



Research Ethics Board Standard Operating Procedures

Composition and Management of the REB

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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 membership composition and management requirements of the Women's College Hospital (WCH) Research Ethics Board (REB).

Individual members of the WCH REB must be qualified through training, experience and expertise to ascertain the acceptability of proposed research in terms of ethical principles and applicable regulations, guidelines and standards pertaining to human subjects or human materials protection.

2.0 DEFINITION(S):

See Glossary of Terms

3.0 RESPONSIBILITY:

The WCH REB Chair and Research Ethics Coordinator are responsible for ensuring that the composition of the WCH REB meets applicable regulatory requirements.

4.0 PROCEDURES:

To promote reviews of the highest quality possible, the WCH REB must include appropriate diversity. Therefore, selection of members must include considerations of race, gender, cultural backgrounds, professional expertise, clinical and research experience, scientific and non-scientific expertise, and sensitivity to such issues as community attitudes to assess the research submitted for review.

4.1 Selection of REB Members

- 4.1.1 New REB members will be selected from the hospital and from the community by the REB Chair and a delegate of the CEO in consultation with the Chair of the WCH Medical Advisory Committee.
- 4.1.2 In the selection of REB members, equal consideration shall be given to qualified persons of both genders. No appointment shall be made solely on the basis of gender.
- 4.1.3 The WCH REB will make every effort to include cultural and ethnic minorities to represent the population cared for by the research community at Women's College Hospital (WCH), within the scope of available expertise needed to conduct its functions.
- 4.1.4 REB membership will consist of members from a variety of professions.
- 4.1.5 REB members will be selected based on the needs of the WCH REB as outlined below and per applicable regulations, guidelines and standards.

4.2 Composition of the WCH REB

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- 4.2.1 Membership of the REB will be in compliance with Health Canada (Division 5, Part C.05.001 of the Food and Drug Act), Tri Council Policy Statement on Ethical Conduct for Research Involving Humans (TCPS2, Article 6.4), the International Conference on Harmonization Good Clinical Practices (ICH-GCP 3.2.1), the Ontario Personal Health Information Protection Act (PHIPA) (S.15), US Food and Drug Administration Code of Federal Regulations (US FDA CFR 56.107), and Office for Human Research Protections (OHRP) (46.107);
- 4.2.2 The Manager and the WCH REB Chair monitor REB membership composition for appropriate membership in relation to the volume of protocol submissions. Membership shall consist of at least 5 members and shall include members of the hospital (Faculty, trainees and employees) who are actively involved in health-related research and/or knowledgeable and interested in research ethics. Institutional senior administrators are not to be members of the REB. Members should represent both medical and non-medical departments at WCH, and the composition of REB must be such that a majority of the REB members are Canadian citizens or permanent residents, as defined under the Immigration and Refugee Protection Act. In compliance with the TCPS2 the composition of the REB shall include the following:
- at least two members have expertise in relevant research disciplines, fields and scientific methodologies covered by the REB; one of whom is from a medical discipline;
 - at least one member is knowledgeable in ethics;
 - at least one member is knowledgeable in Canadian laws relevant to biomedical research;
 - at least one member is knowledgeable in privacy issues;
 - at least one member is knowledgeable in complementary or alternative health care, if possible.
 - at least one community member has no affiliation with the sponsor, institution, investigator, and who is not part of the immediate family of a person who is affiliated with the institution;
 - diversity of members including consideration of race, gender and cultural backgrounds.
- 4.2.3 Alternate members will not be counted in the total REB membership, but listed as alternate to a regular REB member;
- 4.2.4 The REB should consist of a broad representation from across therapeutic areas and include physicians, nurses/health care professionals with clinical and/or research expertise, community members, and members with expertise in research ethics, relevant law, privacy legislation and may consist of other related disciplines such as pharmacy, epidemiology and biostatistics.

4.3 REB Chair

- 4.3.1 The WCH REB Chair is an administrative position within WCH appointed by the CEO in consultation with the Chair of the Medical Advisory Committee (MAC), a subcommittee of the WCH Board of Directors.

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- 4.3.2 The Chair reports administratively to the CEO or delegate and liaises with the University of Toronto (UofT) on research ethics matters, as specified under the current affiliation agreement between WCH and UofT.
- 4.3.3 The term of office for the REB Chair is two years and is renewable for a maximum term of four years.

4.4 External Reviewers

- 4.4.1 At his/her discretion, the WCH REB Chair may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available to the WCH REB. Invitations to serve as an external WCH REB Reviewer shall be coordinated through the Research Ethics Office (REO). In the event that the external reviewer serves as a paid consultant to the WCH REB, CEO approval will be required in advance in keeping with the WCH Purchasing Policy.
- 4.4.2 The external reviewer may be required to submit a written report and to participate via teleconference, or to attend a WCH REB meeting to lend his/her expertise to the discussions.
- 4.4.3 All external reviewers shall sign a Confidentiality and Conflict of Interest Agreement.
- 4.4.4 External reviewers may not contribute to the WCH REB's decision and their presence or absence shall not be used in establishing quorum.
- 4.4.5 Documentation of key information provided by external reviewers will be summarized in the REB minutes and if available, the written report will be placed in the specific study's REB file in the REO.

