Section 400	**Review of Research**
Title	**Initial Review – Criteria for SLC-REB Approval**
SOP Code	**404.001**
Effective Date	**June 13, 2018**

Site Approvals

Signature of Responsible Individual:	
Research Services Officer	Anthony Wright Digitally signed by Anthony Wright Date: 2018.06.13 13:34:10 -04'00'

1.0 PURPOSE

This standard operating procedure (SOP) describes the minimum requirements that research proposals involving human participants must meet in order to be approved by the SLC-REB, independent of the review pathway (i.e., full board or delegated review).

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 and ensure compliance with applicable regulations and guidelines. The scope of SLC-REB's oversight is limited to those activities defined in the TCPS2 (2014) as "research" involving "human participants".

3.0 RESPONSIBILITIES

The Research Services Officer is responsible for ensuring that the requirements of this SOP are met.

The SLC-REB Chair or designee is responsible for ensuring that a decision is made for every submission that is reviewed by the SLC-REB, that the decision is clearly

understood, and that the delegation of responsibility for considering any further information prior to issuing approval is clearly agreed.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

All research involving human participants must meet certain criteria before SLC-REB approval may be granted. Initial SLC-REB approval of the ethical acceptability of the research is based on assessment of a complete submission to the SLC-REB. The Research Services Officer may consult the researcher for additional information as necessary.

Following initial review of the research, the SLC-REB should be prepared to make a determination as to the ethical acceptability of the research.

In addition to SLC-REB approval, the requirements of the organization/institution where the research will be conducted must also be met before the research can begin (e.g., external REB approvals, department approvals, adequate resources, etc.).

5.1 Minimal Criteria for Approval of Research

In order for the research to receive SLC-REB approval, the SLC-REB will take the following into consideration:

5.1.1 The application has been signed by the researcher and, if applicable, by a designated organizational official, indicating that the researcher has the qualifications to conduct the research;

5.1.2 Any potential conflicts of interest are declared and are managed appropriately to prevent any compromises to the safety or well-being of the participants or to the integrity of the data;

5.1.3 There is a state of clinical equipoise when there is a comparison of two or more treatment arms;

5.1.4 The research will generate knowledge that could be generalized and lead to improvements in health or well-being;

5.1.5 The methodology is scientifically sound and capable of answering the research question;

5.1.6 The risks to participants are minimized by:

- Using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk, and
- By using procedures already being performed on the participants for diagnostic or treatment purposes whenever appropriate;

5.1.7 The risks to participants are reasonable in relation to the anticipated benefits, if any, and the importance of the knowledge that will be generated;

5.1.8 The selection of participants is equitable. In making this assessment, the SLC-REB will take into account the purpose of the research and the research setting. The SLC-REB will consider the scientific and ethical reasons for including/excluding vulnerable populations;

5.1.9 There are sound scientific and ethical reasons for excluding classes of persons who might benefit from the research;

5.1.10 When some or all of the participants, such as children, prisoners, the elderly, pregnant women, those with mental health issues, and those with diminished capacity for self-determination are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the research protocol;

5.1.11 When the researcher plans to remunerate, compensate or gift participants, the amount and method of payment to participants is appropriate to ensure that there is no coercion or undue influence and that information regarding

payment to participants including method, amounts and schedule is provided to participants when applicable;

5.1.12 Informed consent will be sought from each prospective participant or from the participant's legally authorized representative, in accordance with and to the extent required, by applicable regulations and the TCPS;

5.1.13 The informed consent form will accurately explain the research and contain the required elements of consent;

5.1.14 The informed consent process will be appropriately documented in accordance with the TCPS and regulations;

5.1.15 There will be provisions for on-going data and safety monitoring procedures that are appropriate to the size, complexity, phase, and level of risk of the research;

5.1.16 There will be adequate provisions to protect the privacy of participants and to maintain the confidentiality of data;

5.1.17 There will be adequate provisions for the timely publication and dissemination of the research results;

5.2 Additional Criteria

5.2.1 Studies proposing access to or collection of personal information require consideration of additional items to ensure the protection of the privacy of the personal information and to determine whether appropriate privacy legislation is adhered to;

5.2.2 If data linkage of meta-data is proposed, a description on how the data will be linked and how risks of identification of participants will be mitigated must be provided;

5.2.3 Additional criteria for research involving Indigenous peoples in Canada, or research on materials related to human reproduction, or genetic research, or

children, or prisoners, or pregnant women shall be applied when applicable in accordance with ethical guidelines or regulations;

5.2.4 Research Involving First Nations, Inuit or Metis participants the researcher shall provide an explanation of the process for engaging the relevant community and obtaining necessary approvals or provide details why community engagement will not be sought;

5.2.5 If Personal Health Information (PHI) is to be collected, a description of the potential sources should be provided, as well as explanations to:

- How the data will be used in the research?
- Will it be linked to other information?
- How will it be linked?
- Why the linkage is required?
- Who will have access to the PHI?
- What data security measures are in place to protect the PHI?

5.2.6 An explanation of why the research cannot be conducted without the PHI and any foreseeable harms and benefits that may arise from the use of the PHI, and a plan to address these issues.

5.3 Duration of SLC-REB Approval Period

5.3.1 The SLC-REB shall make the final determination as to the nature and frequency of continuing research ethics review in accordance with a proportionate approach to research ethics review. For research lasting longer than one year, researchers shall submit, at minimum, an annual report with sufficient details to enable the SLC-REB to make an informed judgement about the continued ethical acceptability of the ongoing research project;

5.3.2 The SLC-REB may require review more often than annually when there is a high degree of risk to participants;

5.3.3 The SLC-REB may consider reviewing the research more often than annually in light of new information during a renewal review that increases the initial assessment of risk.

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.

7.0 REVISION HISTORY

SOP Title	Version	Updates
Initial Review – Criteria for SLC-REB Approval	v.404.001 June 13, 2018	Original: This SOP was developed based on previous SLC policies and the TCPS using the CAREB/N2 standardized REB SOP format.