

St. Lawrence College Research Ethics Board
(SLC-REB):

**Review Process for Research Involving
Human Participants**



St. Lawrence
College

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1. Projects Requiring Review

Research requiring ethical review extends far beyond medical or pharmaceutical experimentation or testing. In fact, there are very few situations in which one can use someone else's information without an ethical review.

If the research involves any of the following situations, the researcher is required to submit an application to the SLC-REB:

- Any research proposal, funded or not, that involves human participants
- Is conducted by St. Lawrence College faculty, staff or students;
- Is conducted on the premises of the College;
- Is conducted with or involves the use of facilities or equipment belonging to the College;
- Is conducted as part of an applied research project
- Involves College students, staff or faculty, parents/guardians, alumni, clients, partners or any individuals external to the college in any jurisdiction (local, national, international)
- Is conducted by College students for courses or theses;
- Is conducted by College staff to satisfy requirements for external courses or theses (may also require review by external REB);
- Satisfies a requirement by the College for a certificate, diploma or Applied Degree program or for completion of course of study;
- Is certified by an Associate Vice-President or department Chair to satisfy an obligation of a faculty appointment at the College, or
- Is conducted by or under the direction of any employee or agent of the College in connection with his or her institutional responsibilities.

Research involving human remains, cadavers, tissues, biological fluids, embryos or fetuses, or records from human participants (chart review; use of data for new purposes) also requires ethics review by the SLC-REB before any research is conducted.

This policy applies regardless of whether:

- The research is funded or not;
- The research is to be published or not;
- A similar project has been approved elsewhere or not;
- The research is a pilot study or a fully developed project;
- The research is primarily for teaching or training purposes or whether the primary purpose is the acquisition of knowledge.

2. Projects Not Requiring Review

Without limiting the generality of the foregoing, the following specific areas are identified by the TCPS as being exempt from ethics review and approval by a Research Ethics Board:

- Research about a living individual involved in the public arena, or an artist, that is based entirely on publicly available information, documents, records, works, performances, or archival materials. Such research **requires** review when it is based in part or in whole on third party interviews, or if the participant is approached directly for interviews or for access to private papers.
- Data collected for program or college decision making and which will not be reported in any form as “research” (e.g. program review, faculty, student and course evaluations).
- Curriculum projects that undergraduate students engage in but do not disseminate as “research” – do not require a REB review but must be approved by the faculty or department.
- Quality assurance studies, performance reviews or testing within normal educational requirements. Performance reviews or studies that contain an element of research may need ethics review.

3. Levels of REB Review

There are two levels of review: full board review and delegated review. Projects that meet the standard for minimal risk can undergo delegated review. All other studies undergo a full board review. In addition, thesis projects in the BAA for Behavioural Psychology are reviewed by a delegated subcommittee of the SLC-REB called the Research Ethics Committee – Psychology (REC-P).

Minimal risk is defined in the [TCPS2 \(2014\), Chapter 2, Section B](#) as : “research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.” Above the threshold of minimal risk, the research warrants a higher degree of scrutiny and greater provision for the protection of the interests of prospective participants. There is a similar threshold regarding undue or excessive offers of benefit.

- In order to facilitate research, levels of “proportionate review” have been established and are carried out by the SLC-REB in keeping with that standard.

Full board and delegated reviews are conducted based on an initial assessment of potential harm as it relates to minimal risk. These levels are as follows:

i. Full Board Review

A full board review is the default review process and is required if the proposed research project poses greater than minimal risk to participants. A full board review is undertaken by the SLC-REB members at a monthly meeting and details involve:

- In depth review of the application, population at risk and methodology and procedures as they relate to contact/storage/dissemination of research;
- May be commissioned at the decision of the chair;
- All members participate (quorum must be met);
- Applicant may present case but not be present at decision time.

The SLC-REB meets monthly and makes every effort to accommodate the needs of any individual conducting research through St. Lawrence College.