4.5 Terms of Appointment for REB Members

- 4.5.1 REB members will normally serve for a term of two years. By mutual consent between a member and the WCH REB Chair, the member may be appointed for additional terms.
- 4.5.2 The terms of service will be staggered, wherever possible, to ensure continuity.

4.6 Resignations and Debarring of Members

- 4.6.1 An REB member may resign before the conclusion of his/her term upon provision of notice to the Manager or the REB Chair.
- 4.6.2 REB members may be asked to step down from the REB if they are absent from more than 25% of scheduled REB meetings.
- 4.6.3 The REB Chair may otherwise remove members from the REB if they are not fulfilling their duties.
- 4.6.4 Every effort will be made to recruit a similarly qualified replacement prior to the departure of an REB member to preserve the experience and continuity of function of the WCH REB.

4.7 Compensation

- 4.7.1 REB members do not receive financial compensation for their role;
- 4.7.2 REB members may be reimbursed for parking and other miscellaneous expenses associated with full REB meeting attendance;

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4.7.3 The REB Chair and Vice-Chair are financially compensated in accordance with their respective Letter of Appointment.

4.8 Conflicts of Interest

All REB members sign a Confidentiality and Conflicts of Interest Agreement, agreeing to abide by the Disclosure and Documentation of Conflicts of Interest REB SOP.

4.9 Liability Coverage

REB members are insured for errors and omissions in the performance of their role as REB members under the WCH insurance policy with HIROC (Healthcare Insurance Reciprocal Corporation of Canada), subject to the terms and conditions of that policy.

4.10 Documentation and Posting of the REB Membership List

4.10.1 REO staff will maintain an updated electronic REB membership list.

4.10.2 The REB membership list will be reviewed and updated as required or with the initiation of new terms or the conclusion/termination of existing terms. The effective date of the updated REB membership list will be consistent with a convened meeting date;

4.10.3 REO staff will forward the updated Public REB Membership List to the appropriate member of the WCH Strategic Communications Team for posting on the REB website. The list includes the name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., description of each member's chief anticipated contribution to the REB deliberations; any employment or affiliation with the institution; and gender for all REB members.

4.10.4 A detailed membership list will be stored and locked in the REO. This list will contain member contact information. It will be kept confidential and accessible only by REB members and REO staff.

4.10.5 The WCH Research Ethics Coordinator will update the REB membership roster and Office of Human Research Protections (OHRP) registration to reflect membership changes. OHRP will be notified within 90 days of any change. Previous versions will be archived.

4.10.6 The WCH Research Ethics Coordinator will maintain REB registration with the US OHRP.

4.11 Contents of REB Member Personnel Files

4.11.1 The following list outlines the contents of personnel files for all current and past WCH REB members:

- Current and updated curricula Vitae
- Documents related to education, expertise and REB member letters of appointment
- Original signed and dated Welcome Letter
- Completed REB New Member Checklist
- Signed Confidentiality Agreement and Acknowledgement concerning Conflicts of Interest for REB Members or Observers
- Documentation of the Institution's mandatory research ethics training

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4.12 Creation and Maintenance of REB Member Personnel Files

- 4.12.1 All REB membership documentation will be stored and locked in the REO.
- 4.12.2 The WCH Research Ethics Coordinator will create REB member personnel files as directed by the Manager
- 4.12.3 The REO will review REB member personnel files annually for completeness and will update accordingly.

1.0 REFERENCES:

1. Health Canada (Division 5, Part C.05.001 of the Food and Drug Act)
2. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2) Article 6.4, 6.5
3. Ontario Personal Health Information Protection Act (PHIPA), S.15
4. The International Conference on Harmonization Good Clinical Practices, Section 3.2.1
5. US Office for Human Research Protections 45 Code of Federal Regulations Title 46.107
6. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21, Parts 56.107
7. FDA Information Sheets, FAQ Section II, Questions 14 and 15
8. Women's College Hospital Research Ethics Board Terms of Reference version: 01-SEP-2012
9. Women's College Hospital Purchasing Policy (1.90.001)
10. Women's College Hospital Research Ethics Board Standard Operating Procedure – *Disclosure and Documentation of Conflicts of Interest* (REB-SOP-I-07-001);
11. Sunnybrook Health Sciences Centre Research Ethics Board Standard Operating Procedure– *Composition and Management of the REB* (REB-SOP-II-01.003)