

SOP Title	UOIT REB Administration
Number.Version	REB SOP 106 Disclosure and Documentation of Conflicts of Interest
Version Date	October 28, 2011
Approval Date	October 28, 2011
Approved By	REB
Revised and Approved	November 16, 2016

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;
- Researchers; and
- Institutional.

This SOP also describes the requirements for the management of COI and procedures that are predicated on full disclosure.

2.0 General Procedures Statement

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

In the environment of research, openness and honesty are indicators of integrity and responsibility – characteristics that promote quality research and strengthen the research process. Therefore, conflicts should be eliminated, effectively managed, and declared when they cannot be eliminated.

2.1 REB Members

All REB members and its office personnel are responsible for disclosing any real, potential, or perceived conflicts of interest and for ensuring that the requirements of this standard operating procedure are met.

As per the *Tri-Council Policy Statement (TCPS) 2*, the REB as an entity, or in the persons of members who make up the Board, also holds trust relationships with participants, research sponsors, researchers, research stakeholders, and the public.

For example, REB members are in conflict of interest when:

- their own research projects are under review by their REB;
- they are co-investigators or co-authors (within the last three years); or
- they are in a supervisory or mentoring relationship with graduate student applicants.

Conflicts of interest based on collaborations or disputes with colleagues, students or others may be ongoing or of limited duration. REBs have an obligation to ensure that the fairness and

transparency of research ethics review is not compromised by real, potential, or perceived conflicts of interest.

2.2 Researchers

According to the current *TCPS 2*, researchers' conflicts of interest arise from:

- Interpersonal relationships, e.g., family or community relationships;
- Financial partnerships;
- Other economic interests;
- Academic interests; or
- Any other incentives that may compromise integrity and respect for the core principles of the *TCPS 2*.

Conflicts may arise from an individual's involvement in dual and multiple roles within or outside the Institution. While it may not be possible to eliminate all conflicts of interest, researchers are expected to identify, minimize, or otherwise manage their individual conflicts in a manner that is satisfactory to the REB.

2.3 Institution

As per UOIT's "Conflict of Interest in Research Policy", conflict of interest may take various forms and may arise in various contexts. Broadly speaking, a conflict of interest will exist whenever a University Member has an interest, pecuniary or otherwise, which may conflict or be perceived to conflict, with the Member's conduct of his/her University activities. To this end, a potential, perceived, actual, and/or apparent conflict of interest must be properly and promptly disclosed, appropriately considered, and managed in keeping with best practices, policies, and jurisdictional laws.

3.0 Specific Procedures

3.1 REB Members – Disclosure of Conflicts of Interest

The REB must be perceived to be fair and impartial, immune from pressure either by the research sponsors, researchers whose research is being reviewed, research stakeholders/affiliated organizations, and the public.

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 human participants.

REB members who fail to comply with this standard operating procedure may have their appointments rescinded in keeping with Standard Operating Procedure 104 – *Membership, Composition, Roles and Responsibilities*.

3.1.1 REB Meeting Administration

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

When the agenda is distributed, REB members are expected to disclose as soon as possible, any conflicting interest(s) for any of the meeting items/projects on the agenda.

The REB Chair or designee reviews the agenda prior to the REB meeting to identify potential COI. 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 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 the REB is reviewing research in which a member of the REB has a conflict of interest, the member must declare the nature of the COI and offer evidence to the REB. If a COI is determined, the REB member must be recused for the deliberation and decision processes.

The REB member's recusal will be recorded in the minutes and the REB member will not be counted towards quorum. Quorum will be constituted by whomever is left.

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

3.1.2 REB Office Personnel and External Ad Hoc Advisors

All REB Office Personnel are expected to disclose any conflicts that arise and will be referred to the REB Chair or designee.

Any REB Office Personnel whose job status or compensation is impacted by research that is reviewed by the REB must recuse themselves from any meeting 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.

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 the start 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 an ad hoc advisor is unclear as to whether a COI exists, he/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.

3.1.3 REB Reviewer Assignment

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 delegated review/project shall be assigned to another REB member.

3.1.4 REB Review of Researcher Conflict of Interest

The REB reviewer will review each application for disclosure of COI.

The REB reviewer shall focus on those aspects of the COI that may reasonably affect human participant protection and the steps taken should be context-based and commensurate with the risks.

In determining the appropriate action, the REB reviewer may take into consideration information presented by the Researcher such as:

- The nature of the research
- The magnitude of the interest or the degree to which the conflict is related to the research
- The extent to which the interest could affect the research

- Whether a specific individual is unique in his/her clinical or scientific qualifications to conduct the research
- The degree of risk to the human participants involved in the research that is inherent in the research, and/or
- The management plan for the COI already developed by the Researcher.

If the Researcher indicates on the REB application form that a conflict exists, the REB will determine whether the disclosed COI is likely to affect or appear to affect the design, conduct or reporting of the research. The REB may approve the research and may require a management plan, which may include changes at the Researcher's or sponsor's expense, to eliminate or to mitigate the conflict. Required actions may include but are not limited to: modifying or limiting the participation of the Researcher in all or in a portion of the research; monitoring the consent process; disclosure of the conflict to research participants, organizational committees, journals, and so on. The REB has the final authority to determine whether a COI has been eliminated or managed appropriately.

3.2 Researcher – Disclosure of Conflicts of Interest

A researcher's failure to comply with this standard operating procedure may be considered Administrative Non-Compliance as per Standard Operating Procedure 210.

Researchers submitting research applications to the REB are required to declare any COI including those of his/her sub/co-Researcher(s), research staff, and their immediate families (which includes spouses, domestic partners and dependent children) and close relationships.

The Researcher is additionally required to provide information on the clinical trial budget, as applicable, when submitting a research application.

Such disclosures shall be in writing and sufficiently detailed to allow accurate and objective evaluation of conflict.

The Researcher shall disclose any conflicts to the REB at the following times:

- With the initial REB application
- At each continuing review of the research project
- Whenever a COI arises such as changes in responsibilities or financial circumstances.

The Researcher shall cooperate with the REB and with other officials involved in the review of the pertinent facts and circumstances regarding any COI disclosed, and shall comply with all the requirements of the REB and with his/her institutional COI policies to eliminate and/or to manage the conflict. The REB may reject research that involves a COI that cannot be appropriately managed.

The Researcher shall ensure that all requirements from any COI reviews are appropriately incorporated into the corresponding informed consent documents and research, as applicable.

Any COI management plan will be documented in the final project files. Any discussions at an REB meeting regarding the COI and the management plan will be documented in the REB meeting minutes.

3.3 Institution – Disclosure of Conflicts of Interest

Please refer to UOIT's "Conflict of Interest in Research Policy" for a complete understanding of the University's policy.

Additionally, REB meetings are closed to employees of the institution unless they are REB members, REB Office Personnel, permitted as observers, or invited by the REB to provide information, and only after signed confidentiality agreements are in place.

4.0 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* for the duration of the appointment or as determined by the REB. 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 agenda items/projects under review at the REB meeting and the decision on the management of the conflict. The REB management plan for research COI declarations will be documented in the appropriate research files. The minutes will also record the recusal of an REB member.

REB Office Personnel must comply with REB COI standard operating procedures.