Section 400	**Review of Research**
Title	**Ongoing SLC-REB Review Activities**
SOP Code	**405.001**
Effective Date	**September 12, 2018**

Site Approvals

Signature of Responsible Individual:	
Research Services Officer	Anthony Wright Digitally signed by Anthony Wright Date: 2018.09.12 09:27:05 -04'00'

1.0 PURPOSE

This standard operating procedure (SOP) describes the procedures for the ongoing review activities that occur after the initial SLC-REB approval of a research project and prior to the formally scheduled renewal of the research project.

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 and researchers are responsible for ensuring that the requirements of this SOP are met.

The researcher is responsible for reporting to the SLC-REB any new information generated throughout the course of the research that might affect the rights, safety and

well-being of research participants, including reportable events that meet the reporting criteria as per this SOP.

The researcher is responsible for reporting to the SLC-REB any information about the conduct of the research that could affect the rights, safety and well-being of research participants, including information about any serious or continuing non-compliance.

When action is taken to ensure the protection of the rights, safety, and well-being of participants (e.g., for an unanticipated problem involving risks to participants or others), the SLC-REB Chair or designee is responsible for reporting to the researcher and to the appropriate St. Lawrence College official(s). The SLC-REB Chair or designee has the authority to notify the sponsor and/or the appropriate regulatory authorities of any events that meet the reporting criteria. The SLC-REB Chair or designee may delegate regulatory authority reporting (as applicable) to St. Lawrence College official(s).

The SLC-REB Chair or designee is responsible for reviewing all reportable events submitted to the SLC-REB as well as any proposed amendments to the research, and for determining the type of review (i.e., delegated or full board) or action required.

The SLC-REB members are responsible for reviewing and for recommending the appropriate course of action for any new information, reportable events or proposed amendments that are assigned to them or that are assigned to a full board meeting.

4.0 DEFINITIONS

Adverse Event: Any untoward experience associated with participation in a research project (e.g., a participant gets hurt, a privacy or confidentiality breach, a participant's complaint about the research project).

Serious Adverse Event (SAE): An Adverse Event or suspected adverse reaction is considered "serious" if, in the view of the investigator or the sponsor, it results in any of the following outcomes: death; a life-threatening adverse event; inpatient hospitalization or prolongation of existing hospitalization; a persistent or significant incapacity or

substantial disruption of the ability to conduct normal life functions; or a congenital anomaly/birth defect.

Unanticipated Issues: Issues that occur during the conduct of research; may increase the level of risk to participants or have other ethical implications that may affect participants' welfare; and were not anticipated by the researcher in the research proposal submitted for research ethics review.

5.0 PROCEDURE

It may be that the real risk/benefit ratio can be evaluated only after the research has begun; therefore, in addition to the formally scheduled continuing review, the SLC-REB must receive and review any new information generated throughout the course of the research that might affect the rights, safety and well-being of research participants. Such information may include:

- Modifications or changes to the previously approved research,
- Reports of unanticipated problems involving risks to participants or others,
- Reports of any serious or continuing non-compliance,
- Reports of any changes significantly affecting the conduct of the research or increasing the risk to research participants,
- Results of any interim analysis or Data and Safety Monitoring Board (DSMB) assessments,
- Deviations to the previously approved research,
- Adverse events that meet the reporting criteria,
- Reports of any privacy breaches,
- Summary reports of any audits and inspections,
- Any other new information that may affect adversely the safety of the research participants or the conduct of the research,

Modifications to the approved research may not be initiated without prior SLC-REB review and approval except where necessary to eliminate apparent immediate hazards to human participants. If changes are made to eliminate immediate hazards, the researcher must notify the SLC-REB immediately.

5.1 Amendments to the Approved Research

5.1.1 The researcher is responsible for submitting to the SLC-REB any changes to the approved research in the form of an amendment;

5.1.2 Changes to the approved research include modifications, such as: modifications to the research, to the consent form, changes in participant materials (e.g., wallet cards, diary cards, recruitment materials), changes in the research team, etc.;

5.1.3 When the amendment includes a change to the consent form, the researcher must indicate their recommendation for the provision of the new information to current and/or past research participants;

5.1.4 The researcher may indicate the type of review being requested (i.e., full board, delegated review or acknowledgement for a minor correction). Supporting correspondence documentation and/or background information may be appended to the amendment submission;

5.1.5 The SLC-REB Chair or designee reviews the amendment to determine the appropriate level of SLC-REB review required (i.e., full board or delegated review);

5.1.6 The SLC-REB Chair or designee also may use delegated review procedures for review of amendments when conditions are met for delegated review;

5.1.7 If the proposed change represents more than minimal risk, it shall be reviewed by the SLC-REB at a full board meeting;