Applications in which **ANY** of the following are identified will require a full board review:

a) Consent Reasons

- Undue influence: The participant is a member of a vulnerable group or is ill and the project involves the use of a treatment.
- Inability to consent: The participant is cognitively impaired or is a child.
- Deception: The true purpose of the project will not be revealed to the participants for scientific reasons.

b) Methodologic Reasons

- Random assignment: The project involves random assignment to treatment and control (treatment as usual) groups.

c) Risk of Harm Reasons

- Invasive procedures: This project involves testing a new drug, surgical technique or other invasive procedure.
- Minor adverse effects (A): The project involves collecting information that might be embarrassing or uncomfortable for participants.
- Minor adverse effects (B): There is a reasonable belief that the project may cause minor adverse effects for participants.
- Lack of anonymity: Individually identifiable information will be used.
- Data linking: Individually identifiable information will be used to link several databases together in order to gather more complete information.
- Electronic recording: Audio or video taping without the participant's knowledge.

ii. Delegated Review

Some applications are eligible for a delegated review. An eligible application generally involves the coordinated efforts of the Chair and one other member, which may mean a review can be conducted between full meetings of the SLC-REB. ***A request for a delegated review may be referred to a full board review if any member of the board suggests changes to the application, or identifies the application contains any of the above criteria requiring full board review.***

Applications considered for a delegated review must meet one of the following conditions:

- The proposed project does not present more than minimal risk to participants
- Current approval status through another REB
- Continuation or resumption of previously approved research study

Applicants requesting a delegated review will submit their application to the Research Ethics Officer who will forward to the SLC-REB. If the SLC-REB Chair and one other member concur the application meets the criteria for a delegated review, these two members will review and determine whether approval is granted. A delegated review will ONLY be conducted if the project consists of research that is of low ethical concern and minimal risk based on the principles set out in the Tri-Council Policy Statement.

All delegated reviews will be brought to the SLC-REB at the next scheduled meeting for information and, if necessary, discussion.

iii. Research Ethics Committee- Psychology Review (REC-P)

As the SLC-REB meets on a monthly basis and it is not always feasible for all undergraduate proposals to be reviewed in such a short timeframe, it was determined that a Research Ethics Committee - Psychology would facilitate a timely ethics review process. The REC-P was created to facilitate the review and manage the volume of applications received. All applications and reviews are reported to the SLC-REB. This is a common practice among academic institutions. Review procedures and timelines will be given to the students early

in the Fall semester. For more information, consult the [Guidelines for Research Ethics for Behavioural Psychology Thesis Projects](#)

Students of the Bachelor's Degree program in Behavioural Psychology conducting Research with Humans should send their protocols for review to the Research Ethics Committee - Psychology. The REC-P has been delegated the authority by the SLC-REB to review minimal risk research, especially final year thesis research, by students in the Bachelor's Degree program in Behavioural Psychology. The B.A.A. program in Behavioural Psychology relies heavily on agencies' support for field placements, upon which thesis projects are frequently based. The process of obtaining ethics approval should not interfere with the student's ability to perform typical placement activities, so it is essential that students receive timely ethics approval for their projects. In addition, it is possible that students may need to revise their project during placement due to circumstances beyond their control and due to the nature of the human services field.

Contact: Professor [Marie-Line Jobin](#) - Bachelor's Degree program in Behavioural Psychology, Applied Thesis Coordinator and REC-P Chair, for additional information.

SLC-REB Research Ethics Approval Process

SLC-REB Research Ethics Approval is not meant to hinder the research process. In most cases, the application will assist you in planning your research effectively, and once approved, you can be assured the research methodology is both ethical and scientifically sound.

The Research Department will provide consultation and coaching through all stages of the application process. Please contact the *Research Ethics Officer, Jeremy Butler, at reb@sl.on.ca* as soon as you have an idea for a research project.

i. Assessing Need for REB Ethical Review

As noted above, most situations that involve asking others to provide "primary" or personal information will require a review. Exemptions include standard quality assurance (eg., satisfaction surveys) or performance assessment (employee or student evaluation).

However, in those cases where the surveys or assessments will be used to present statistics or publish information externally, ***a review may be required.***

Err on the side of caution. At the end of this document are some FAQ/Scenarios that may help clarify situations that will or will not require review. Consult these pages and the [Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans](#) to help or contact the SLC-REB Research Ethics Officer.

ii. Completing the Application

The application form must be completed IN FULL. In those sections that do not apply to your research project, please enter N/A. To assist you, the form is interactive, and will indicate with “highlighting” where responses are required.

Again, the Research Department is available to help you through the process and recommends you contact them once you’ve reviewed the form.

iii. Submitting Applications

Applications are received by the Research Ethics Officer. An electronic copy or a hard copy with the required signatures must be received by the application deadline. Electronic copies should be e-mailed to Jeremy Butler, reb@sl.on.ca.

