

Title	Conflicts of Interest – REB Members and REB Office Personnel
SOP Code	105A.004
Effective Date	15-May-2023

Site Approvals

Name and Title (typed or printed)	Signature	Date MM/DD/YYYY
Meera Sidhu, Research Ethics Manager	<i>M Sidhu</i>	12/01/2023
Steven Smith, Deputy Vice-Principal Research	<i>Steven Smith</i>	12/04/2023

1.0 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.

2.0 SCOPE

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

3.0 RESPONSIBILITIES

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.

4.0 DEFINITIONS

See Glossary of Terms.



5.0 PROCEDURE

COI (real, potential or perceived) arises when an individual in a position of trust has competing professional or personal interests. Such competing interests influence their professional judgment, objectivity and independence and can 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 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 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.

5.1 REB Reviewer Assignment

- 5.1.1 The REB Chair or designee reviews the agenda before the REB meeting to identify potential COI.
- 5.1.2 When the agenda is distributed, REB members are expected to disclose, as soon as possible, any ~~conflicting interest~~ **COI(s)** for any of the **research studies projects** on the agenda.
- 5.1.3 If a REB member is 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, and the member shall follow the decision of the REB regarding any actions required to mitigate their real or perceived COI.
- 5.1.4 If a COI is identified in the reviewer **research ethics application** assignments, the ~~project~~ **research ethics application** is assigned to another REB member.



5.2 Full Board Meeting

- 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 minutes.
- 5.2.2 If a COI is declared and/or determined as such, the REB member may be asked to provide information about the research **ethics application** but must be recused for the deliberation and decision.
- 5.2.3 The REB member's recusal will be recorded in the minutes and the REB member will not be counted towards quorum.
- 5.2.4 If recused, the REB member ~~should~~ **will** abstain from voting on/approving the minutes of that meeting.

5.3 Delegated Review

- 5.3.1 The REB Chair or designee will assess ~~projects-research~~ **ethics applications** undergoing the delegated review to determine potential COI.
- 5.3.2 REB members involved in the delegated review process are expected to disclose any conflicting interests.
- 5.3.3 If a COI is identified, the **project research study/application will be is-** assigned to another REB member.

5.4 REB Chair

- 5.4.1 If the REB Chair declares a COI, the Vice-Chair or alternate REB member will assume the REB Chair's responsibilities for the specific **project research ethics application**.

5.5 REB Office Personnel

- 5.5.1 All REB Office Personnel are expected to disclose any ~~conflicts~~ **COIs** that arise and any REB Office Personnel whose job status or compensation is impacted by research that the REB reviews must recuse themselves when such research **studies** are reviewed.



5.5.2 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.

5.5.3 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.

5.6 External Ad Hoc Advisors

5.6.1 At their discretion, the REB Chair or designee may invite individuals with competence in particular areas to assist in the review of issues that require expertise beyond or in addition to that available on the REB.

5.6.2 All ad hoc advisors must sign a Confidentiality of Information and Conflict of Interest Agreement prior to the commencement of their consultation and disclose any COI to the REB Chair.

5.6.3 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.

5.6.4 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.

5.7 Documentation

5.7.1 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.

5.7.2 REB members sign a Confidentiality of Information and Conflict of Interest Agreement annually or as determined by the organization.

5.7.3 The signed Confidentiality of Information and Conflict of Interest Agreement is filed in the REB office.

5.7.4 The REB minutes will record any COI that are declared on any of the **projects- research ethics applications** under review at the REB meeting

and the decision on the management of the **conflict COI**.

- 5.7.5 The REB minutes will also record the recusal of an REB member.
- 5.7.6 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 organization. REB Office Personnel must also comply with REB COI SOPs.
- 5.7.7 The signed Confidentiality of Information and Conflict of Interest Agreement will be retained.
- 5.7.8 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.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP105A.001	15-Sept-2014	Original version
SOP105A.002	08-Mar-2016	No revisions needed
SOP105A.003	08-Oct-2019	No revisions needed
SOP105A.004	15-May-2023	No revisions needed
SOP 105A.004	1-Dec-2023	Queen's Specific Revisions/Clarifications added to the N2 SOPs with modifications in bolded text