclose any conflicts of interest including but not limited to vested interest in, or scientific management responsibility for any applications being considered at the meeting.

4.2.8 If requested, investigators, or their delegates and/or team members may attend the REB meeting to present their project and respond directly to any comments or questions raised by the REB.

4.2.9 Any individual not listed on the current REB membership list may not participate in the decision-making processes of the REB

4.3 Meeting Minute Preparation

4.3.1 The WCH Research Ethics Coordinator or Assistant creates the outline of the meeting minutes using the WCH REB Meeting Minutes Template;

4.3.2 The WCH Research Ethics Coordinator and Assistant records the key REB discussions.

4.3.3 The REB's concerns, clarifications, and recommendations to the investigator as discussed at the REB meeting are included in a REB comment letter that is sent to the investigator.

4.4 Meeting Minute Approval

4.4.1 The WCH Research Ethics Coordinator or Assistant includes the previous month's minutes in the REB meeting package for distribution to the REB members

4.4.2 The minutes are presented at the next convened REB meeting for review and approval.

4.4.3 It is the responsibility of REB members to review, recommend changes, and approve the meeting minutes.

4.4.4 If modifications to the minutes are required, this will be done by the WCH Research Ethics Coordinator or Assistant and presented to the WCH REB Chair for final approval.

4.5 Documentation

4.5.1 REB meeting minutes and/or attendance record includes the following items:

- time meeting commenced and adjourned;
- names of REB members in attendance (present or teleconference);
- name of REB members absent;
- presence of guests and ex-officio members;
- use of external reviewers and their specialty as applicable;

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- declaration of any real, potential, or perceived researcher conflicts of interest;
- members recused due to conflicts of interest for each project;
- summary of key discussions and issues including the basis for requiring changes in or for rejecting research;
- reference to any written reviews and or review template (as applicable);
- decisions taken by the REB regarding approval or disapproval.

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

4.5.3 Meeting agendas, minutes and completed reviewer forms are stored as per Part C Division D of the Food and Drug Regulations and Health Canada.

4.5.4 The agendas, meeting minutes, and reviewer forms are only accessible to REB members, REO staff, or other representatives of WCH authorized by the Vice President, Research. They may also be inspected by authorized regulatory personnel (e.g. Health Canada, FDA, etc).

5.0 REFERENCES:

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2) Article 6,10; 7.4;
2. International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (GCP), 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 (CFR), Tile 21 Parts 56.107, 56.108, 56.109,56. 115;
5. FDA Information Sheets;
6. OHRP Guidance on Written IRB Procedures;
7. OPRR Memo *"IRB Meetings Convened via Telephone Conference Call"*