



Section 400	Review of Research
Title	SLC-REB Approval Renewal
SOP Code	406.001
Effective Date	September 12, 2018

Site Approvals

Signature of Responsible Individual:	
Research Services Officer	

1.0 PURPOSE

This standard operating procedure (SOP) describes the procedures for the continuing review of research that is overseen by the SLC-REB, and the criteria for continued SLC-REB approval.

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

Research Services Office personnel are responsible for ensuring that the requirements of this SOP are met.



The SLC-REB Chair or designee and the assigned SLC-REB reviewer(s) are responsible for conducting an in-depth review of all submitted materials for their assigned research projects.

All other SLC-REB members are responsible for reviewing the submitted materials for each research application in enough depth to be prepared to discuss the research meaningfully at a full board meeting.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

The SLC-REB shall have established procedures for conducting the continuing review of approved research involving human participants at intervals appropriate to the degree of risk, but not more than once a year. Periodic review of research activities is necessary to determine whether approval should be continued or withdrawn.

5.1 SLC-REB Approval Renewal by the Full Board Review

5.1.1 The researcher is required to submit a SLC-REB Renewal Request Form for continuing review of research at a frequency to be determined by the SLC-REB and which will be defined at the time of the initial approval of the research, or as otherwise revised;

5.1.2 At a minimum, the SLC-REB requires that an application for continuing review be submitted once per year until all of the data has been collected, all contact with research participants has concluded and the closure of the research has been acknowledged by the SLC-REB;

5.1.3 The SLC-REB may determine that the research requires continuing review more frequently than once per year by considering the following:

- The nature of any risks posed by the research,
- The degree of uncertainty regarding the risks involved,
- The degree of vulnerability of the participant population,
- The projected rate of enrolment and estimated research closure date,
- Whether the research involves novel or interventions or emergent design,
- The SLC-REB believes that more frequent review is required;

5.1.4 The SLC-REB Renewal Request Form is due by the anniversary date of the original SLC-REB approval or by the submission deadline for the applicable SLC-REB meeting (i.e., the expiry date must be on or after the SLC-REB meeting date and prior to the date of the subsequent SLC-REB meeting);

5.1.5 To assist the researchers in submitting on time, a courtesy reminder(s) prior to the expiry date may be generated;

5.1.6 The Research Services Officer reviews the SLC-REB Renewal Request Form for completeness, and requests any clarifications, missing documents or other information from the researcher, as applicable;

5.1.7 The SLC-REB may request verification from sources other than the investigator that no material changes have occurred since previous SLC-REB review. For example:

- Based on the results of a previous audit or inspection (internal or external),
- Suspected non-compliance,
- Studies involving persons or groups that may be vulnerable due to their circumstances,



- Studies involving a potentially high risk to participants,
- Suspected or reported protocol deviations,
- Participant or research staff complaints,
- Any other situation that the SLC-REB deems appropriate;

5.1.8 The Research Services Officer will assign the research renewal request to the agenda of the next SLC-REB meeting if the research meets the criteria for full board review;

5.1.9 A summary report of the researcher's request for renewal assigned to the SLC-REB meeting may be attached to the SLC-REB meeting agenda;

5.1.10 For research that meets the criteria for full board review, the SLC-REB will discuss the research at a full board meeting and will make a decision regarding the continued approval of the research, as well as any other additional determinations regarding the conduct of the research, as applicable.

5.2 SLC-REB Approval Renewal by Delegated Review

5.2.1 When the research received initial approval via delegated review it may undergo delegated review at the time of continuing review;

5.2.2 Research that was previously reviewed by the full board may also be reviewed at the time of continuing review using delegated review procedures if the conditions are met;

5.2.3 The Research Services Officer reviews the SLC-REB Renewal Request Form for completeness, including verification of the currently approved informed consent form(s), and requests any clarifications, missing documents or other information as applicable;

5.2.4 The Research Services Officer will forward the application to the SLC-REB Chair or designee;



5.2.5 The SLC-REB Chair or designee may request additional information or clarification, as necessary, and will make a decision regarding the continued approval of the research and the continued conduct of the research;

5.2.6 Upon reviewing the SLC-REB Renewal Request Form that was sent for delegated review, if the SLC-REB Chair or designee determines that the risks are now greater than minimal, the SLC-REB Chair or designee will refer the application for review by the full board.

5.3 SLC-REB Approval Renewal Determinations

5.3.1 To grant a continuation of the approval of the research the SLC-REB must determine that:

- There have been no material changes to the research or to the informed consent form that have not been previously submitted and approved,
- There is no new conflict of interest or new information that has emerged that might adversely affect the safety or the well-being of research participants,
- Risks to research participants are mitigated and reasonable in relation to the anticipated benefits,
- Selection of research participants is equitable,
- Informed consent processes continue to be appropriate and documented,
- Adequate provisions are in place for monitoring and data protection to ensure the safety and privacy of participants and confidentiality and integrity of the data,



- Any complaints from research participants have been followed-up appropriately;

5.3.2 The SLC-REB may also make additional determinations, including:

- Request changes to the informed consent form(s),
- Request changes for the continuing review interval (based on risks),
- Impose special precautions (e.g., frequency of monitoring, the requirement for interim reports or duration of approval period),
- Require modifications to the research,
- Suspend or terminate SLC-REB approval.

5.4 Lapsed SLC-REB Approval

5.4.1 If a SLC-REB Renewal Request Form is not submitted by the anniversary date of SLC-REB approval, a warning or suspension notice will be issued to the researcher. When suspended, the researcher must stop all research activities until the suspension is lifted. The Research Services Officer will follow-up with the researcher to ensure that the application for continuing review is submitted as quickly as possible in order to lift the suspension;

5.4.2 In the event of a lapse in approval, the researcher is responsible for notifying the SLC-REB if there is a need to continue research-related medical treatment of current research participants for their safety and well-being. The researcher shall provide as much detail as possible about the proposed continued activities. The SLC-REB Chair or designee will review the request as quickly as possible and discuss the proposed continued activities with the researcher;



- 5.4.3 The researcher must document the reasons for the lapse and identify the steps taken to prevent future lapses;
- 5.4.4 If the SLC-REB approval lapses and the researcher wants to continue with the research, the SLC-REB will complete the review of the research as soon as possible and the researcher may resume the suspended activities once approval of the research has been issued. The lapse in approval will be documented as a non-compliance event.

5.5 Termination of SLC-REB Approval

- 5.5.1 If SLC-REB approval has lapsed and repeated attempts to contact the researcher have failed by the Research Services Office, the Research Services Officer shall inform the Chair of the SLC-REB, who will decide whether or not a full board review is required so that a decision can be made to terminate the approval and close the application file.
- 5.5.2 Research projects with lapsed SLC-REB approval that are designated "*Terminated*" by the SLC-REB shall be reported at full board meetings.

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
SLC-REB Approval Renewal	v.406.001 September 12, 2018	Original: This SOP was developed based on previous SLC policies and the TCPS using the CAREB/N2 standardized REB SOP format.