Title	Conflicts of Interest – Researcher
SOP Code	REB-SOP 105B.002
N2/CAREB SOP CODE	SOP 105B.002
Effective Date	2020-03-20

Status	Name and Title	Date
Author of Harmonized Template	SOPs, Institutional REBs	2019-04-01
Approved	MUHC REB Full Board Meeting	2025-09-17
Approved	MUHC Board of Directors *d'établissement*	2025-10-07

Table of Contents

1 PURPOSE

This standard operating procedure (SOP) describes the role of the Research Ethics Board in the co-management of situations of real, potential, or perceived Conflicts of Interest (COI) involving Researchers and research staff engaged in human participant research. Specifically, the SOP describes the requirements and procedures for disclosure and management of COI, as well as the review and decision-making process of the REB.

2 SCOPE

This SOP pertains to the review by the REB of the COI disclosed in the context of research activities that involve human participants and that take place under its jurisdiction.

3 RESPONSIBILITIES

All REB members, designated REB staff, and Researchers are responsible for ensuring that the requirements of this SOP are met.

Researchers are responsible for identifying and 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 conduct or reporting of the research.

The institution is responsible for ensuring formal oversight of COI in research.

4 DEFINITIONS

See Glossary of Terms.

5 PROCEDURES

A 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, independence, and, consequently, the decision-making process.

To maintain public confidence, to protect participants, and to ensure independence and scientific and social value, the REB contributes to the co-management of COI linked to research activities conducted with human participants and that take place under its jurisdiction.[3] COI must be avoided whenever possible. If a COI cannot be avoided, procedures must be in place to mitigate the conflict;[4] these procedures must be described in the "management plan" submitted by the Researcher.

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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 2022, hereafter "TCPS2"; Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization (WHO), 2000, hereafter "TDR", glossary.

2 TCPS2.

3 TCPS2.

4 TCPS2.

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, or by other professional and/or nonprofessional sources.

In general, 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 or are barriers to the scientific and social value of the research. In addition to this norm, the REB is guided by the following values in the course of its deliberations regarding COI:

- **Co-management**: Promoting a collaborative approach to managing conflicts of interest, while entrusting the final decision to the REB.
- **Scientific integrity:** Maintaining the rigour, objectivity, and reliability of research activities.
- **Pragmatism:** Tolerating a conflict of interest when it can be managed without compromising participant well-being or scientific integrity.
- **Protection:** Giving priority to the interests and safety of participants, while also protecting the interests of the institution.
- **Proportionality:** Tailoring conflict of interest management measures to the seriousness and nature of the identified risks. Depending on the risks involved, it may be appropriate to avoid, manage, or eliminate conflict of interest situations.
- **Transparency:** Ensuring full disclosure of situations that could influence a research project in order to preserve public trust.

As part of its assessment of actual, potential, or perceived conflicts of interest in the research context, the REB may refer to or be guided by various applicable policies, depending on the specific situation:

- Regulatory framework for research of the McGill University Health Centre or a distinct policy on conflicts of interest in research, as applicable
- Other MUHC policies related to conflicts of interest
    - HPO 065 Regulations on Conflicts of Interest
- Policies of an external site affected by the conflict of interest
- Policies on conflicts of interest of McGill University (where relevant)
    - Regulation on Conflicts of Interest
    - Recognizing Conflict of Interest
- External regulations:
    - Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2)
    - *Politique sur la conduite responsable en recherche des Fonds de recherche du Québec*
- Code of Ethics of relevant professions, such as:
    - *Code de déontologie des médecins*
    - *Code de déontologie des infirmières et infirmiers*

This present SOP is not intended to prohibit Researcher relationships with companies; however, the REB should ensure that COI that have not been identified or managed do not jeopardize participant protection, the integrity of the ethics review, or the conduct of the research.

5.1 Identification of Situations with a Conflict of Interest

5.1.1 In the context of research activities involving human participants, actual, potential, or perceived conflicts of interest include, in particular, situations where at least one of the individuals concerned:

- Falls within one of the situations set out in a relevant institutional policy;
- Orients the institution's research activities in such a way as to serve the interests of an external entity in which they, either directly or through their business activities or close relations, hold a financial or other type of interest;
- Conducts research activities on behalf of an external entity without regard for the rights of the institution or its research center.

5.1.2 The Researcher is responsible for identifying actual, potential, or perceived conflicts of interest of all members of their research team. However, any person or entity (e.g., the Research Agreements Office or its equivalent, the body responsible for budget approval, a department head, or the REB) may flag the existence of a conflict situation that has not been declared by a Researcher.

