



**Ontario Shores**  
Centre for Mental Health Sciences

## REB STANDARD OPERATING PROCEDURES MANUAL

**Name of SOP: Conflicts of Interest – REB Members  
and REB Office Personnel**  
**REB SOP # 023C**

**Issued by: Research Ethics Board Office**  
**Date of Issue: 2016-03-02**  
**Revised: YYYY/MM/DD**

### **Purpose:**

This standard operating procedure (SOP) describes potential Conflicts of Interest (COI) for Research Ethics Board (REB) members (including the REB Chair and any ad hoc advisors) and REB Office Personnel, and describes the requirements and procedures for disclosure and management of COI

### **Scope:**

This SOP pertains to REBs that review human participant research in compliance with applicable regulations and guidelines.

### **Description:**

COI (real, potential or perceived) arise 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 COI may exist even if no unethical or improper act results from the conflict.

REBs should 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 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 organizations or the Investigators 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.

### **Procedure:**

#### **1) REB Reviewer Assignment:**

The REB Chair or designee reviews the agenda prior to the REB meeting to identify any potential COI

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

If a member is unclear as to whether a COI exists, he or she must contact the REB Chair or designee to seek clarification. The REB Chair or designee 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;

If a COI is identified in the reviewer assignments, the project is assigned to another REB member

## **2) Full Board Meeting:**

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

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;

The REB member's recusal will be recorded in the minutes and the REB member will not be counted towards quorum

If recused, the REB member should abstain from voting on/approving the minutes of that meeting

## **3) Delegated Review:**

The REB Chair or designee will assess projects undergoing the delegated review process to determine potential COI

REB members involved in the delegated review process are expected to disclose any conflicting interests

If a COI is identified, the project is assigned to another REB member

## **4) REB Chair:**

In the event that the REB Chair declares a COI, the Vice-Chair or alternate REB member will assume the REB Chair's responsibilities for the specific project(s)

## **5) REB Office Personnel:**

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;

Any disclosure of a COI by REB Office Personnel should be referred to the REB Chair or designee for the development of a management plan

If REB Office Personnel are unclear as to whether a COI exists, they must contact the REB Chair or designee to seek clarification. The REB Chair or designee will determine whether the circumstances should be defined as a COI

## **6) External Ad Hoc Advisors:**

At his/her discretion, the REB Chair 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 REB

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

Any disclosure of a COI by an ad hoc advisor should be referred to the REB Chair or designee for the development of a management plan, as applicable

If ad hoc advisors are unclear as to whether a COI exists, they must contact the REB Chair or designee to seek clarification. The REB Chair or designee will determine whether the circumstances should be defined as a COI.

#### **7) Documentation:**

- 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
- REB members sign a Confidentiality of Information and Conflict of Interest Agreement annually, or as determined by the organization
- The signed Confidentiality of Information and Conflict of Interest Agreement is filed in the REB office
- 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
- The REB minutes will also record the recusal of an REB member
- 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 organization. REB Office Personnel must also comply with REB COI SOPs
- The signed Confidentiality of Information and Conflict of Interest Agreement will be retained;
- 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

#### **Responsibility:**

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

#### **References:**

- 1) N2 CAREB REB SOPs v1 *SOP 105A.001* (September 2014) <https://oicronca.box.com/s/95k7ydj574579ajvbe06>
- 2) 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: (short name: TCPS 2) <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>
- 3) ICH: E6 - Guidance for industry: Good Clinical Practices (GCP): (April 1996) <http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf>
- 4) U.S. Department of Health and Human Services (HHS): Code of Federal Regulations (CFR), Title 45 Part 46.103, Part 46.108 <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>
- 5) U.S. Department of Health and Human Services (HHS): Office for Human Research Protections

(OHRP) Policy & Guidance Library  
<http://www.hhs.gov/ohrp/policy/index.html>

- 6) Ontario Shores Research Ethics Board Terms of Reference, Functions and Responsibilities (2009)