Research Ethics Board

Standard Operating Procedure

SOP File #	**REB.SOP.105B**
Title	Conflict of Interest – Researcher
Effective Date	July 1, 2021
Next Review	2026
Next Administrative Review	2023

1. **Purpose**
   This standard operating procedure (SOP) describes potential Conflicts of Interest (COI) for Researchers and research team members engaged in human participant research, and the requirements and procedures for disclosure and managing COI.

2. **Definitions**
   See the MSVU **REB Glossary of Terms (REB.INFO.001)**

3. **Scope**
   This SOP pertains to Research Ethics Boards (REBs) that review human participant research in compliance with applicable policies and guidelines.

4. **Responsibilities**
   All REB members, REB Office Personnel and Researchers are responsible for ensuring that the requirements of this SOP are met.

   Researchers are responsible for disclosing any real, potential, or perceived COI to the REB.

   The REB is responsible for determining whether the disclosed COI is likely to affect or appear to affect the design, conduct, or reporting of the research.

5. **Procedures and/or Specific Policies**
   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.

   Researchers and research team members should identify and manage COI to maintain public confidence and trust and to maintain the independence and integrity of the research process. If a COI cannot be avoided, procedures should be in place to manage and/or to mitigate the conflict.

This SOP is not intended to prohibit Researcher relationships with organizations or companies; however, the REB should ensure that participant protection, the integrity of the ethics review, and the conduct of the research are not jeopardized by an unidentified and unmanaged COI.

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 Researchers whose research is being reviewed, or by other professional and/or nonprofessional sources.

The standard that guides decisions about considering COI is whether an independent observer could reasonably question whether the individual's actions or decisions could be influenced by factors other than the rights, welfare, and safety of research participants.

5.1. **Researcher Disclosure of Conflicts of Interest**

5.1.1. Researchers submitting research applications to the REB are required to declare any COI including those of their sub/co-Researcher(s), research team members, and immediate family members (which includes spouse, domestic partners and dependent child), and close relationships;

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

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

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

5.1.4. The Researcher shall cooperate with the REB and with other Organizational representatives 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 their organizational COI policies to eliminate and/or to manage the conflict;

5.2. **REB Review of Researcher Conflict of Interest**

5.2.1. The REB will review each application for disclosure of COI;

5.2.2. If the Researcher indicates on the REB application 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;

5.2.3. The REB review 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;

5.2.4. In determining the appropriate action, the REB 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 their clinical or scientific qualifications to conduct the research,
- The degree of risk to 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;

5.2.5. The REB may approve the research and may require researchers to provide a management plan, which may include changes at the Researcher's or sponsor's/funder's expense, to eliminate or to mitigate the conflict. Required actions may include, but are not limited to:

- Divestiture or termination of relevant economic interests,
- Mandating Researcher recusal from research,
- Modifying or limiting the participation of the Researcher in all or in a portion of the research,
- In cases involving equity, by imposing a bar on insider trading or requiring the transfer of securities to an independent financial manager or blind trust, or limited the timing of sales or distributions,
- Monitoring research (i.e., independent review of data and other retrospective review for bias, objectivity, comprehensiveness of reporting (versus withholding data)),
- Independent clinical review of appropriateness of clinical care given to research participants, if applicable,
- Monitoring the consent process, and/or
- Disclosure of the conflict to organizational committees, research participants, journals, and the data safety monitoring boards (if applicable);

5.2.6. The REB has the final authority to determine whether a COI has been eliminated or managed appropriately;

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

5.2.8. After review by the REB and input by the appropriate Organizational Official, if applicable, the REB may reject research that involves a COI that cannot be appropriately managed.

6. References

See References listed (if applicable)

7. Acknowledgements

The development of this document has benefited directly from similar documents made public by the Tri-Council, as well as several Canadian universities. In some instances, specific formulations drawn from these sources have been incorporated into this document. Specific iterations were drawn from the following:

- Standard Operating Procedures for Observational Health and Non-Clinical Trial Research Ethics Boards - N2/CAREB-ACCER REB SOPs – Canadian Association of Research Ethics Boards (retrieved June 2021)
- N2/CAREB-ACCER REB SOPs - N2 Network of Networks - Resources - N2 Canada (retrieved May 2021)

8. SOP History

SOP Number	Key Changes	Effective Date
REB.SOP.105A	Minor revisions for EDI Language	July 30, 2021
REB.SOP.105A	New - Implementation of new SOP outlining Conflict of Interest for Researchers	July 1, 2021