



Section 800	Responsibilities of Researchers
Title	Researcher Qualifications and Responsibilities
SOP Code	801.001
Effective Date	September 29, 2018

Site Approvals

Signature of Responsible Individual:	
Research Services Officer	

1.0 PURPOSE

This standard operating procedure (SOP) describes the qualifications and responsibilities of the researcher who engages in research involving human participants.

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

All Researchers, SLC-REB members, and Research Services Office personnel are responsible for ensuring that the requirements of this SOP are met.



4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Research involving human participants shall only be conducted by individuals appropriately qualified by education, training, and experience to assume responsibility for the proper conduct of the research and for the protection of human research participants.

Researchers are required to conduct the research in compliance with applicable regulations and guidelines, and to comply with all SLC policies and SLC-REB SOPs pertaining to research activities.

5.1 Researcher Qualifications

- 5.1.1 The researcher shall make available to the SLC-REB their current CV (if requested) and medical license number (if applicable) and their relevant training and experience, in sufficient detail for the SLC-REB to make an objective judgment regarding the researcher's qualifications, if necessary;
- 5.1.2 Where applicable, the researcher must be a physician with a specialty qualification in their field and with current professional qualifications entitling them to provide health care under the applicable laws;
- 5.1.3 The researcher shall have completed appropriate training regarding the requirements of conducting and overseeing research;
- 5.1.4 Where applicable, all specified organizational officials must approve the application to the SLC-REB;
- 5.1.5 The organizational approver's signature attests that:

- They are aware of the proposal and support its submission for SLC-REB review,
- The application is considered to be feasible and appropriate,
- Any internal requirements have been met,
- The researcher is qualified and has the experience and expertise to conduct this research,
- The researcher has sufficient space and resources to conduct this research;

5.1.6 Any concerns raised in the SLC-REB review of the researcher's qualifications will be communicated to the researcher and must be satisfied prior to SLC-REB approval of the application.

5.2 Researcher Responsibilities

5.2.1 The researcher is responsible for complying with the decisions and responsibilities set out by the SLC-REB and in accordance with SLC policies. In addition, it is the researcher's responsibility to comply with all applicable ethical guidelines, regulations, and ensure that (if applicable):

- The researcher and their staff members are appropriately qualified by education, training and experience to assume responsibility for the proper conduct of the research and for protection of human research participants,
- The researcher has adequate resources to properly conduct the research and conducts the research following written SOPs,
- All real, potential, or perceived conflicts of interest are declared to the SLC-REB at the time of the initial application, and as they arise,
- The SLC-REB review and approval is obtained before engaging in research involving human participants,



- All necessary documentation is signed by the responsible researcher, as applicable,
- Informed consent, when required, is obtained from participants in accordance with applicable regulations prior to their enrollment into the research, and using the most current informed consent document(s) approved by the SLC-REB (as applicable),
- The researcher personally conducts or supervises the described investigation(s),
- The research is conducted in compliance with the approved research. Where applicable, reports should be submitted to the SLC-REB, regarding deviations, serious, unexpected adverse events and privacy breaches,
- Any changes in the approved research are not initiated or implemented without SLC-REB review and approval, except where necessary to eliminate an immediate hazard(s) to the participant(s),
- Premature termination or suspension of the research is reported to the SLC-REB,
- Accurate and complete records are maintained according to applicable regulatory requirements,
- Written summaries of the research status are submitted to the SLC-REB at least annually, or more frequently if required by the SLC-REB, and an application for continuing review is submitted to the SLC-REB prior to the expiration of SLC-REB approval,
- Any other unexpected finding or new research knowledge that could affect the risk/benefit ratio of the research is reported to the SLC-REB,
- The SLC-REB is notified if there is a change in researcher,

- The SLC-REB is notified immediately if his/her medical or dental license or hospital privileges are suspended, restricted or revoked (if applicable) or should his/her qualifications otherwise no longer be appropriate,
- The SLC-REB is notified when the research is complete;

Note: (If applicable) the obligations of a researcher holding a Clinical Trial Application (CTA) with Health Canada (i.e., sponsor-Researcher) include both those of a sponsor and those of a researcher.

5.2.2 The sponsoring organization is responsible for maintaining current CVs and medical licenses (if appropriate) for each of its researchers. The sponsoring organization is responsible for immediately advising the SLC-REB should it become aware of any information that would indicate that the qualifications of the researcher may no longer be appropriate.

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
Researcher Qualifications and Responsibilities	v.801.001 September 29, 2018	Original: This SOP was developed based on previous SLC policies and the TCPS using the CAREB/N2 standardized REB SOP format.