# SOP 004_04

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| Title | Conflicts of Interest - Organization |
| 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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| **Neelu Sehgal**<br>Director, Interprofessional Practice & Research<br>Chief Nursing Executive, Erie Shores Health Care | | |
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**1.0 PURPOSE**

This standard operating procedure (SOP) describes potential Conflicts of Interest (COI) in the relationship between the Organization establishing the Research Ethics Board (REB) and the REB itself, and the requirements and procedures for disclosure and for managing potential COI within this relationship.

**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**

Organizational policies should address the roles, responsibilities and process for identifying, eliminating, minimizing or otherwise managing COI relevant to research, including disclosure to REBs. Management of COI includes, but is not limited to, prevention, evaluation, disclosure and the application of appropriate remedies as defined by the organization.

The REB must be fair and impartial, immune from pressure by sponsors and funders, the Organization and Researchers whose research is submitted for review. In the interest of public trust and the integrity of the ethics review, the REB must act independently from the Organization under whose authority they were established and given their mandate, and avoid or manage real, potential or perceived COI. The Organization must respect the autonomy of the REB and ensure that the REB has the appropriate financial and administrative independence to fulfill its primary duties.

The standard that should guide decisions about determining conflicting interests is whether an independent observer could reasonably question whether the Organization's actions or decisions could be influenced by factors other than the rights, welfare and safety of research participants.

**4.1 Disclosure of Conflict of Interest**

4.1.1 All Organizational employees must be familiar with their respective Conflict of Interest Policy (if applicable) and must complete a Disclosure of Conflict of Interest Form(s) (if applicable) at the time of hire and annually thereafter, or as per organizational policy;

4.1.2 Prior to engaging in any of the professional activities listed in the Conflict of Interest Policy, employees must seek the approval of the appropriate Organizational Official to ensure that no conflict exists in doing so;

4.1.3 REB members shall be apprised of the organizational structure with emphasis placed on the independent nature of the relationship between the REB and the Organization. The actions of the REB members relating to their responsibilities to protect human research participants shall not be measured or evaluated in terms of organizational or financial goals;

4.1.4 REB meetings are closed to employees of the organization unless they are REB members, REB Office Personnel, permitted as observers, or invited by the REB to provide information, and only after signed confidentiality agreements are in place;

4.1.5 Organizational senior administrators shall not serve as REB members nor observe REB meetings when their presence may influence REB deliberations.

**4.2 Management of Conflicts of Interest**

4.2.1 The REB Chair or designee must be notified if an organizational COI relating to the REB is declared or discovered;

4.2.2 The REB Chair or designee must be notified immediately if any organizational employee attempts to, or appears to attempt to, influence the ethics review process or to obtain preferential treatment;

4.2.3 The REB Chair or designee will review the available information to determine if a conflict exists, and to determine those aspects of the COI that might reasonably affect human research participant protection;

4.2.4 The REB Chair or designee may require a management plan, which may include actions to eliminate or to mitigate the conflict. Required actions may include, but are not limited to:
• Divestiture or termination of relevant interest,
• Recusal of REB Office Personnel whose job status or compensation is impacted by research that is reviewed by the REB,
• If Organizational staff members are involved, inform the appropriate responsible organizational management personnel to develop and implement a management plan for remediation;

4.2.5 If the REB Chair or designee is unable to satisfactorily manage the COI, or if there are unresolved concerns about any undue influence on the REB, the REB Chair or designee will bring this to the appropriate Organizational Officials for determination of the appropriate course of action.

**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).