GUIDANCE NOTES ON CONFLICT OF INTEREST

INTRODUCTION

This guidance note is intended to provide researchers with guidance on what constitutes conflict of interest (COI), the mechanisms for reporting real or perceived COI, and the procedures through which such conflicts will be reviewed and assessed by the REB.

GUIDANCE NOTE #1: DEFINITION OF CONFLICT OF INTEREST

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) defines COI as "the incompatibility of two or more duties, responsibilities, or interests (personal or professional) of an individual or institution as they relate to the ethical conduct of research, such that one cannot be fulfilled without compromising the other."

There are multiple types of COI, including:

- Financial: the researcher or related persons stand to gain financially in the undertaking or outcome of the research. Example:
    - The researcher holds significant shares in the for-profit company sponsoring the research.
- Personal: The researcher or related persons has a direct or indirect interest in the undertaking or outcome of the research, or has a personal relationship that may compromise their objectivity and/or lead to undue influence: Example:
    - The researcher's family member enrolls as a participant in the trial.
- Professional: the researcher has an outside professional interest that may conflict with their role in the research, or stands to gain professionally from the undertaking or outcome of the study in a way that may be reasonably expected to compromise their objectivity or bias the research. Example:
    - The researcher will receive a special promotion if the research hypothesis is successfully proven.
- Competing Interest: the researcher or related persons has an adversity in interest related to the research. Example:
    - The researcher is conducting a clinical trial while serving as a board member for another company developing a medication in direct competition with the investigational product.

Conflicts of interest can be **real**, **potential**, or **perceived**. Not all conflicts of interest are problematic or imply wrong-doing. For instance, many researchers stand to gain professionally from conducting and publishing the results of research. Such career advancement is generally

accepted and encouraged. It is when COI have the potential to compromise the integrity of the research or the safety and trust of participants that such conflicts must be managed.

GUIDANCE NOTE #2: SUBMISSION REQUIREMENTS

The Principal Investigator is required to declare all real, potential, or perceived conflicts of interest by anyone responsible for the design, conduct, or reporting or the research, or their immediate family members, on the initial application form. This declaration must include a management strategy for avoiding, eliminating or mitigating any such conflicts.

In accordance with Article 3.2 of the TCPS 2, all COI, including the possibility of commercialization of research findings, must be declared during the consent process, including a declaration of COI on the participant consent form, where applicable.

COIs may change or develop over the course of a research project. In such instances, researchers must submit an updated conflict of interest disclosure form to the FHREB.

The FHREB will take into account the likelihood that the researcher's objectivity and/or the research integrity will be compromised as a result of the COI, magnitude of harm that is likely to arise from the COI, and the appropriateness of the management strategy.

GUIDANCE NOTE #3: FINANCIAL CONFLICTS OF INTEREST

Financial conflicts of interest is the generally the most quantifiable and readily identifiable form of conflict of interest. Significant financial interests that may cause a real, perceived, or potential conflict of interest and should be reported to the REB include:

1. Remuneration from the research sponsor (i.e., salary or other payment for services such as consulting fees, honoraria, paid authorship) that exceeds $5,000 in aggregate over the previous 365 days

2. Equity interest in the research sponsor that includes any stock, stock option, or ownership interest that exceeds $5,000 in aggregate over the previous 365 days

3. Intellectual property rights and proprietary interests in the research (e.g., patents, copyright, trademark, or licensing agreement)

4. Employment with the agency or company sponsoring the research

5. Financial interest in the research with a value that exceeds 5% ownership

6. Financial interest in the research with a value that cannot be readily determined

7. Appointment to the board of directors of the agency or company sponsoring the research
8. Financial interest that requires disclosure to the sponsor or funding source
9. Compensation or financial interest that may be affected by the outcome of a study
10. Any financial interest that may interfere with the design, conduct, reporting of the research, and/or the safety of the participants

Payments to the Principal Investigator by a sponsor for conducting a clinical trial, as outlined in the clinical trial agreement, do not require a conflict of interest declaration to the FHREB. However, such payments may be perceived as a conflict of interest to the participants. As such, they must be declared on the consent form, as applicable.

3.1 Studies funded by the United States Public Health Service (including National Institutes of Health [NIH])

Studies funded by the United States Public Health Service are subject to additional financial conflict of interest disclosure requirements, as set out by the United States Code of Federal Regulations (42CFR50).

GUIDANCE NOTE #4: MANAGING CONFLICTS OF INTEREST

COI generally fall into two categories: 1) COI that is permissible with an appropriate and adequate management strategy, and 2) COI that is not permissible.

Researchers should seek to design research projects in a manner that **avoids** real, potential, and perceived COI. Where avoidance is not possible or feasible, researchers should seek to **minimize** and **mitigate** the COI.

Minimization and mitigation strategies may include (but are not limited to):

a. Removing the researcher from the study
b. Modifying or limiting the participation of the researcher in all or a portion of the research
c. Divestiture of relevant economic or financial assets
d. Independent monitoring of the research
e. Additional independent peer-review of the research design

The FHREB will work with the researcher to develop an appropriate and adequate management plan, where necessary.

In cases where the COI is not permissible, the research will not be approved by the FHREB.