



Section 800	Responsibilities of Researcher
Title	Conflicts of Interest – Researcher
SOP Code	802.001
Effective Date	December 14, 2018

Site Approvals

Signature of Responsible Individual:	
Research Services Officer	

1.0 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.

2.0 SCOPE

This SOP pertains to the SLC-REB and establishes its authority and jurisdiction to review human participant research conducted under the auspices of St. Lawrence College (SLC or College) and ensure compliance with applicable regulations and guidelines. The scope of SLC-REB's oversight is limited to those activities defined in the TCPS as "research" involving "human participants".

3.0 RESPONSIBILITIES

Research Services Office personnel 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 SLC-REB.

The SLC-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 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Conflicts of Interest (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 Conflict of Interest (COI) may exist even if no unethical or improper act results from the conflict.

Researchers and research staff should identify and manage COI to maintain the 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.

This SOP is not intended to prohibit researcher relationships with companies; however, the SLC-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.

SLC-REB should identify and manage COI to maintain the public confidence and trust and to maintain the independence and integrity of the ethics review. If a COI cannot be avoided, procedures should be in place to mitigate the conflict.



The SLC-REB should be perceived as fair and impartial, immune from pressure either by the sponsor, affiliated organizations or the researchers whose research is being reviewed, or by other professional and/or nonprofessional sources.

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.

5.1 Researcher Disclosure of Conflicts of Interest

- 5.1.1 Researchers submitting research applications to the SLC-REB are required to declare any COI including those of their sub/co-researcher(s), research staff, and their immediate families (which includes spouse, domestic partners and dependent children), and close relationships;
- 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 Such 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 SLC-REB at the following times:
 - With the initial SLC-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 cooperate with the SLC-REB and any St. Lawrence College official(s) involved in the review of the pertinent facts and circumstances regarding any COI disclosed, and shall comply with all the requirements of the SLC-REB and with any other St. Lawrence College COI policies to eliminate and/or to manage the conflict;



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

5.2 SLC-REB Review of Researcher Conflicts of Interest

5.2.1 The SLC-REB will review each application for disclosure of COI;

5.2.2 If the researcher indicates on the SLC-REB application that a conflict exists, the SLC-REB will determine whether the disclosed COI is likely to affect or appear to affect the design, conduct, or reporting of the research;

5.2.3 The SLC-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;

5.2.4 In determining the appropriate action, the SLC-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 their 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 SLC-REB may approve the research and may require a management plan, which may include changes at the researcher's or sponsor'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,
- In cases involving equity, by imposing a bar on insider trading or requiring the transfer of securities to an independent financial manager or blind trust, or by limiting the timing of sales or distributions,
- Monitoring research (i.e., independent review of data and other retrospective review for bias, objectivity, comprehensiveness of reporting (versus withholding data),
- Independent clinical review of appropriateness of clinical care given to research participants, if applicable,
- Monitoring the consent process, and/or
- Disclosure of the conflict to organizational committees, research participants, journals, and the data safety monitoring boards;

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

5.2.7 Any COI management plan will be documented in the final project files. Any discussions at the SLC-REB meeting regarding the COI and the management plan will be documented in the SLC-REB meeting minutes;

5.2.8 After review by the SLC-REB and input by the appropriate St. Lawrence College official(s), if applicable, the SLC-REB may reject research that involves a COI that cannot be appropriately managed.

6.0 REFERENCES

Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans; Tri-Agency Framework: Responsible Conduct of Research; SLC-Policy: Ethical Conduct of Research Involving Humans; SLC-Policy: Research Integrity.

7.0 REVISION HISTORY

SOP Title	Version	Updates
Conflicts of Interest - Researcher	v.802.001 December 14, 2018	Original: This SOP was developed based on previous SLC policies and the TCPS using the CAREB/N2 standardized REB SOP format.