5.1.8 Amendments that may be classified as more than minimal risk may include:

- Addition of genetic testing, new genetic tests, or tissue banking where genetic testing may or will be performed,
- Addition of an open label extension phase following a randomized trial,
- Emergency amendments that arise because of participant safety and may include, but are not limited to:
  - A change in drug dosing/duration of exposure,
  - A change in recruitment that may affect confidentiality or the perception of coercion,
  - A change in experimental procedure or research population;

5.1.9 For amendments requiring full board review, the Research Services Officer assigns the amendment to the next available full board meeting. For amendments that meet the criteria for delegated review, the Research Services Officer will forward the amendment to the SLC-REB Chair or designee;

5.1.10 When an amendment involves a revised consent, the SLC-REB will consider the recommendations of the researcher in determining if, how, and when the new information should be provided to the research participants and whether further consent is required;

5.1.11 The SLC-REB must find that the criteria for approval are still met in order to approve the amendment;

5.1.12 The amended research may not be implemented prior to the SLC-REB review and approval, except when necessary to eliminate immediate hazards to participants.

5.2 Adverse Events

SLC researchers must report all adverse events (which includes serious and unanticipated issues) to the SLC- REB within the appropriate time for the type of event. External researchers must report to the SLC-REB all adverse events that

involve St. Lawrence College faculty, staff, or students, unanticipated issues, and external unanticipated serious adverse events ~~the following to the SLC-REB~~ within the appropriate time:

- Any adverse event that in the opinion of the researcher meets the definition of an adverse event or unanticipated issue must be reported to the SLC-REB no later than **14 days** after the researcher becomes aware of the issue,
- Serious Adverse Events (SAE) must be reported within **7 days** after the researcher becomes aware of the issue,
- Serious Adverse Events **involving death** must be reported with **48 hours** of the researcher becoming aware of the issue,
- If applicable, the completed sponsor's unexpected SAE form must be appended to the reportable event form,
- All reports submitted to the SLC-REB must have all research participant identifiers removed (i.e., participant research number only),
- The sponsor's unexpected SAE report (if applicable) must be signed by the researcher or medical designee,
- Once an adverse event or unanticipated issue is acknowledged by the SLC-REB, subsequent important follow-up reports related to the adverse event should be submitted when available. If applicable, the sponsor's follow-up reporting form(s) signed by the researcher or medical designee must be appended to the updated reportable event. All initial and subsequent follow-up reports will be retained with the reportable event.

5.3 Reporting Adverse Events

Researchers must report all adverse events (including serious and unanticipated issues) to the SLC-REB within the appropriate time for the type of event:

- The report submitted to the SLC-REB must include **all** of the following information:
  - The description of the adverse event(s),
  - All previous safety reports concerning similar adverse events,
  - An analysis of the significance of the current adverse event(s) in light of the previous reports, and
  - The proposed research changes, informed consent form changes or other corrective actions to be taken by the researcher or sponsor in response to the event(s),
  - If applicable, actions taken to notify participants for safety reasons;

5.4 Other Reportable Events

The researcher is responsible for reporting to the SLC-REB other events or findings, such as:

- Any new information (e.g., sponsor's safety notice or action letter) that would cause the sponsor to modify the Investigator's Brochure, the research or the consent form, or would prompt other action by the SLC-REB to ensure protection of research participants,
- Any changes to the risks or potential benefits of the research, such as:
  - An interim analysis indicates that participants have a lower rate of response to treatment than initially expected,
  - Safety monitoring indicates that a particular side effect is more severe, or more frequent than initially expected,
  - Information is published from another research project that shows that an arm of the research is of no therapeutic value,
- A change in Health Canada or FDA safety labeling or withdrawal from marketing of a drug, device, health product, genetic therapy or biologic used in research,

- The researcher is also responsible for submitting to the SLC-REB other types of reportable events, such as:
  - DSMB reports,
  - Interim analysis results,
  - Any unanticipated problems or other events that could significantly impact the overall conduct of the research or alter the SLC-REB's approval or favorable opinion to continue the research,
- A change to the research that was initiated without prior SLC-REB review to eliminate an apparent immediate hazard to a research participant,
- Any unanticipated problems or other events that could significantly impact the conduct of the research at the site (e.g., concerns of non-compliance),
- Other reportable events must be submitted to the SLC-REB within a time frame specified by the SLC-REB;

5.5 Deviations to Previously Approved Research

The researcher must report to the SLC-REB any deviations that meet the following reporting criteria:

- Deviations that in the opinion of the researcher jeopardize the safety of research participants, or that jeopardize the research efficacy or data integrity,
- Any sponsor-approved waivers to the participant eligibility criteria,
- Any change in the approved process for obtaining consent (e.g., improper translation, current ICF not implemented),
- Any deviations that lead to an SAE,

