



Research Ethics Board Standard Operating Policies and Procedures

Disclosure and Documentation of Conflicts of Interest

SOP NO:	REB-SOP-I-07.002	Revision Date:	January 3, 2017
CATEGORY	Research Ethics Board	Reviewed/Effective Date:	January 3, 2017
SUB-CATEGORY	Section I: General	Original Issue Date:	March 26, 2014
ISSUED BY:	Research Ethics Office		
APPROVED BY	Vice President, Research		

The WCH 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 address the risk of possible conflicts of interest (COI) for Women's College Hospital (WCH) Research Ethics Board (REB) members (including the Chair and Vice-Chair), and Research Ethics Office (REO) staff and extends to individuals who are not REB members but may be asked to review a project because of their expertise.

Conflicts of interest may arise when activities or situations place an REB member in a real, potential or perceived conflict between the duties or responsibilities related to research, and personal, institutional or other interests. These interests include, but are not limited to, business, commercial or financial interests pertaining to the individual, their family members, friends, or their former, current or prospective professional associates.

Such competing interests may influence professional judgment, objectivity and independence and can potentially influence the outcome of a decision, for personal benefit. A conflict of interest does not necessarily imply wrongdoing, as conflicts of interest depend on circumstances, and not on the character of the REB member. Conflicts of interest may exist even if no unethical or improper act results from the conflict.

REBs should identify and manage conflicts of interest to maintain the public confidence and trust and to maintain the independence and integrity of ethics review. If a conflict of interest cannot be avoided, procedures should be in place to mitigate the conflict.

The REB must be perceived to be fair and impartial, immune from pressure either by the sponsor, affiliated institutions or the Investigators whose protocols are being reviewed, or by other professional or nonprofessional sources.

The standard that guides decisions about determining conflicts of interest is whether an independent observer could reasonably question whether the individual's actions or decisions are based on factors other than the rights, welfare, and safety of research participants.

2.0 DEFINITION(S):

See Glossary of Terms

3.0 RESPONSIBILITY:

This SOP applies to the REB Chair, Vice-Chair, REB Members and Research Ethics Office (REO) staff.



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All WCH REB members, including the Chair and Vice-Chair, consultants to the WCH REB and REO personnel are responsible for disclosing and managing any potential or actual conflicts of interest.

4.0 PROCEDURES:

4.1 COI for REB Members

REB members are considered to be in conflict when:

- their own research projects are under review by the WCH REB;
- they are co-investigators on a research project under review by the WCH REB;
- they are in a supervisory relationship with a student/trainee application under REB review;
- they have an interpersonal or financial relationship with the researcher(s) whose project is under review by the WCH REB;
- they may be substantially affected by the research.

4.2 WCH REB Reviewer Assignment

- 4.2.1 When the meeting agenda is distributed, WCH REB members are expected to disclose as soon as possible, in writing, any conflicting interest(s) for any of the projects on the agenda;
- 4.2.2 If an REB member is unclear as to whether a conflict of interest exists, he or she must contact the REB Chair to seek clarification. The REB Chair will determine whether the circumstances should be defined as a conflict of interest and the members shall follow the REB and/or REB Chair's decision regarding any actions required to mitigate his/her real or perceived conflict of interest;
- 4.2.3 If a conflict of interest is identified in the reviewer assignment, the project will be assigned to another WCH REB member.

4.3 Convened Meeting

- 4.3.1 At the outset of the meeting, WCH REB members are reminded of their obligation to orally disclose/declare any real, potential or perceived conflicts of interest. All declared conflicts of interest will be recorded in the meeting minutes;
- 4.3.2 If a conflict of interest is declared and determined as such, the member may be asked to provide information about the study, but must be recused for the deliberation and decision;
- 4.3.3 The member's recusal will be recorded in the minutes and the member will not be counted towards quorum.

4.4 Delegated Review

- 4.4.1 The REB Chair or designee will assess projects undergoing the delegated review process to determine potential conflicts of interest;
- 4.4.2 WCH REB members involved in the delegated review process are expected to disclose any conflicts of interest;



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- 4.4.3 If a conflict of interest is identified, the project will be assigned to another WCH REB member.

4.5 WCH REB Chair

- 4.5.1 In the event that the Chair declares a conflict of interest, the Vice-Chair or alternate WCH REB member will assume the Chair's responsibilities for the specific project(s).

4.6 REO Personnel

- 4.6.1 All WCH REO personnel are expected to disclose any conflicts that arise and any personnel whose job status or compensation is impacted by research that is reviewed by the REB must recuse themselves when such protocols are reviewed;
- 4.6.2 Any disclosure of conflict of interest by REO staff should be referred to the Chair for the development of a management plan;
- 4.6.3 If an REO staff member is unclear as to whether a conflict of interest exists, he or she must contact the Chair to seek clarification. The Chair will determine whether the circumstances should be defined as a conflict of interest.

4.7 External Ad Hoc Reviewers

- 4.7.1 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 on WCH REB;
- 4.7.2 All ad hoc reviewers must sign a *Confidentiality of Information and Conflict of Interest Agreement* prior to commencement of their consultation, and disclose any conflicts of interest to the Chair.

4.8 Researchers

Matters pertaining to possible conflicts of interests by researchers are referred to the [WCRI Conflicts of Interest Policy \(7.10.0002\)](#) and the [Tri- agency Framework: Responsible Conduct of Research](#).

4.9 Documentation

- 4.9.1 All WCH REB members, guests and ad hoc reviewers sign a *Confidentiality of Information and Conflict of Interest Agreement*, agreeing to abide by the WCH REB conflicts of interest and confidentiality policies
- 4.9.2 The signed *Confidentiality of Information and Conflict of Interest Agreements* is filed in the REO;
- 4.9.3 The WCH REB meeting minutes will record any conflicts of interest that are declared on any of the projects under review at the meeting, and the decision on the management of the conflict;
- 4.9.4 The recusal of any WCH REB member will also be recorded in the WCH REB minutes;
- 4.9.5 At the time of hire, all REO staff will sign confidentiality and conflict of interest agreements as a condition of their employment with WCH, agreeing to abide by WCH Conflict of interest and



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confidentiality policies (included those issued by WCRI). REO personnel must also comply with WCH REB conflict of interest SOPs;

- 4.9.6 The signed *Confidentiality of Information and Conflict of Interest Agreements* will be filed with the REO.

4.10 Education and Training in COI

REB members and REO staff are required to participate in education and training activities related to conflict of interest issues as required by WCH.

5.0 REFERENCES:

1. Holland Bloorview Research Ethics Board Standard Operating Procedure (REB-106), Disclosure and Documentation of Conflicts of Interest
2. US Food and Drug Administration Information Sheets, *Guidance for Institutional Review Boards and Clinical Investigators*, Section II
3. Ontario Cancer Research Ethics Board Standard Operating Policies and Procedures (105A.002), Managing Conflicts of Interest – Ontario Cancer Research Ethics Board Members & Ontario Cancer Research Ethics Board Office Personnel
4. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2)
5. U.S. Food and Drug Administration (FDA) 21 CFR 56.107 (e)
6. US Department of Health Services (HHS) 45 Code of Federal Regulations (CFR) 46.107(e)
7. U.S. Office of Human Research Protections (OHRP) *“Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection”*
8. U.S. FDA Guidance Document: *“Financial Disclosure by Clinical Investigators”*
9. Women’s College Hospital Conflict of Interest Policy (1.10.008)
10. Women’s College Research Institute Conflicts of Interest Policy (7.10.0002)