Title	Conflicts of Interest – Researcher
SOP Code	REB-SOP 105B.001
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	2020-02-13
Acknowledge receipt ***Approved***	MUHC Board of Directors	2020-03-20 2021-03-22

Table of Content

1 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 SCOPE

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

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 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.

4 DEFINITIONS

See Glossary of Terms.

5 PROCEDURES

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 and independence and can potentially influence the outcome of a decision, for personal benefit.

REBs should identify and manage COI to maintain public confidence and trust and to maintain the independence and integrity of the ethics review.[3] All possible efforts should be made to avoid COI. If a COI cannot be avoided, procedures should be in place to mitigate the conflict.[4]

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.

---

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 2014, hereafter "TCPS2", Chapter 7; Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization (WHO), 2000, hereafter "TDR", glossary.

2 TCPS2, ch. 7.

3 TCPS2, ch. 7.

4 TCPS2, ch. 7.

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.

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.

5.1 Researcher Disclosure of Conflicts of Interest

5.1.1 Researchers are required to declare, in the research application they submit to the REB, any real, potential or perceived personal or institutional COI that may affect their research[5];

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

5.1.3 COI disclosures shall be in writing and sufficiently detailed to allow accurate and objective evaluation of conflict;

5.1.4 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;

5.1.5 The Researcher shall comply with all the requirements of the REB and with COI policies to eliminate and/or to manage the conflict;

5.1.6 The Researcher shall declare any COI in the informed consent documents.

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 conduct or reporting of the research;

5.2.3 The REB review shall focus on those aspects of the COI that may affect human participant protection and the steps taken should be context-based and commensurate with the risks[6];

[5] TCPS2, art. 7.4.
[6] TCPS2, p. 98.

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 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;

5.2.5 The REB may approve the research and may require a management plan. Required actions may include, but are not limited to:

- Making changes to the Researcher's or sponsor's expenses, including divestiture or termination of relevant economic interests,
- Mandating Researcher recusal from the research,
- Modifying or limiting the participation of the Researcher in all or in a portion of the research,
- Monitoring research (i.e., independent review of data and other retrospective review for bias, objectivity, comprehensiveness of reporting of results (versus withholding data)),
- Monitoring the consent process, and/or
- Disclosure of the conflict to appropriate institutional bodies, research participants, journals, and data safety monitoring boards;

5.2.6 The REB 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[7];

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.[8]

6 REFERENCES

See footnotes.

[7] TCPS2, p. 98.
[8] TCPS2, p. 98.

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)

8 APPENDICES