



Research Ethics Board Standard Operating Procedures

Duties of the Research Ethics Board Members

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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 duties of Women's College Hospital (WCH) Research Ethics Board (REB) members.

Each REB member's primary duty is the protection of the rights and welfare of the individual human beings who serve as participants in research studies. In order to fulfill his or her duties, REB members must be versed in regulations governing human participants' protection and biomedical research ethics.

2.0 DEFINITION(S):

See Glossary of Terms

3.0 RESPONSIBILITY:

This SOP applies to the REB Chair, Vice Chair, all REB members and REO staff.

The WCH REB Chair and Research Ethics Coordinator are responsible for clearly articulating all required duties associated with membership on the REB to potential and current REB members.

4.0 PROCEDURES:

4.1. Attendance

- 4.1.1. REB members are expected to attend all regularly scheduled meetings as well as educational events. Members may be asked to step down if they are unable to fulfill their duties;
- 4.1.2. Corresponding and alternative members (if applicable) are expected to attend a minimum of two meetings per year as well as the formal educational events.

4.2. Term of Service

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. The terms of service will be staggered to ensure continuity.

4.3. Duties

All REB members (with the exception of ex-officio members), including corresponding and alternate members as applicable, are expected to review all distributed materials, be prepared to discuss each project, and provide his or her input at convened meetings. Each REB member is expected to fulfill specific duties based on their role(s) on the REB as outlined below. More than one member may fulfill each role.



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- 4.3.1. **Community Members:** shall not be affiliated with the sponsor, institution or investigator not be part of the immediate family of a person who is affiliated with the institution. It is preferable that community members are not currently engaged in research or legal work as their principal activities. Their primary role is to reflect the perspective of the participant.
- 4.3.2. **Non-Scientific Members:** are expected to provide input on areas relevant to their knowledge, expertise and experience, professional and otherwise. These members should advise the REB if additional expertise in a non-scientific area is required to assess whether the research protocol adequately protects the rights and welfare of subjects, and to comment on the comprehension of the consent document.
- 4.3.3. **Scientific Members:** are expected to contribute to the evaluation of a study on its ethical, scientific, and statistical merits, and standards of practice. These members should also advise the REB if additional expertise in a scientific or non-scientific area is required to assess whether the research protocol, consent document and other research materials adequately protect the rights and welfare of subjects.
- 4.3.4. **Members knowledgeable in relevant law:** are expected to alert the REB to legal issues and their implications, not to provide formal legal opinions or to serve as legal counsel for the REB.
- 4.3.5. **Members knowledgeable in research ethics:** are expected to alert the REB to potential ethical concerns and provide options and recommendations.
- 4.3.6. **Members knowledgeable in privacy:** are expected to alert the REB to privacy issues.
- 4.3.7. **External Reviewers:** are individuals with competence in special areas who may be asked by the WCH REB Chair to assist in the review of issues that require expertise beyond or in addition to that available on the REB. The external reviewer may be required to submit a written report and participate via teleconference, or to attend a WCH REB meeting to lend his/her expertise to the discussions. External reviewers may not contribute to the REB's decision and their presence or absence shall not be used in establishing quorum.
- 4.3.8. **WCH REB Chair:** In addition to the duties noted above, the WCH REB Chair is responsible for performing his or her duties as described in the WCH REB Chair Terms Role Profile.
- 4.3.9. **WCH Vice Chair:** An REB Vice-Chair will assist and/or act on behalf of the WCH REB Chair in particular REB matters and at REB meetings, either as general procedure, or on a case-by-case basis.

4.4. Primary Reviewers

In addition to the duties described in section 3.3 above, REB members may be appointed as primary reviewers to review assigned research projects in greater detail and lead the discussion on the assigned research projects at an REB meeting. The REB utilizes the primary and secondary reviewer model for initial review. Reviewers are assigned by the WCH REB Chair or delegate based on the REB member's expertise and experience, with consideration of distribution of workload among REB members.

4.4.1. The Primary Reviewer

- conducts an in-depth review of the assigned research project materials;

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- submits his/her written review of the assigned research project to the REO in advance of the next convened REB meeting;
- presents his/her assessment of the research at the convened REB meeting, leads the discussion and recommends a decision regarding approval or disapproval of the research;
- may be required to review additional material (e.g. investigator responses) for the purpose of research ethics approval.

4.4.2. The Secondary Reviewer

- conducts an in-depth review of the assigned research project(s) focusing on the REB application, informed consent, and budget;
- is encouraged to submit his or her written review of the assigned research project to both the primary reviewer and the REO in advance of the next convened REB meeting;
- speaks to his or her assessment of the research at the convened REB meeting, adds to the discussion as appropriate, and recommends a decision regarding approval or disapproval of the research;
- may be required to review additional material (e.g. investigator responses) for the purpose of research ethics approval.

4.5. Continuing Education

All REB members are expected to participate in continuing education activities, including attendance during REB Training and Education Sessions, conferences, seminars and/or reading pertinent articles/books.

4.6. Conflicts of Interest

All REB members and external reviewers are expected to disclose conflicts of interest prior to the review and/or discussion of items on the REB meeting agenda. When the relevant agenda item is brought forward for discussion, the REB member disclosing the conflict shall excuse themselves for the duration of that discussion.

5.0 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. The International Conference on Harmonization Good Clinical Practices, Section 3
4. US Office for Human Research Protections 45 Code of Federal Regulations Title 46.107
5. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21, Parts 56.107
6. FDA Information Sheets, FAQ Section II, Questions 14 and 15
7. Women's College Hospital Research Ethics Board Terms of Reference
8. Women's College Hospital Research Ethics Board Chair Role Profile
9. Women's College Hospital Conflict of Interest Policy (Policy Number 1.10.08)_____



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10. Sunnybrook Health Sciences Centre Research Ethics Board Standard Operating Procedure– *Duties of Research Ethics Board Members* (REB-SOP-IV-04.003)



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APPENDIX I

[Women's College Hospital Conflict of Interest Policy \(Policy Number 1.10.08\)](#)