

St. Lawrence College

Policy on Ethical Research Involving Humans

Preamble

St. Lawrence College (SLC) endorses the principles set out in the Tri-Council Policy Statement "Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 1998 (with 2000, 2002 updates)" found at URL:

<http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>

The College's policy is intended to ensure that the highest ethical standards in the conduct of research involving human participants are maintained at SLC in compliance with the Tri-Council Policy Statement.

Research involving human participants is premised on a fundamental moral commitment to advancing human welfare, knowledge, and understanding, and to examining cultural dynamics. Researchers, the institutions they work for and funding agencies undertake or fund research involving human subjects for many reasons, for example: to alleviate human suffering, to validate social or scientific theories, to dispel ignorance, to analyze policy, and to understand human behaviour and the evolving human condition.

Research involving human subjects imparts at least three general categories of benefits:

- The basic desire for new knowledge and understanding;
- The quest to advance knowledge that may benefit research participants, such as improved treatments for illnesses, the discovery of information affecting their welfare, the identification of historical, written, oral or cultural traditions, or the satisfaction of making a contribution to society through research; or
- The need for information that will benefit particular groups and/or society as a whole, such as insights into political behaviours that may produce better policy, information about the incidence of disease that may improve public health, sociological data about lifestyles that may lead to social reform, or findings that illuminate past and present realities.

SLC believes that the cardinal principle of modern research ethics is respect for human dignity.

Accordingly the College has developed this policy to protect the multiple and interdependent interests of the person. Respect for human dignity entails high ethical obligations towards persons whose diminished competence and/or decision-making capacities make them vulnerable. Children, institutionalized persons, or others who are vulnerable are entitled, on grounds of human dignity, caring, solidarity, and fairness, to special protection against abuse, exploitation or discrimination.

Justice connotes fairness and equity. Procedural justice requires that the ethics review process have fair methods, standards, and procedures for reviewing research protocols, and that the process be effectively independent. Justice also concerns the distribution of benefits and burdens of research. Distributive justice means that no segment of the population should be burdened unfairly with the harms of research. It thus imposes particular obligations toward individuals who are vulnerable and unable to protect their own interests in order to ensure that they are not exploited for the advancement of knowledge. Distributive justice also imposes duties to neither neglect nor discriminate against individuals and groups who may benefit from advances in research.

This policy requires that all research projects involving human participants undertaken by members of the College community - consisting of all faculty, staff and students, including students carrying out research as part of class assignments - fall within the jurisdiction of the SLC Research Ethics Board, irrespective of the source of financial support (if any) and irrespective of the location of the project. Research from the outside community that accesses resources or participants at SLC is also required to undergo review. Review is also necessary for human remains, cadavers, tissues, biological fluids, etc., taken in routine situations but which are later used for educational or research purposes.

Research involving naturalistic observation of participants in, for example, political rallies, demonstrations or public meetings would not require review if it can be expected that the participants are seeking public visibility.

1. The SLC Research Ethics Board for Review of Research Involving Human Participants

The Research Ethics Board for Review of Research Involving Human Participants (REB) is a standing committee of the college; board members shall be appointed by the President on the advice of the Vice-President Academic and shall report to the Vice-President Academic.

1.1 Responsibilities

- a. developing policies regarding ethical issues relating to the use of human participants in research and teaching projects;
- b. reviewing for ethical approval all projects requiring the use of human participants;
- c. reviewing annually all policies regarding ethical issues relating to the use of human participants in research projects to ensure that policies remain current;
- d. dealing with matters concerned with human-based research referred to the REB by the Vice-President Academic of SLC;
- e. preparing an annual report for submission to the Applied Research Advisory Committee;
- f. participating in continuing education organized by SLC research administrators for the College community in matters relating to research ethics and the use of human participants in research.

1.2 Composition

The REB shall be made up of no less than 6 members plus a non-voting secretary, including both men and women, and shall include at least:

- a. One community representative with no formal affiliation with the College.
- b. Four College members in different disciplines with broad expertise in the methods or in areas of research covered by the REB (research involving human participants or the use of human tissue).
- c. One College or external member with broad knowledge in ethics or experience in the evaluation of ethical implications of research involving human participants.
- d. The REB will have access to a legal expert (other than the College's legal counsel) knowledgeable in the applicable law.
- e. The REB shall require a quorum of at least two thirds of its members at all meetings concerned with the ethical approval of research proposals, including the members in categories 1.2 a), b) and c) above.
- f. The Chair will be elected by the Committee, normally for two years.
- g. REB members shall serve for three-year terms that normally may be renewed once. Initially, appointments shall range from two to four years to allow for continuity of membership when members are being changed.

- h. The REB membership shall be the responsibility of the Vice-President Academic who shall seek advice from the Deans and the Applied Research Advisory Committee prior to making appointments to the REB. Members will be selected in accordance with the Tri-Council Policy and, whenever possible, at least one REB member shall be from staff or the local community of each of the three St. Lawrence campuses.

1.3 Meetings and Decision-Making

The REB shall meet on a regular basis (frequency to be at least once every two months) to review all proposals requiring human participants. All research receiving ethical approval through the expedited review process (See 2.6) will be reported to the REB by the Chair. Research not delegated to expedited review will be reviewed at the meeting, and the decision to grant ethical approval will be based on a consensus of the REB whenever possible. If a consensus is not reached and the vote is therefore not unanimous, the position of those disagreeing will be included in the communication to the researcher. In the event of a tie vote, the matter under consideration will be considered not passed.

An annual schedule of REB meetings for the forthcoming academic year will be published each June.

