



Section 400	Review of Research
Title	Delegated Review
SOP Code	402.001
Effective Date	June 13, 2018

Site Approvals

Signature of Responsible Individual:	
Research Services Officer	

1.0 PURPOSE

This standard operating procedure (SOP) describes the processes for determining when research meets the criteria for delegated ethics review and the associated delegated review procedures.

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 is responsible for determining if research is eligible for delegated review. In some circumstances, the SLC-REB Chair or designee may



delegate this task to the Research Services Officer or qualified faculty; however, the responsibility for oversight remains with the SLC-REB Chair or designee.

The SLC-REB Chair or designee or qualified SLC-REB member(s) is responsible for conducting the delegated review.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

SLC-REB uses a proportionate approach to ethics assessment based on the general principle that the more invasive or harmful the proposed and ongoing research, the greater should be the care in assessing the research. Full board review by the SLC-REB is the default requirement for all research involving human participants unless the SLC-REB decides to authorize delegated review based primarily on the harms that are expected to arise from the research. While all research must be reviewed adequately, requirements for proportionate review allow the SLC-REB to provide a higher level of scrutiny, and correspondingly more protection, for the most ethically challenging research.

In practice, the proportionate review implies different levels of SLC-REB review for different research projects. The two levels used by the SLC-REB are full board review or delegated review by one or more experienced SLC-REB members, as determined by the SLC-REB Chair or designee.

5.1 Determination of Qualification for Delegated Review

5.1.1 Full board review is the default for most new research projects submitted to the SLC-REB; however, some research may be eligible for delegated review;



5.1.2 Submissions that meet the following criteria may be eligible for delegated review:

- Research projects that involve no more than minimal risk,
- Minor or minimal risk changes to approved research,
- Continuing review of approved minimal risk research,
- Continuing review of research that is more than minimal risk for which enrolment is closed permanently and all research-related interventions for all participants are complete and the only remaining research activities are post-intervention activities or follow-up of participants; or, where the remaining research activities are limited to data analysis; or, where no participants have been enrolled and no additional risks have been identified,
- Continuing review of research that is more than minimal risk when there has been little or no modification of the research; and when there has been no increase in risk to or other ethical implications for participants since the initial review by the full SLC-REB; if permissible under all applicable governing regulations,
- The submission by the researcher in response to the SLC-REB review as a condition of approval, as authorized by the SLC-REB,
- Changes to consent documents that do not affect the rights and welfare of research participants or involve increased risk, or affect data integrity, or require significant changes in research procedures,
- Reportable events, including adverse events and safety updates such as reports from Data and Safety Monitoring Boards (DSMB);

5.1.3 The SLC-REB Chair or designee may use delegated review procedures for the review of other types of minor changes including, but not limited to, the following:



- Participant materials such as: recruitment posters or scripts, diaries, validated questionnaires, clinical trial identification/wallet cards,
- Authorized translations of English versions of documents previously approved by the SLC-REB;

5.1.4 The SLC-REB Chair or designee may be authorized by the full board to use delegated review procedures for the review of miscellaneous items such as changes to meeting minutes that previously received approval with conditions at a full board meeting;

5.1.5 When determining if initial review of research or modifications to previously approved research are eligible for delegated review, the SLC-REB Chair or designee will take into consideration the methods used to conduct the research, recruitment practices, participant population, confidentiality of data, and all regulatory and ethics guidance requirements as applicable.

5.2 Delegated Review Process

5.2.1 The Research Services Officer will perform an initial screening of the submission. Those submissions that meet a pre-defined set of criteria for delegated review as determined by the SLC-REB may be forwarded for delegated review. For all other submissions, the SLC-REB Chair or designee will make the determination of whether the submission meets the criteria for delegated review;

5.2.2 For research that meets the criteria, delegated review may be conducted by the SLC-REB Chair, or by one or more qualified SLC-REB member(s);

5.2.3 The SLC-REB Chair or designee reviewing research under delegated review must not have a conflict of interest in the research;

5.2.4 In reviewing the research under delegated procedures, the SLC-REB Chair or designee may exercise all of the authorities of the SLC-REB, except that they



may not disapprove the research; the research may be disapproved only after it has been reviewed by the SLC-REB at a full board meeting;

- 5.2.5 SLC-REB member(s) conducting a delegated review will contact the SLC-REB Chair or designee to request the expertise of an ad hoc advisor, if applicable. Ad hoc advisors may not participate in the final decision regarding approval of the research;
- 5.2.6 If the SLC-REB Chair or designee subsequently determines that the level of risk for the submission is greater than minimal, the submission will be referred to a full board meeting for review;
- 5.2.7 The SLC-REB Chair or designee will record the decision regarding the designation of the research (i.e., either requiring full board or delegated review) and the outcome of the review. The responsible Research Services Office personnel may issue the review or decision letter.

5.3 Notification of the SLC-REB

At its next full board meeting, the SLC-REB will be informed of research that was reviewed and approved using delegated review procedures.

5.4 Documentation

- 5.4.1 The type of SLC-REB review conducted (i.e., full board or delegated) is documented in the SLC-REB records and noted in the decision letter issued to the researcher, where appropriate;
- 5.4.2 The SLC-REB meeting agendas and minutes will include a list of submissions that were reviewed and approved using delegated review procedures from the time that the agenda for the previous SLC-REB meeting was issued.

6.0 REFERENCES

Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans; Tri-Agency Framework: Responsible Conduct of Research (TCPS2, 2014); SLC-Policy: Ethical Conduct of Research Involving Humans (2017); SLC-Policy: Research Integrity (2017).

7.0 REVISION HISTORY

SOP Title	Version	Updates
Delegated Review	v.402.001 June 13, 2018	Original: This SOP was developed based on previous SLC policies and the TCPS using the CAREB/N2 standardized REB SOP format.