The REB meets monthly. The deadline for applications is TWO weeks before the meeting. Delegated reviews will be accommodated when eligible for that process, but please note if an application does NOT meet the criteria for a delegated review it will be held for the next meeting. Even a delegated review may have to wait to the next full board meeting depending on the availability of the Chair and other members.

iv. Process of Approval

The SLC-REB will endeavour to confirm a decision for each application reviewed during regular meetings of the Board as soon as possible following the decision. Decisions may be

deferred if there is no quorum, or the Board wishes to have the applicant present the application. There are four possible decisions rendered:

a) Approved

You will be notified of the decision electronically following the meeting, and you may commence your project. An official SLC-REB Approval Letter for the project will be issued by the Research Services Office electronically for your files.

b) Approval with Recommendations

You will be notified of the decision electronically following the meeting, but research may not begin. Issues within the application will be identified by the SLC-REB and detailed instructions for the revision will be given in an official letter via e-mail. Once the researcher has modified the application, it must be resubmitted to the Research Services Office. The revisions will be verified by the Research Ethics Officer. If the revisions are complete, they will be approved by the Chair of the REB. The Research Services Office will then issue a SLC-REB Approval letter and recruitment of participants can commence.

c) Pending Approval

The application presents significant concerns that require a full resubmission. The project cannot proceed. In keeping with the SLC-REB Policy: Ethical Research Involving Humans and the Tri-Council Policy Statement (TCPS2, 2014), feedback is provided to the applicant outlining the areas of concerns. These may include clarity of purpose, importance of research, relevance of proposed contact methodologies, etc. The applicant is encouraged to revise the application and resubmit for review at the next SLC-REB meeting. The researcher may also choose to request a meeting with the SLC-REB.

d) Not Approved

The research project cannot proceed. This decision is generally only rendered when a Pending application cannot mitigate risk effectively, or proposes risks greater than the proposed benefits of the investigation.

e) Appeals

An appeal in writing may be submitted to:

Cam McEachern
Director, Research
St. Lawrence College
100 Portsmouth Ave
Kingston, Ontario K7L 5A6
(613) 544-5400 x1586

***An independent REB will review an appeal in as timely a manner as is reasonably possible.

v. Amendments

During the course of research, a researcher may encounter situations that will alter their project's goals or objectives. It is the responsibility of the researcher to notify the REB if circumstances require the researcher to amend, or change, the approved application.

While certain aspects of the proposed project may change outside of the researcher's control, you must notify the REB of any amendments that affect the population to be contacted or the nature of the contact. This may require an additional review (which generally meets the criteria for an expedited review and will be convened as soon as possible).

Example 1:

The researcher estimated there would be 100 students in the BBA program to participate in a particular survey. Only 20 respondents were available. This represents a "change" from

the original application, but **does not require a resubmission**. The researcher may address the number of respondents and its impact on the hypothesis, but is not relevant to the REB.

Example 2:

During the course of a project, the researcher realized that the proposed (and approved) questions for a survey were not providing relevant data to the research question. The questions would need to be changed. Changing questions or interview methods (anonymous survey to focus group), **do require a resubmission**.

For Assistance, please contact:

Jeremy Butler, Research Ethics Officer
reb@sl.on.ca

vi. Termination of Project

Upon completion of the project, a Termination of Project Form is to be submitted to the Research Services Office. A copy of this form is included with your SLC-REB approval, and is also available online through the SLC-REB's website.

SLC-REB approvals are valid for one year. It is expected researchers will have completed data collection within this period. For projects continuing to require SLC-REB approval, the Termination of Project form should be used to request an extension.

Quick Notes:

We're here to help!

The Applied Research Department can assist you with:

- Guidelines for writing a consent form (and samples!)
- Guidelines for developing telephone surveys
- Guidelines for developing questionnaires
- Research and assist in preparing external grant applications
- Secure partners for collaboration
- Provide project management services
- Assist you through SLC-REB process

Contact Jeremy Butler, Research Ethics Officer, at reb@sl.on.ca.

Filing your REB Application

The SLC-REB meets monthly, usually on the 3rd Friday of every month. The deadline for an application submission to appear on the REB Agenda is announced (2 weeks) prior to the meeting date.

Email reb@sl.on.ca.

Definitions

What is Research?

SLC College recognizes that using definitions to classify projects as research can be problematic because there are no universal definitions of the terms research, quality improvement, or program evaluation. However, a number of organizations, agencies and governing bodies or associations have developed definitions which are informative and useful and which have been adopted by this college.

