

TITLE:	Standard Operating Procedure (SOP) Disclosure and Documentation of Conflict of Interest – REB Members & REB Office Personnel	NUMBER:	NSHA REB-SOP-1-006A
Effective Date:	April 2014	Revision:	September 29, 2017
Applies To:	NSHA REB Members and REB Office Personnel		

1. PURPOSE:

The purpose of this standard operating procedure (SOP) is to describe possible conflicts of interest (COI) for Nova Scotia Health Authority Research Ethics Board (NSHA REB) members (including the REB Executive Chair/Co-Chairs and any ad hoc advisors), and REB Office Personnel, and to describe the requirements and procedures for disclosure and management of COI.

2. POLICY:

A COI may arise when activities or situations place an individual or institution in a real, potential or perceived conflict between the duties or responsibilities related to research, and personal, institutional or other interests. Such competing interests may influence 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.

COI must be assessed when conducting research as they may jeopardize the integrity of the research and the protection offered to participants. It is the goal of the NSHA REB to eliminate conflicts when possible and effectively manage and disclose conflicts when elimination is not feasible.

The REB must be perceived to be fair and impartial, immune from pressure either by the sponsor, 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 individual's actions or decisions are based on factors other than the rights, welfare and safety of the participants.

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

3. DEFINITIONS:

Conflict of interest: circumstance of a person (e.g., Investigator or Research Ethics Board (REB) member) or organization in a real, perceived or potential conflict between their duties or responsibilities related to research and their personal, institutional or other (secondary) interests.

4. PROCEDURES:

4.1. REB Reviewer Assignment

- 4.1.1. The REB Manager reviews the agenda prior to the REB meeting to identify potential COI;
- 4.1.2. When the agenda is distributed, REB members are expected to disclose as soon as possible, any conflicting interest(s) for any of the projects on the agenda;
- 4.1.3. If a member is unclear as to whether a COI exists, he or she must contact the REB Manager to seek clarification. The REB Manager will determine whether the circumstances should be defined as a COI and the member shall follow the REB's decision regarding any actions required to mitigate his/her real or perceived COI;
- 4.1.4. If a COI is identified in the reviewer assignments, the project is assigned to another REB member.

4.2. Full Board Meeting

- 4.2.1. At the outset of the meeting, REB members are reminded of their obligation to orally disclose/declare any real, potential or perceived COI. All declared COI will be recorded in the REB meeting minutes;
- 4.2.2. If a COI is declared and determined as such, the REB member may be asked to provide information about the research, but must be recused for the deliberation and decision;
- 4.2.3. The REB member's recusal will be recorded in the minutes and the REB member will not be counted towards quorum.
- 4.2.4. If recused, the REB member should abstain from voting on/approving the minutes of that meeting;
- 4.2.5. In the event that a member's COI and subsequent withdrawal from the REB meeting disrupts quorum, the REB can ensure that a substitute member attend to maintain quorum for the meeting;

4.3. Delegated Review

- 4.3.1. The REB Manager will assess projects undergoing the delegated review process to determine potential COI;
- 4.3.2. REB members involved in the delegated review process are expected to disclose any conflicting interests;
- 4.3.3. If a COI is identified, the project is assigned to another REB member.

4.4. NSHA REB Co-Chair(s)

- 4.4.1. In the event that the assigned REB Co-Chair declares a COI, the alternate REB Co-Chair will assume responsibility for the specific project(s).

4.5. NSHA REB Office Personnel

- 4.5.1. All REB Office Personnel are expected to disclose any conflicts that arise and any REB Office Personnel whose job status or compensation is impacted by research that is reviewed by the REB must recuse themselves when such research is reviewed;
- 4.5.2. Any disclosure of a COI by REB Office Personnel should be referred to the REB Executive Chair or Manager for the development of a management plan;
- 4.5.3. If REB Office Personnel are unclear as to whether a COI exists, they must contact the REB Executive Chair or Manager to seek clarification. The REB Executive Chair or Manager will determine whether the circumstances should be defined as a COI.

4.6. External Ad Hoc Advisors

- 4.6.1. At his/her discretion, the REB Chair(s) or Manager 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 REB;
- 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 REB Chair(s).
- 4.6.3. Any disclosure of a COI by an ad hoc advisor should be referred to the REB Chair(s) or Manager for the development of a management plan, as applicable.
- 4.6.4. If ad hoc advisors are unclear as to whether a COI exists, they must contact the REB Executive Chair or Manager to seek clarification. The REB Executive Chair or Manager will determine whether the circumstances should be defined as a COI.

4.7. Documentation

- 4.7.1. All REB members, guests and ad hoc advisors sign a *Confidentiality of Information and Conflict of Interest Agreement* and agree to abide by the REB COI and confidentiality policies;
- 4.7.2. REB members sign a *Confidentiality of Information and Conflict of Interest Agreement* declaring conflict of interest annually;
- 4.7.3. The signed *Confidentiality of Information and Conflict of Interest Agreement* is filed in the REB main office;
- 4.7.4. The REB minutes will record any COI that are declared on any of the projects under review at the REB meeting, and the decision on the management of the conflict;
- 4.7.5. The REB minutes will also record the recusal of an REB member;
- 4.7.6. At the time of hire, all REB Office Personnel 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 Nova Scotia Health Authority. REB Office Personnel must also comply with REB COI SOPs;
- 4.7.7. The signed *Confidentiality of Information and Conflict of Interest Agreement* will be retained;
- 4.7.8. The REB management plan for Research COI declarations will be documented in the appropriate research files. Any discussion at the REB meeting regarding the COI and the management plan will be documented in the REB meeting minutes.

5 REFERENCES

- 1) Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2 2014), Chapter 7

6 RELATED DOCUMENTS:

- 1) Confidentiality of Information and Conflict of Interest Agreement

Version History

Effective Date	Major Revisions (e.g. Standard 4 year review)	Minor Revisions (e.g. spelling correction, wording changes, etc.)
October 21, 2016		Reflect the change from nine DHA's to one
September 29, 2017		Harmonized with CAREB/N2 SOP's