

TITLE	105a: Conflicts of Interest – Board Members and REO Personnel
SCOPE	The activities of the Health Research Ethics Board (HREB) operating under the direct authority of the Health Research Ethics Authority (HREA)
APPROVAL AUTHORITY	Ethics Director
EFFECTIVE DATE	April 2021

1.0 PURPOSE

This standard operating procedure (SOP) describes potential conflicts of interest (COI) for HREB members (including the HREB Chairperson and any ad hoc advisors), Appeal Board members, members of any research ethics body appointed by the HREA and Research Ethics Office (REO) Personnel, and describes the requirements and procedures for the disclosure and management of COI.

2.0 DEFINITIONS

See the Glossary of Terms.

For the purposes of this SOP, Board refers to the HREB, Appeal Boards, and any other research ethics bodies appointed under the HREA Act and/or approved by the HREA Board of Directors.

3.0 RESPONSIBILITIES

Board members and REO Personnel are responsible for disclosing any real, potential or perceived COI and for ensuring that the requirements of this SOP are met.

4.0 PROCEDURE

A COI (real, potential or perceived) arises when a person in a position of trust has competing professional or personal interests. Such competing interests may influence their professional judgment, objectivity and independence and can potentially influence the outcome of a decision, for personal benefit. A COI may exist even if no unethical or improper act results from the conflict.

In the environment of research, openness and honesty are indicators of integrity and responsibility, characteristics that promote quality research and can only strengthen the research process. Therefore, conflicts shall be eliminated when possible, and shall be effectively managed and disclosed when they cannot be eliminated.

All Boards shall identify and manage COI to maintain the public confidence and trust and to maintain the independence and integrity of the ethics review. If a COI cannot be avoided, procedures shall be in place to mitigate the conflict.

Boards must be perceived to be fair and impartial, immune from pressure from sponsors, affiliated organizations or the Researchers whose research is being reviewed, or by other professional and/or non-professional sources.

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

4.1 HREB Reviewer Assignment

- 4.1.1 The HREB Chairperson or designee will review the agenda prior to the HREB meeting to identify potential COI.
- 4.1.2 When the agenda is distributed HREB members will, as soon as possible, disclose any conflicting interest(s) for any of the projects on the agenda.
- 4.1.3 If members are unclear as to whether a COI exists, they will contact the HREB Chairperson or designee to seek clarification. The HREB Chairperson or designee will determine whether the circumstances should be defined as a COI and members shall follow the decision regarding any actions required to mitigate their real or perceived COI.
- 4.1.4 If a COI is identified in the reviewer assignments, the project will be assigned to another HREB member.
- 4.1.5 If a potential COI relating to a reviewer is alleged by a Researcher, details supporting the rationale for the COI shall be reported to the Chairperson of the HREB (or designee if the Chairperson is the person allegedly conflicted) and the Ethics Director (ED). The Chairperson or designee and the ED will determine if a COI exists. The [Secretariat on Responsible Conduct of Research](#) may be consulted as necessary to determine COI. The Chairperson or designee will determine what course of action is required to manage the COI. All decisions, the reasons for the decisions, and the COI management plans made or approved by the Chairperson regarding the allegation will be communicated to the reviewer and the Researcher in a timely manner. A COI will be documented in the applicable Board meeting minutes.

4.2 HREB Meeting

- 4.2.1 At the outset of the meeting, HREB members will be reminded of their obligation to orally disclose/declare any real, potential or perceived COI. All declared COI will be recorded in the HREB meeting minutes.

- 4.2.2** If a COI is declared and determined as such, the HREB member may be asked to provide information about the research, but must be recused for the deliberation and decision.
- 4.2.3** The HREB member's recusal will be recorded in the minutes and the HREB member will not be counted towards quorum. In the event that a member's COI and necessary withdrawal from the meeting will threaten the maintenance of quorum, the HREB will ensure that a substitute member will be in attendance to maintain quorum.
- 4.2.4** If recused, the HREB member shall abstain from voting on/approving the section of the minutes of that meeting.