5.1.3 The REB may refer the failure to disclose an actual, potential, or perceived conflict of interest to the institutional body responsible for reviewing allegations of breaches of responsible research conduct.

5.2 Researcher Disclosure of Conflicts of Interest

5.2.1 The Researcher declares, in the research application they submit to the REB, any real, potential or perceived personal or institutional COI that may affect their research project[5];

5.2.2 The Researcher is additionally required to provide information on the budget and funding sources of the research project, as applicable, when submitting a project for review;

5.2.3 The Researcher submits their COI disclosures in writing; the disclosures must be sufficiently detailed to allow accurate and objective evaluation of conflict;

5.2.4 The Researcher explains why the COI cannot be prevented.

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

- With the initial REB application,
- At each continuing review of the project (as described in MUHC REB SOP 405A),
- Whenever a COI arises, such as changes in responsibilities or financial circumstances;

[5] TCPS2, art. 7.4.

5.2.6 The Researcher submits a COI management plan using the template provided by the REB.

5.2.7 The Researcher shall declare any COI in the informed consent documents, if applicable.

5.3 REB Review of Researcher Conflict of Interest

5.3.1 The REB will review each application for disclosure of COI;

5.3.2 For each disclosure, the REB also verifies that a COI management plan has been submitted and that the plan is complete and relevant to the specific project for which it was submitted.

5.3.3 If the Researcher indicates on the REB application that a conflict exists, the REB chair or their delegate will determine whether the disclosed COI is likely to affect or appear to affect the conduct or reporting of the research. In doing so, they confirm that the disclosure is relevant to the project. The existence of various interests does not mean that they will necessarily be in conflict in the context of a given project.

5.3.4 The REB Chair or their delegate will seek to confirm that the Research Agreements Office (or its equivalent) has considered or will consider declared conflicts of interest when preparing the relevant contracts and agreements. Similar steps may also be taken with the body responsible for approving project budgets.

5.3.5 The REB Chair or their delegate identifies the level of risk posed by the declared situation and determines which REB members should participate in the assessment of the declared conflict of interest. Depending on the specific case and at the discretion of the REB Chair or their delegate, the REB's decision-making process may include the following steps:

- Consultation with the REB Chair or one or more of their delegates;
- Consultation with the principal investigator (generally required for any complex conflict);
- Consultation with an institutional committee that may be convened;
- Consultation with the Organizational Ethics Office (for conflicts of interest with an institutional component);
- External consultation (e.g., for projects involving an Indigenous community).

5.3.6 All individuals involved in the review must confirm their independence and that they do not have any conflicts of interest in relation to the situation under review.

5.3.7 The REB Chair or their delegate identifies the interests that are in conflict, evaluates those aspects of the COI that may affect human participant well-being and/or the scientific and social value, and they assess whether the measures described in the management plan take into consideration the context, are commensurate with the risks, and, ultimately, appear adequate[6];

[6] TCPS2.

5.3.8 In determining the appropriate actions, the REB Chair or their delegate takes into consideration the information presented by the Researcher, including:

- 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 has unique 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;

5.3.9 Taking into consideration the above, the REB may approve the measures proposed in the management plan or require alternative ones. The required measures can include, but are not limited to:

- Obligation to avoid:
  - Making changes to the Researcher's or sponsor's financial interests, including divestment or renunciation of the economic interests in question,
- Full restriction:
  - Mandating the Researcher's recusal from the research project,
- Target restriction:
  - Modifying or limiting the Researcher's participation in all or in a portion of the research,
- Independent monitoring:
  - Monitoring the conduct of the research project (i.e., independent review of data and other retrospective review to verify bias, objectivity, comprehensiveness of reporting of results to ensure no selective reporting),
  - Ensuring monitoring of the consent process, and/or
- Disclosure:
  - Requiring the Researcher to disclose the conflict to appropriate institutional bodies, research participants, journals, and data and safety monitoring boards;

5.3.10 The Researcher abides by all of the REB's requirements and relevant COI policies to eliminate or manage the conflict.

5.3.11 The REB Chair or their delegate has the final authority to determine whether a COI has been eliminated or managed appropriately. The REB may reject research that involves a COI that has not been appropriately managed or issue conditions prior to approval[7];

5.3.12 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.[8]

6 REFERENCES

See footnotes.

7 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
REB-SOP 105B.001	2020-03-20	Original version(MUHC Board of Directors acknowledged 2020-03-20; approved 2021-03-22)
REB-SOP 105B.002	2025-10-07	Clarification of the role of the institution; Additional explanations regarding the REB review process; Modification of footnote references; Correction of typos, grammar, and translation

8 APPENDICES

[7] TCPS2.
[8] TCPS2.