



SOP Title	Managing Conflicts of Interest – HSREB Members & REB Office Personnel
Number.Version	105A.004
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Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics		05/11/2016
Dr. Joseph Gilbert Chair, Health Sciences Research Ethics Board		05/11/2016

1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the potential conflicting interests for the Health Sciences Research Ethics Board (HSREB) members (including the Chair, Vice-Chair(s) and consultants) and REB office staff. This SOP also describes the requirement and procedures for disclosures and management of conflicts of interest.

2. GENERAL POLICY STATEMENT

Conflict of interest (real, potential or perceived) arises when an individual in a position of trust has competing professional or personal interests. Such competing interests may influence his or her professional judgment, objectivity and independence and can potentially influence the outcome of a decision, for personal benefit. A conflict of interest may exist even if no unethical or improper acts result from the conflict.

REBs should identify and manage conflicts of interest to maintain the public confidence and trust to maintain the independence and integrity of the ethics review. If a conflict of interest cannot be avoided, procedures should be put into 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 professionals and/or nonprofessional sources.

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

3. RESPONSIBILITY

This SOP is applicable to all members of the HSREB including the Chair, Vice-Chair and consultants, and to all REB office personnel.

4. DEFINITIONS

See Glossary of Terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. HSREB Reviewer Assignment

5.1.1. The Ethics Officer (EO) reviews the agenda prior to the HSREB meeting to identify any potential conflicts of interest;

5.1.2. When the agenda is distributed, HSREB members are expected to disclose, in writing, as soon as possible any conflicting interest(s) for any of the projects on the agenda;

5.1.3. If a member is unclear as to whether a conflict of interest exists, he or she must contact the HSREB Chair or designee for clarification. The HSREB Chair or designee will determine whether the circumstances should be defined as a conflict of interest and the member shall follow the REB's decision regarding any actions required to mitigate his/her conflict of interest;

5.1.4. If a conflict of interest is identified in the reviewer assignments, the project is assigned to another HSREB member.

5.2. **Convened Meeting**

5.2.1. All HSREB members are reminded of their obligation to orally disclose/declare any conflict of interest at the beginning of the meeting. All declared conflicts of interest will be recorded in the meeting minutes;

5.2.2. If a conflict of interest is declared and determined as such, the member may be asked to provide additional information about the study, however must be excused for the deliberation of the decision;

5.2.3. If the member is asked to leave for the decision this is recorded in the minutes and their vote is not counted towards quorum.

5.3. **Delegated Review**

5.3.1. The HSREB Chair or designee will assess the project undergoing the delegated review process to determine any potential conflicts of interest;

5.3.2. HSREB members involved in the expedited review process are expected to disclose any conflicting interests;

5.3.3. If a conflict of interest is identified, the project is assigned to another HSREB member.

5.4. **HSREB Chair**

In the event that the HSREB Chair declares a conflict of interest, the Vice-Chair or designee will assume the Chair's responsibilities for the specific project(s).

5.5. **Office Personnel**

5.5.1. All Office of Human Research Ethics (OHRE) staff 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 HSREB must excuse themselves when such a protocol is reviewed;

5.5.2. Any disclosure of conflict of interest by OHRE staff should be referred to the HSREB Chair for the development of a management plan;

5.5.3. If an OHRE staff member is unclear as to whether a conflict of interest exists, he or she must contact the HSREB Chair to seek clarification. The HSREB Chair will determine whether the circumstances should be defined as a conflict of interest.

5.6. External Ad Hoc Reviewers

- 5.6.1. At his/her discretion, the HSREB 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 by the HSREB;
- 5.6.2. All ad hoc reviewers must sign a *Visitor Confidentiality Agreement* prior to commencement of their consultation, and disclose any conflicts of interest to the HSREB Chair.

5.7. Documentation

- 5.7.1. All guests and ad hoc reviewers sign a *Visitor Confidentiality Agreement*, agreeing to abide by the HSREB conflict of interest and confidentiality policies;
- 5.7.2. HSREB members sign a *Confidentiality & Conflict of Interest Undertaking* annually;
- 5.7.3. HSREB members representing non-affiliated community members will also sign the *Conflict of Interest: Non-Affiliation Declaration for Community Members* annually
- 5.7.4. The signed *Confidentiality & Conflict of Interest Undertaking, Visitor Confidentiality Agreements and Conflict of Interest: Non-Affiliation Declaration for Community Members* are filed in the HSREB in each members file or in a visitor file;
- 5.7.5. The HSREB minutes will record any conflicts of interest that are declared on any of the projects under review at the meeting along with the decision on the management of conflict;
- 5.7.6. The HSREB minutes will also record the HSREB member that was excused from the decision and vote;
- 5.7.7. At the time of hire, all OHRE staff will sign *Confidentiality & Conflict of Interest Undertaking* forms as a condition of their employment with the University of Western Ontario, agreeing to abide by the policies.

6. REFERENCES

- 6.1. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2010 (TCPS2),;
- 6.2. US Department of Health and Human Services (HHS) CFR Title 45 Part 46.107e;
- 6.3. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21, Part 56.107(e);
- 6.4. National Institutes of Health (NIH) NOTICE: OD-00-039 Required Education in the Protection of Human Research Participants: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>;
- 6.5. Office for Human Research Protections (OHRP) "*Financial Relationships and Interests in Research Involving Human Subjects; Guidance for Human Subject Protection*";
- 6.6. FDA Information Sheets, *Guidance for Institutional Review Boards and Clinical Investigators*, Section II.

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
105A.001	Original	01/21/2014
105A.002	Reformatting and minor administrative changes for clarity	05/22/2014

	Revision to section 7.0 References	
105A.003	Addition of 5.5.3	10/25/2014
105A.004	Minor Administrative Changes	05/10/2016