- Deviations must be reported within a time-frame specified by the SLC-REB; deviations that lead to an SAE should be reported within a time-frame specified by the SLC-REB;

5.6 Privacy Breaches

The researcher must report to the SLC-REB any unauthorized collection, use, or disclosure of personal information including, but not limited to:

- The collection, use and disclosure of personal information that is not in compliance with the jurisdictional legislation or its regulation,
- Circumstances where personal information is stolen, lost or subject to unauthorized use or disclosure or where records of personal information are subjected to unauthorized copying, modifications or disposal,
- In the researcher context, any unauthorized collection, use or disclosure of personal information that was not authorized under the research and approved in the plan that was submitted to the SLC-REB,

The breach shall be reported to the SLC-REB and, if applicable, to the appropriate St. Lawrence College official(s) as soon as the researcher becomes aware of the breach;

5.7 Audit or Inspection Findings

The researcher shall report to the SLC-REB a summary of any relevant audit or inspection findings following a Health Canada inspection, an FDA or other regulatory audit, an internal QA audit or other audits at the site.

5.8 Research Participant Complaint

The researcher shall report to the SLC-REB, any complaint from a participant when the participant reports concerns about their rights as a research participant or about ethical issues related to the research.

5.9 Review of Reportable Events by the SLC-REB

5.9.1 The Research Services Officer will screen the reportable event submission for completeness;

5.9.2 Privacy breaches are reviewed by the SLC-REB Chair or designee, and any recommendations including remedial action are determined in consultation with St. Lawrence College's Privacy Office. The privacy breach report is forwarded to the SLC-REB Chair or designee for review and final acknowledgement;

5.9.3 The Research Services Officer may route the submission back to the researcher to request clarifications, missing documents or additional information;

5.9.4 The Research Services Officer will forward the submission to the designated SLC-REB reviewer(s);

5.9.5 The assigned SLC-REB reviewer(s) will conduct a review of the report and determine if any action or follow-up is required;

5.9.6 The assigned reviewer(s) may request further information from the researcher;

5.9.7 When reviewing a reportable event, the SLC-REB should:

- Assess the appropriateness of any proposed corrective or preventative measures by the sponsor and/or researcher,
- Consider any additional appropriate measures that may or may not have been identified or proposed by the sponsor and/or researcher,

- Consider whether the affected research still satisfies the requirements for SLC-REB approval; in particular whether risks to research participants are still minimized and reasonable in relation to the anticipated benefits, if any, to the research participants and the importance of the knowledge that may reasonably be expected to result,
- Consider whether some or all of the research participants should be notified of the events (i.e., if it may affect the participant's willingness to continue participation in the research), and
- Consider whether suspension or termination of the ethics approval of the research is warranted;

5.9.8 If the event does not raise concerns and does not appear to involve risks to research participants or others, the SLC-REB Chair or designee acknowledges the report, and no further action is required;

5.9.9 If the SLC-REB Chair or designee determines that the event meets the criteria for an unanticipated problem, and if immediate action is required to protect the safety of research participants, they may suspend ethics approval of the research pending review by the full board, providing the justification for such action is documented;

5.9.10 If the event raises concerns or involves risk to research participants such that SLC-REB action may be required, the item is added to the agenda of the next full board meeting;

5.9.11 For reportable events reviewed at a full board meeting, the SLC-REB determines whether further action is required. Possible actions that could be taken by the SLC-REB include, but are not limited to:

- Placing a hold on the research pending receipt of further information from the researcher,

- Requesting modifications to the research,
- Requesting modifications to the consent form,
- Providing additional information to past participants,
- Notifying current participants when such information might affect the participants willingness to continue to take part in the research, and requiring that current participants re-consent for ongoing participation,
- Altering the frequency of continuing review,
- Observing the research or the consent process,
- Requiring additional training of the researcher and research staff,
- Termination or suspension of the research,
- If the SLC-REB determines that the event does not raise concerns about risks to research participants, the SLC-REB may decide that no further action needs to be taken;

5.9.12 When action is taken to ensure the protection of the rights, safety, and wellbeing of participants (e.g., for an unanticipated problem involving risks to participants or others) the SLC-REB chair or designee is responsible for reporting to the researcher and the St. Lawrence College official(s), and has the authority to notify the sponsor and the appropriate regulatory authorities (as applicable). The SLC-REB Chair or designee may delegate regulatory authority reporting (as applicable) to St. Lawrence College official(s).

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
Ongoing SLC-REB Review Activities	v.405.001 September 12, 2018	Original: This SOP was developed based on previous SLC policies and the TCPS using the CAREB/N2 standardized REB SOP format.