4.3 Delegated Review

- 4.3.1** The HREB Chairperson or designee will assess projects undergoing the delegated review process to determine potential COI.
- 4.3.2** HREB members involved in the delegated review process will disclose any conflicting interests to the REO. If there is uncertainty about a COI, section 4.1.3 will be followed.
- 4.3.3** If a COI is identified, the project will be assigned to another HREB member.

4.4 HREB Chairperson

- 4.4.1** In the event that the HREB Chairperson declares a COI, an alternate Chairperson (if applicable) or alternate HREB member will assume the HREB Chairperson's responsibilities for the specific project(s).

4.5 REO Personnel

- 4.5.1** All REO Personnel will disclose any COI to the HREB Chairperson and/or ED for the development of a management plan.
- 4.5.2** If REO Personnel are unclear as to whether a COI exists, they must contact the HREB Chairperson and/or ED to seek clarification. The HREB Chairperson and/or ED will determine whether the circumstances should be defined as a COI.

4.6 External Ad Hoc Advisors

- 4.6.1** At their discretion, the HREB Chairperson or designee 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 the HREB.

- 4.6.2 All ad hoc advisors must sign a *Confidentiality of Information and Conflict of Interest Agreement* prior to commencement of their consultation, and disclose any COI to the HREB Chairperson.
- 4.6.3 Any disclosure of a COI by an ad hoc advisor shall be referred to the HREB Chairperson. The HREB will develop a management plan, as applicable.
- 4.6.4 If ad hoc advisors are unclear as to whether a COI exists, they must contact the HREB Chairperson or designee to seek clarification. The HREB Chairperson or designee will determine whether the circumstances should be defined as a COI.

4.7 Appeal Board Meeting

- 4.7.1 When the agenda is distributed, Appeal Board members will disclose as soon as possible, any conflicting interest(s) for any of the projects on the agenda. If a COI is declared and determined as such, the Appeal Board member may be asked to provide information about the research, but must be recused for the deliberation and decision.
- 4.7.2 At the outset of the meeting, Appeal Board members will be reminded of their obligation to orally disclose/declare any real, potential or perceived COI. All declared COI will be recorded in the meeting minutes.
- 4.7.3 If members are unclear as to whether a COI exists, they must contact the Appeal Board Chairperson or designee to seek clarification. The Chairperson or designee will determine whether the circumstances should be defined as a COI and the members shall follow the decision regarding any actions required to mitigate their real or perceived COI.
- 4.7.4 Section 4.1.5 also applies to the Appeal Board

4.8 Documentation

- 4.8.1 All Board members, guests and ad hoc advisors will sign a *Confidentiality of Information and Conflict of Interest Agreement* and agree to abide by the relevant COI and confidentiality policies. The signed Confidentiality of Information and Conflict of Interest Agreement will be filed by REO Personnel.
- 4.8.2 Board minutes will record any COI that is declared on any of the projects under review at the Board meeting, and the decision on the management of the conflict.
- 4.8.3 Board minutes will also record any recusal of a Board member.
- 4.8.4 At the time of hire, all REO Personnel will sign a *Confidentiality of Information and Conflict of Interest Agreement* as a condition of their employment with the organization agreeing to abide

by the COI and confidentiality policies of the organization. REO Personnel will also comply with relevant COI SOPs. The signed Confidentiality of Information and Conflict of Interest Agreement will be retained in the REO.

- 4.8.5** The management plan for COI declarations will be documented in the appropriate research files. Any discussion at the Board meeting regarding the COI and the management plan will be documented in the Board meeting minutes.

5.0 REFERENCES

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 7, Article: [tcps2-2018-en-interactive-final.pdf \(ethics.gc.ca\)](#).

HREA Confidentiality of Information and Conflict of Interest Agreement Form