Title	Conflicts of Interest – Researcher
SOP Code	105B.004
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Site Approvals

Name and Title (typed or printed)	Signature	Date MM/DD/YYYY
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1.0 PURPOSE

This standard operating procedure (SOP) describes potential Conflicts of Interest (COI) for Researchers and research staff engaged in human participant research and the requirements and procedures for disclosure and managing COI.

2.0 SCOPE

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

3.0 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.

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.

Researchers and research staff 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 mitigate the conflict.

This SOP is not intended to prohibit Researcher relationships with 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 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 institutional, professional, and/or nonprofessional 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 Researcher Disclosure of Conflicts of Interest

5.1.1 Researchers submitting research **ethics** applications to the REB are required to declare any COI, including those of their sub/co-researcher (s), research staff, and their immediate families (which includes spouse, domestic

partners and dependent child), and close relationships.

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

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

5.1.4 The Researcher shall disclose any ~~**conflicts**~~ **COI** to the REB at the following times:

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

5.1.5 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 their organizational COI policies to eliminate and/or to manage the conflict.

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

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 Suppose the Researcher indicates on the REB application that a ~~**conflict**~~ **COI** exists. In that case, 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 **COI** 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 study,
- The degree of risk to the human participants involved in the study that is inherent in the study, and/or,
- The Researcher has already developed the management plan for the COI.

5.2.5 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 mitigate the ~~**conflict**~~ **COI**. The researcher may be required to provide a management plan for review by the REB. Required actions may include, but are not limited to:

- **Appropriate disclosure of COI on participant-facing documents such as the consent form or letter of information,**
- Divestiture or termination of relevant economic interests,
- Mandating Researcher recusal from research,
- Modifying or limiting the participation of the Researcher in all or a portion of the research,
- In cases involving equity, by imposing a bar on insider trading requiring the transfer of securities to an independent financial manager or blind trust, or limiting 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.

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 recorded in the meeting minutes.

5.2.8 After review by the REB and input by the appropriate Organizational Official, if applicable, the REB may only accept research that involves a COI that can be appropriately managed.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP105B.001	15-Sept-2014	Original version
SOP105B.002	08-Mar-2016	No revisions needed
SOP105B.003	08-Oct-2019	5.2.5: inclusion of: 'The researcher may be required to provide a management plan for review by the REB'
SOP105B.004	15-May-2023	Changed his/her to their
SOP105B.004	1-Dec-2023	Queen's Specific Revisions/Clarifications added to the N2 SOPs with modifications in bolded text