

Title	Conflicts of Interest – REB Members and Support Staff
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1 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 Support Staff, and describes the requirements and procedures for disclosure and management of COI.

2 SCOPE

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

3 RESPONSIBILITIES

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

4 DEFINITIONS

See Glossary of Terms.

5 PROCEDURES

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.¹ These interests include, but are not limited to, business, commercial or financial interests pertaining to the institution and/or the individual, their family members, friends, or their former, current or prospective professional associates.² 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.

REBs should identify and manage COI to maintain public confidence and trust and to maintain the independence and integrity of the ethics review.³ All possible efforts should be made to avoid COI. If a COI cannot be avoided, procedures should be in place to mitigate the conflict.⁴

The REB must be fair and impartial, immune from pressure either by the sponsor, affiliated organizations, the institution, or the Researchers whose research is being reviewed.

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.

5.1 REB Reviewer Assignment

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

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 2014, hereafter "TCPS2", Chapter 7; Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization (WHO), 2000, hereafter "TDR", glossary.

² TCPS2, ch. 7.

³ TCPS2, ch. 7.

⁴ TCPS2, ch. 7.

5.1.2 When the agenda is distributed, REB members are to disclose, as soon as possible, any conflicting interest(s) for any of the projects on the agenda⁵;

5.1.3 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;

5.1.4 If a COI is identified in the reviewer assignments, the project is assigned to another REB member.⁶

5.2 REB Meetings

5.2.1 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 minutes⁷;

5.2.2 If a COI is declared and determined as such, the REB member must be recused for the review, deliberation and decision. The Researcher may be asked to provide information about the projected research to the other REB members⁸;

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

5.3 REB Chair

5.3.1 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).

5.4 REB Support Staff

5.4.1 Any disclosure of a COI by REB Support Staff should be referred to the REB Chair or designee for the development of a management plan;

5.4.2 If REB Support Staff 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.

⁵ TCPS2, art. 7.3.

⁶ *Avis sur les conditions d'exercice des comités d'éthique de la recherche désignés ou institués par le ministre de la Santé et des Services sociaux en vertu de l'article 21 du Code civil, Gazette officielle du Québec, Part I, vol. 35, 1998, hereafter "Avis", p. 1040.*

⁷ TDR, s. 7.1.

⁸ *Avis, p. 1040; TCPS2, art. 7.3; TDR, s. 7.1; Plan d'action ministériel en éthique de la recherche et en intégrité scientifique, Gouvernement du Québec, Ministère de la Santé et des Services sociaux, June 1998, hereafter "PAM", p. 23.*

5.5 External Ad Hoc Advisors

- 5.5.1 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 REB⁹; the REB Chair or designee will make sure that the ad hoc advisor has no COI;
- 5.5.2 If ad hoc advisors become in a COI situation or 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.

5.6 Documentation

- 5.6.1 All REB members, guests and ad hoc advisors agree to abide by the REB COI policies;
- 5.6.2 REB members sign a *Confidentiality of Information and Conflict of Interest Agreement* at the time of their nomination;
- 5.6.3 The signed *Confidentiality of Information and Conflict of Interest Agreement* is filed in the REB office;
- 5.6.4 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;
- 5.6.5 At the time of hire, all REB Support Staff sign a *Confidentiality of Information and Conflict of Interest Agreement* and agree to abide by the COI policies;
- 5.6.6 The REB management plan for Research COI declarations will be documented in the appropriate research files; namely, in the REB correspondence.

6 REFERENCES

See footnotes.

⁹ *Avis*, p. 1039; ICH Harmonised Tripartite Guideline – Guidelines for Good Clinical Practice E6(R1), Health Canada, 1997, hereafter “ICH GCP”, s. 3.2.6; TDR, s. 4.6; PAM, p. 22.

7 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
REB-SOP 105A.001	2020-03-20	Original version

8 APPENDICES