



Section 300:	SLC-REB Functions and Operations
Title:	Document Retention, Access, Archiving, and Destruction
SOP Code:	303.001
Effective Date:	May 18, 2018

Site Approvals

Signature of Responsible Individual:	
Research Services Officer	

1.0 PURPOSE

This standard operating procedure (SOP) describes the SLC-REB submission requirements, administrative review procedures, and document management, including document security, retention and archiving. This SOP applies to documents submitted to the SLC-REB for initial and continuing review, SLC-REB administrative documents, as well as to all research related documents controlled by researchers (faculty and students) at SLC.

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

The SLC-REB Chair or designee, the Research Services Office personnel, and researchers are responsible for ensuring that the requirements of this SOP are met.



4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

The researcher is responsible for knowing the data retention requirement for their research project and for ensuring the secure, long-term, storage of their research data during the collection and retention cycle.

The Research Services Office shall retain all relevant records (e.g., documents reviewed and approved or disapproved, SLC-REB meeting minutes, correspondence with Researchers, written SOPs, SLC-REB membership rosters) to provide a complete history of all actions related to the SLC-REB review and approval of submitted research. Such records shall be retained for the length of time required by applicable regulations and guidelines.

Relevant records will be made accessible to authorized regulatory authorities, representatives of the organizations, researchers and funding agencies within a reasonable time upon request.

5.1 Researcher Responsibilities

- 5.1.1 Research data shall be stored according to the sensitivity and level of confidentiality assured by the researcher and associated with the data. For example, at minimum, data should be stored in a secure location, such as a locked filing cabinet in a locked office. For identifiable data stored on mobile devices (e.g., computers, external hard drives, phones, and recording devices), the mobile device should be password protected and the files encrypted. Personal identifiable information security should be in accordance with Federal and Provincial regulations and best practices.



5.1.2 Researchers are required to take appropriate steps to protect their participants' privacy and confidentiality throughout the life of the research data retention, including following proper destruction procedures deemed appropriate for the sensitivity of their data. See the [Office of the Privacy Commissioner of Canada, Personal Information Retention and Disposal: Principles and Best Practices \(2014\)](#).

5.2 Student Course-Based Research Projects

5.2.1 Student course-based research is recognized as a student research activity, whereby:

- the research is conducted for training or student assessment purposes,
- the project activities pose no greater than minimal risk to participants,
- the data collected is anonymous (i.e., there is little or no risk of participants being identified), and
- there is no possibility of disseminating the research results outside of SLC.

5.2.2 Copies of student course-based research project data and final reports shall be retained by both the student and the course instructor for at least one month after submission of the students' final grade in the course, after which time it can be destroyed.

5.3 Research Services Office Research File Retention

5.3.1 The Research Services Office retains the submission materials for all research submitted to the SLC-REB for review and approval;

5.3.2 Research-related documents include, but are not limited to, the following (as applicable):

- Signed SLC-REB initial application,



- Associated attachments (e.g., Informed Consent Form, research tools, recruitment scripts, external REB approvals),
- Correspondence between the SLC-REB and the researcher, including SLC-REB approval letters, requests for modifications, etc.,
- Records of ongoing review activities, such as,
 - Reportable event submissions, including reports of significant new findings, Data and Safety Monitoring Board (DSMB) reports, interim analysis reports, local unanticipated adverse events and non-local (external) unanticipated adverse events, research protocol deviations, privacy or confidentiality breaches, any investigations into allegations of serious or continuing non-compliance, and reports of inspections and audits by regulatory agencies or others,
 - Modifications to the application including amendments to the research and/or any changes to the consent form(s), participant materials or Investigator Brochures,
- Continuing review forms,
- Copies of correspondence between the SLC-REB and regulatory agencies, and
- Reports of any complaints received by the SLC-REB and their resolution.

5.4 SLC-REB Administrative Document Retention

5.4.1 The Research Services Office retains all administrative records related to the SLC-REB;

5.4.2 SLC-REB administrative records include, but are not limited to, the following:

- Agendas and minutes of all SLC-REB meetings;
- Submitted SLC-REB member reviews;



- SLC-REB member records:
 - Current and obsolete SLC-REB membership rosters, including alternate SLC-REB members,
 - CVs and training/qualification documentation of current and past SLC-REB members;
- Signed conflict of interest and confidentiality agreements;
- Current and obsolete SOPs;
- Current and obsolete documentation of the SLC-REB Chair or designee's delegation of authority, responsibilities, or specific functions;

5.4.3 Access to individual research projects and related documents, is role-based to ensure that users only have access to documents and activities that are required by their role;

5.4.4 The SLC-REB records are stored in a physically secure, onsite location with back-up, disaster and recovery systems in place;

5.4.5 The SLC-REB will retain required records (e.g., research-related or SLC-REB administrative documents, as applicable) for a minimum of 7 years after completion/termination of the trial, or for the maximum amount of time stipulated in any applicable governing regulation(s) (e.g., 25 years for Health Canada regulated research);

5.4.6 When the data retention period is expired, the Research Services Office will shred hard copies and erase digital copies in its archives.

5.5 Research Services Office Privacy and Confidentiality

5.5.1 All submissions received by the SLC-REB are considered private and confidential and are normally accessible only to the researcher, SLC-REB members (including the SLC-REB Chair and designee), as well as the Research Services Office personnel;



- 5.5.2 Relevant research project information and associated documents may be made accessible to others outside of the identified research team on record, if the researcher or their research team submits a request for guest access to the research project information;
- 5.5.3 Relevant research project information and associated documents may be made accessible to St. Lawrence College official(s), members of regulatory agencies, and representatives of the sponsor for audit, investigations into ethical conduct, or where there is a legal duty. Access is restricted to the applicable research and the research-related submissions;

6.0 REFERENCES

[Office of the Privacy Commissioner of Canada, Personal Information Retention and Disposal: Principles and Best Practices \(2014\)](#)

7.0 REVISION HISTORY

SOP Title	Version	Updates
Document Retention, Access, Archiving, and Destruction	v.303.001 – May 18, 2018	Original: This SOP was developed based on information from the TCPS2 (2014) and St. Lawrence College previous documents or policies (using the format of CAREB/N2).