SOP 004_03

Title	Conflicts of Interest – Researcher
SOP Code	SOP 004_03
Effective Date	30-June-2023

Site Approval/Authorization to Adopt

Name and Title of Local Personnel (Type or print)	**Signature**	**Date dd/Mon/yyyy**
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1.0 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.

2.0 SCOPE

This SOP pertains to Erie Shores Health Care (ESHC) researchers conducting human participant research in compliance with applicable policies and guidelines and Research Ethics Boards (REBs) that review human participant research in compliance with applicable policies and guidelines.

3.0 RESPONSIBILITIES

Researchers, REB members and REB Office Personnel 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 PROCEDURE

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.

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.

4.1 Researcher Disclosure of Conflicts of Interest

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

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

4.1.4 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;

4.1.5 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 his/her organizational COI policies to eliminate and/or to manage the conflict;

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

4.2 REB Review of Researcher Conflict of Interest

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

4.2.2 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;

4.2.3 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;

4.2.4 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 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;

4.2.5 The REB may approve the research and may require a management plan, which may include changes at the Researcher's or sponsor's/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,
- Monitoring research (i.e., independent review of data and other retrospective review for bias, objectivity, comprehensiveness of reporting (versus withholding data)),
- Monitoring the consent process, and/or
- Disclosure of the conflict to organizational committees, research participants, and journals;

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

4.2.7 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;

4.2.8 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.

5.0 REFERENCES

Health Canada, Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects, (Schedule 1024), June 20, 2001.

Health Canada, Guidance for Industry, Good Clinical Practice: Consolidated Guideline, ICH Topic E6, 1997.

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.

Department of Justice (Canada), Personal Information Protection and Electronic Documents Act (PIPEDA), updated 2006.

Pharmaceutical Inspection Convention, Pharmaceutical Inspection Co-operation Scheme, Annexe 11, Computerised Systems.

US Food and Drug Administration, Code of Federal Regulations, Title 21, Volume 1:

- Part 11, Electronic Records; Electronic Signatures, (21CFR11).
- Part 50, Protection of Human Subjects, (21CFR50).

- Part 54, Financial Disclosure by Clinical Investigators, (21CFR54).
- Part 56, Institutional Review Boards, (21CFR56).
- Part 312, Investigational New Drug Application (21CFR312).
- Part 314, Applications for FDA Approval to Market a New Drug (21CFR314).

US Department of Health and Human Services, Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects (45CFR46).