



<b>Section 400</b>	<b>Review of Research</b>
<b>Title</b>	<b>Suspension or Termination of SLC-REB Approval</b>
<b>SOP Code</b>	<b>408.001</b>
<b>Effective Date</b>	<b>September 21, 2018</b>

### Site Approvals

Signature of Responsible Individual:	
Research Services Officer	

## 1.0 PURPOSE

This standard operating procedure (SOP) describes the procedures associated with the suspension or termination of the SLC-REB approval of research (including the suspension or termination of 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 is responsible for determining whether any information received throughout the course of the research requires the suspension or termination of SLC-REB approval for the research being considered.

The researcher is responsible for notifying the SLC-REB and the organization of any suspensions or terminations of the research and for providing a detailed explanation for the action.

The SLC-REB Chair or designee is not authorized to terminate SLC-REB approval on active research projects; however, the SLC-REB Chair or designee is authorized to suspend SLC-REB approval, which must be reported to the SLC-REB at its next full board meeting. The SLC-REB is authorized to terminate SLC-REB approval following its review at a full board meeting.

The SLC-REB Chair or designee shall notify the researcher, and St. Lawrence College official(s), of any suspension or termination of SLC-REB approval of the research and has the authority to notify the regulatory authorities (as applicable) and the sponsor. The SLC-REB may delegate regulatory authority reporting.

Any research files closed by the Research Services Officer shall be documented as "Closed by RSO" and reported to the full board.

#### **4.0 DEFINITIONS**

See Glossary of Terms.

#### **5.0 PROCEDURE**

As a result of ongoing review activities, the SLC-REB may require that research be modified, suspended or terminated if the risks to the research participants are determined to be unreasonably high. For example, cases in which there are high



numbers of unexpected serious adverse events, or when there is evidence that the researcher is not conducting the research in compliance with applicable regulations and guidelines. The SLC-REB also has the authority to suspend new enrollment and ongoing research activity (if cessation of research activity does not pose a greater risk to participants) while additional information is requested.

A decision to suspend or to terminate the SLC-REB's approval of the research must include consideration of the safety, rights and well-being of the participants already enrolled in the research. Specifically, when considering the continued care of enrolled participants, and how and when the notification to participants of the suspension or termination of the research will take place.

The SLC-REB has the authority to suspend or to terminate the SLC-REB's approval of the research.

The SLC-REB Chair or designee has the authority to suspend ethics approval.

Any requests to lift a suspension or to re-approve the research shall be reviewed by the SLC-REB Chair or designee and may require being reviewed by the full board.

A researcher may decide to voluntarily suspend or terminate some or all research activities; however, this is not considered a suspension or termination of SLC-REB approval.

## **5.1 Suspension or Terminations of Research by the Sponsor**

- 5.1.1 The sponsor of the research may suspend or terminate the research (e.g., following results of interim analyses, due to inadequate drug availability, in response to a Data and Safety Monitoring Board (DSMB) recommendation, due to pre-planned stopping criteria, etc.);



- 5.1.2 The researcher must immediately notify the SLC-REB of any suspensions or terminations of the research and the reasons for the action;
- 5.1.3 Reports of suspensions or terminations of the research by the sponsor will be forwarded to the SLC-REB Chair or designee for review;
- 5.1.4 If the SLC-REB Chair or designee decides to suspend SLC-REB approval of the research, they must notify the SLC-REB at its next full board meeting;
- 5.1.5 If SLC-REB approval is suspended, a subsequent review must be conducted and the SLC-REB suspension must be lifted prior to resumption of the research following the sponsor's lifting of a suspension.

## **5.2 Suspension or Termination of SLC-REB Approval**

- 5.2.1 If any concerns are raised during the SLC-REB's oversight of the research that are related to new information or to the conduct of the research, the SLC-REB may suspend or terminate its approval of the research as appropriate.

These concerns may include:

- The research not being conducted in accordance with the SLC-REB-approved protocol or SLC-REB requirements,
- The research is associated with unexpected serious harm to participants (i.e., as may be determined following SLC-REB review of reportable events or DSMB reports),
- Falsification of research records or data,
- Failure to comply with prior conditions imposed by the SLC-REB (i.e., under a suspension or approval with modifications),
- Repeated or deliberate failure to properly obtain or document consent from research participants,

- Repeated or deliberate failure to limit administration of the investigational drug or device to those research participants under the researcher's supervision,
- Repeated or deliberate failure to comply with conditions placed on the research by the SLC-REB, by the sponsor, or by regulatory agencies,
- Repeated or deliberate failure to obtain prior SLC-REB review and approval of amendments or modifications to the research, or
- Repeated or deliberate failure to maintain accurate research records or submit required reportable event reports to the SLC-REB;

5.2.2 The SLC-REB Chair or designee is authorized to suspend SLC-REB approval of research. If the SLC-REB Chair or designee suspends approval of the research, they must notify the SLC-REB as per applicable requirements;

5.2.3 The SLC-REB is authorized to terminate its approval of the research following a review at a full board meeting;

5.2.4 Prior to suspending or terminating SLC-REB approval, the SLC-REB must consider:

- Risks to current participants,
- Actions to protect the safety, rights and well-being of currently enrolled participants,
- The appropriate care and monitoring of research participants,
- Whether withdrawal of enrolled participants is warranted and the specific procedures for their safe withdrawal,
- Whether participants should be informed of the termination or suspension,
- Whether adverse events or outcomes should be reported to the SLC-REB,



- Identification of a time frame in which the corrective measures are to be implemented;
- 5.2.5 The SLC-REB Chair or designee will notify the researcher of any suspensions or terminations of SLC-REB approval, and the reasons for the decision;
- 5.2.6 Unless otherwise stated by the SLC-REB, when the SLC-REB Chair or designee suspends or terminates ethics approval of the research, no further activities can take place other than the submission of an amendment or reportable events;
- 5.2.7 If the research is suspended or terminated, the SLC-REB Chair or designee will issue a formal letter to the researcher with the reason(s) for the SLC-REB action and the corrective measures proposed by the SLC-REB;
- 5.2.8 If SLC-REB approval of a research or if the conduct of the research has been suspended, the suspension may be lifted after corrective actions are completed to the SLC-REB's satisfaction.

### **5.3 Reporting Suspensions or Terminations**

The SLC-REB Chair or designee will report any suspension or termination of SLC-REB approval to the appropriate St. Lawrence College official(s) and has the authority to notify the regulatory authorities (as applicable), and the sponsor. The SLC-REB may delegate regulatory authority reporting.

## **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
Suspension of Termination of SLC-REB Approval	v.408.001 September 21, 2018	Original: This SOP was developed based on previous SLC policies and the TCPS using the CAREB/N2 standardized REB SOP format.