


Conflict of Interest Policy	HREA-GEN01
Issuing Authority	Health Research Ethics Authority
Signature of Administrative Authority Chairperson, HREA	
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Background: The Health Research Ethics Authority (HREA) is an independent, non-profit corporation established under the HREA Act to ensure that all health research conducted with human participants in Newfoundland and Labrador is conducted in an ethical manner, and to enhance public awareness of the ethical dimension of health research. The HREA is committed to operating with integrity and holds itself to the highest ethical standard, recognizing that accountability and transparency are essential for its operation. Research Ethics Office (REO) Personnel provide administrative and other health research ethical review expertise and support to the HREA and HREB, as per Section 6 of the HREA Act. REO Personnel may also engage with researchers and students to provide education and consultation.

It is the ethical responsibility for everyone who acts on behalf of the HREA to ensure that decisions and actions that affect the HREA are taken in the best interests of the HREA and are not influenced by personal interests. To maintain public and professional trust and confidence, the HREA must deal with real, perceived or potential conflict of interest (COI) in an open, fair, consistent and practical manner.

For the purposes of this policy, Board refers to the Health Research Ethics Board (HREB), Appeal Boards and any other research ethics bodies appointed under the *Health Research Ethics Authority Act* and/or approved by the HREA Board of Directors.

Scope: Individuals, who for the purposes of this policy, refers to HREB members, Appeal Board members, Ad hoc advisors, Committee members, REO Personnel, observers at Board meetings, Researchers and research staff, are responsible for ensuring that the requirements of this policy are met.

Purpose: The purpose of this policy is to:

1. Describe the requirements and procedures for disclosure and management of COI.
2. Describe possible COI situations for Individuals

Policy Statements:

1. Individuals shall assess their own interests, involvement and activities and report any real, perceived, or potential COI. In carrying out this duty, Individuals will take care to disclose activity that a reasonably informed observer might conclude to be in conflict with the Individual's responsibilities to the Board.

2. Individuals shall not use for personal or professional gain any information which a reasonable person would view as privileged or confidential that is acquired as a result of the Individual's HREA-supported activities. Communicating this information to those not authorized to receive it is also prohibited.
3. Individuals shall identify and manage COI to maintain the public trust and confidence and to maintain the independence and integrity of the ethics review. If a COI cannot be avoided, procedures will be put in place to mitigate the conflict.

Procedure:

- Individuals will comply with SOP 105A and 105B, as applicable
- If a potential COI relating to an Individual is alleged, details supporting the rationale for the COI shall be reported to the Chair of the applicable Board and the Ethics Director (ED). The Chair and the ED will determine if a COI exists. The Secretariat on Responsible Conduct of Research may be consulted as necessary to determine COI. The Board Chair will determine what course of action is required to manage the COI. All decisions, the reasons for the decisions, and the COI management plans made or approved by the Board Chair regarding the allegation will be communicated to the applicable Individuals in a timely manner. A COI will be documented in the applicable Board meeting minutes.

RELATED DOCUMENTS

HREA SOP 105A: *Conflicts of Interest – Board Members and REO Personnel*

HREA SOP 105B: *Conflicts of Interest – Researchers*

Health Research Ethics Authority Act: An act to establish a health research ethics authority for the province. (2011). Retrieved from: [SNL2006 CHAPTER H-1.2 - HEALTH RESEARCH ETHICS AUTHORITY ACT \(assembly.nl.ca\)](https://www.legis.gov.on.ca/html/statutes/doc/2011/20110601.htm)

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans: [tcps2-2018-en-interactive-final.pdf \(ethics.gc.ca\)](https://www3.international.gc.ca/ethics/ethics2018-en-interactive-final.pdf)

Appendix A

Conflict of Interest Situations

A Conflict of Interest (COI) is the circumstance of a person or organization in a real, perceived or potential conflict between their duties or responsibilities related to research and their personal, institutional or other (secondary) interests. A COI may exist even if no unethical or improper act results from the conflict. A COI does not imply wrongdoing as a COI depends upon the circumstances and not on the character of an Individual.

A COI may arise in a variety of situations. A limited set of examples is provided below. This list is not exhaustive and should not be construed as a complete scope of possible COI situations or scenarios. An Individual who finds themselves in one of the following circumstances, or one that does not appear on this list, should consult with the applicable Board Chair and/or the Ethics Director, as applicable, to determine the nature of the real, potential or perceived COI.

Financial

A financial COI may arise if an Individual:

- Has a monetary interest directly or indirectly related to a research study;
- Has a personal or family member with a monetary interest either directly or indirectly related to the matter;
- Is an officer, employee or agent of a business or organization which has a monetary interest in the matter; or
- Declares any situation or circumstance that gives rise to a COI between the Individual's own personal, business or other interest or those of a relative, and the matter under discussion.

Use of Privileged or Confidential Information

A COI may arise if an Individual has access to privileged or confidential information that may create an unfair competitive advantage for the Individual or persons or institutions with whom the Individual has financial or business interests. A COI may arise if an Individual has access to knowledge of any forthcoming developments or research results that may influence equity interest in a sponsor/organization.

Examples of secondary interests for a Board member include situations in which the Board member:

- Is a Researcher or sub-researcher on the protocol;
- Is directly involved in the conduct of the research;
- Is in direct competition with the Researcher of the research project for limited resources, funding, sponsorship, or research participants; and/or
- Is considered a personal or professional adversary of the Researcher.

Examples of secondary interests for an Individual include situations in which:

- Their job status or compensation is impacted by the research (e.g., research coordinator, payment for speaking/leading study groups on behalf of the sponsor);
- They are receiving or expecting to receive compensation from the sponsor in which the value of the compensation could be affected by the outcome of the study;
- They act as an officer, director, or agent of the sponsor;
- They have a proprietary interest (e.g., patent, trademark, copyright interest, licensing agreement) in the tested product;
- They have any equity interest in the sponsor (i.e., any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices);
- Their spouse or dependent children have any equity interest in the sponsor;
- Significant payments of other sorts to an Individual, which are payments made by the sponsor exclusive of the costs of conducting the clinical research (e.g., a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria);
- They act as a consultant for the sponsor; and/or
- They have identified themselves for any other reason as having a conflicting interest.