The following summary outlines these definitions to help researchers and REB members decide whether or not a project is research and would therefore require ethics review by the REB:

Research: An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation (TCPS2, 2014).

Applied Research: Original investigation, undertaken to acquire new knowledge, or to apply existing knowledge in a novel way, directed primarily towards a specific practical aim or objective. Ideas are developed into operational form to produce new products, devices, processes, systems, and services or to improve substantially those already produced or installed (CCITAL, Applied Research Policy, 2007).

Quality Assurance: Systematic monitoring and evaluation of the various aspects of a project, service, or facility to ensure that standards of quality are being met (Interagency Advisory Panel on Research Ethics, 2004).

Quality assurance is based on established standards and systematic measurement and evaluation against those standards. In academics, this includes measurement against SLC College's standards for curriculum documentation and delivery, paying particular attention to ongoing feedback of stakeholders (SLC College Strategic Plan, 2005-2010).

Performance Evaluations: Studies related directly to assessing the performance of an organization or its employees or students, within the mandate of the organization or according

to the terms and conditions of employment or training (Interagency Advisory Panel on Research Ethics, 2004).

Amendment: Projects that extend beyond the original application in terms of population to be contacted, questions or procedures to be administered, or perception of risk are considered “amended”, and these amendments must be submitted to the SLC-REB for review.

Minimal Risk: An assessment of risk is based on the probability that the participant will not encounter any harm greater than expected in their everyday life. The reality and perception of “risk” must also be considered. For example, students participating in a research project conducted by their instructor may feel pressured to participate. This represents more than minimal risk and measures to prevent the perception of risk are required.

Please note that these definitions are only a guideline. If you are still unsure about whether the project you wish to undertake is research, you are encouraged to contact the Research Ethics Officer or SLC-REB Chair for further clarification. It is the responsibility of the principal investigator to ensure that an appropriate decision has been reached with the Chair of the SLC-REB in regard to the requirement for SLC-REB Research Ethics Approval. Failure to do so would be a violation of SLC policy. Research projects that are found to have been undertaken before receiving SLC-REB approval may be suspended.

Does My Project Require a Review?

Criteria for Referral to Full REB Review

Consent Reasons

- Undue influence: The participant is a member of a vulnerable group or is ill and the project involves the use of a treatment.
- Inability to consent: The participant is cognitively impaired or is a child.
- Deception: The true purpose of the project will not be revealed to the participants for scientific reasons.

Methodologic Reasons

- Random Assignment: The project involves random assignment to treatment and control (treatment as usual) groups; potential for risk is not the same for all participants.

Risk of Harm Reasons

- Invasive Procedures: This project involves testing a new drug, surgical technique or other invasive procedures.
- Minor adverse effects (A): The project involves collecting information that might be embarrassing or uncomfortable for participants.
- Minor adverse effects (B): There is a reasonable belief that the project may cause minor adverse effects for participants.
- Lack of anonymity: Individually identifiable information

Determining if your project is “research”

Questions to ask when determining whether a project requires SLC-REB Research Ethics

Approval:

If the answer to either of these questions is “yes”, it is likely that the project is defined as research and will require SLC-REB review.

- Is the primary aim of the project to produce new knowledge, to expand existing knowledge or theory, or to apply existing knowledge in a novel way?
- Is there an expectation to share or disseminate results or findings within a professional community through publications or presentations or at conferences?

If the answer to any of these questions is “yes”, it is likely that the project is defined as quality assurance or performance evaluation and therefore does not require review by the REB.

- Is the goal of the project to monitor or improve service delivery or program quality as measured by established standards?
- Is the intent of the project to assess performance of an organization or its employees according to terms and conditions of employment?

Other things to consider

- Intent to publish does not by itself determine the primary purpose of a project.
- Some performance reviews or quality assurance studies do contain an element of research in addition to assessment. These projects do require SLC-REB review.
- Some projects that are not categorized as research and therefore do not require review by the REB do present ethical issues. Individuals administering these projects must ensure that ethical standards are maintained. The SLC-REB guidelines and TCPS documentation may suggest ethical considerations or options for the project administrator to consider even though the SLC-REB has no direct responsibility for these projects.
- The intent of some projects changes over time. If the original intent of a project is QA or program evaluation and this changes to research, the project will need to undergo ethics review, even if underway.