1.4 Authority

The College endorses the ethical principles cited in the "Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 1998 (with 2000, 2002 updates)" and has mandated its REB on Research Involving Human Participants to ensure that all research investigations involving human participants are in compliance with the Statement.

The SLC REB will have jurisdiction over all research involving human participants as well as over all course-based research or assignments that require students to collect information from human participants. All SLC research involving human participants including that of visiting and part-time researchers, will proceed only after ethical approval has been granted by the REB. In addition to approving research, the Committee can reject, propose modifications to or terminate any proposed or on-going research.

2. Procedural Guidelines for the Review of a Research Protocol

2.1 Submission

Investigators who contemplate the use of humans as research participants may obtain informational material and application forms from the Research Services Office acting on behalf of the Vice-President Academic. Each application submitted must be signed by the Principal Investigator and by the relevant Dean. Visiting researchers should contact the Research Services Office well in advance of the anticipated start date of research.

2.2 Ethics Review

The effective working of ethics review - across the range of disciplines conducting research involving human participants - requires a reasonable flexibility in the implementation of common principles. This policy, therefore, seeks to express the shared principles and wisdom of researchers in diverse fields. The following standards and procedures will be used by the REB for ethics review:

- a. All SLC research that involves living human participants requires prior review and approval by the REB in accordance with this policy, before the research is started, except as stipulated below.

- b. Research involving human remains, cadavers, tissues, biological fluids, embryos or foetuses should also be reviewed by the REB. Review by the REB is also necessary for such materials taken in routine situations but which are later used for educational or research purposes.
- c. Research about an individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interviews, is not required to undergo ethics review. Such research only requires ethics review if any participant is approached directly for interviews or for access to private papers, and then only to ensure that such approaches are conducted according to professional protocols.
- d. Quality assurance studies, performance reviews or testing within normal educational requirements are not subject to review.

Certain types of research, particularly in the social sciences and the humanities, may legitimately have a negative effect on public figures in politics, business, labour, the arts or other walks of life, or on organizations. Such research should not be blocked through the use of harms/benefits analysis or because of the potentially negative nature of the findings. The safeguard for those in the public arena is through public debate and discourse and, in extremis, through action in the courts for libel.

Naturalist observation is used to study behavior in a natural environment. Because knowledge of the research can be expected to influence behavior, naturalistic observation generally implies that the human participants do not know that they are being observed, and hence can not have given their free and informed consent. Due to the need for respect for privacy, even in public places, naturalistic observation raises concerns of the privacy and dignity of those being observed. These concerns are accentuated if, for example, the research records permit identification of the human participants, or if the research environment is staged.

In considering research involving naturalistic observation, researchers and the REB should pay close attention to the ethical implications of such factors as: the nature of the activities to be observed; the environment in which the activities are to be observed (in particular, whether it is to be staged for the purposes of the research); and the means of recording the observations (in particular, if the records will allow subsequent identification of the human participants). Naturalistic observation that does not allow for the identification of the human participants, and that is not staged, should normally be regarded as of minimal risk.

2.3 Scholarly Review

In the case of research proposals that present more than minimal risk, the design of the project must be peer reviewed to assure that it is capable of addressing the question(s) being asked in the research. The requirement for appropriate scholarly review will have been met under the following circumstances:

- a. Successful approval by the REB (if research is in the REB's field of expertise).
- b. Successful funding of a grant proposal by a funding agency that uses peer review in its granting process.
- c. Ad hoc independent external peer review reporting directly to the REB.

2.4.1 Principle of Proportionate Review

The REB will use a proportionate approach based on the general principle that the more invasive the research, the greater should be the care in assessing the research.

2.4.2 Expedited Review

Expedited review does not require face-to-face meetings of the REB members. It is usually completed within two weeks of submission of a completed application form. The Chair must report requests for expedited review and results of such reviews to other members of the REB at an appropriate time.

The researcher must choose to apply for expedited or full review and the REB Chair may reject any application for expedited review and refer it to the REB for full review. Expedited review is carried out by the Chair of the REB and one other member of the REB. It is to be implemented only in cases that fulfill one of the following criteria:

- a. research which obviously involves no more than minimal risk (as defined in the Tri-Council Policy Statement, viz : “if potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research, then the research can be regarded as within the range of minimal risk”). Given the heterogeneous nature of subjects, a “reasonable person’s” definition of “minimal risk” as is often employed in the courts concerning subjective harms will also be acceptable to the REB (see Boatright, 1997, p327, for a more extensive description of the “reasonable-person standard”). The researcher is responsible for making the case for minimal risk to the REB.
- b. research projects which have already received approval by the SLC REB, have complied fully with any requirements, have an up to date file, and the applicant is simply renewing the ethical approval certificate without significant changes to the ongoing research process.

2.5 Normal Review Process

The REB shall normally meet face to face in order to review submitted research proposals. In cases of controversial research proposals, the REB may meet face to face with researchers in order to consider the ethical solutions proposed by researchers for problems arising in their studies. The REB shall accommodate reasonable requests from researchers to participate in discussions about their proposals, but the researcher shall not be present when the REB is making its decision. Minutes will be kept for these meetings by a staff member from the Office of the Vice President, Academic, and inserted into the appropriate case files. The minutes must clearly document the Committee’s decisions and be accessible to authorized representatives of the College, researchers and funding agencies.

The REB shall keep an “open file” in a secure place in the Research Services Office for researchers applying for ethical approval. The file shall be opened by the Chair when sufficient information has been submitted by the researcher to start the review process. The original application, descriptions of research and methodology, correspondence, relevant documents, ethical certificates, revised materials, and any comments from the public or other information relevant to the research project shall be kept in the file. It is the responsibility of the researcher to address all the recommendations made by the REB and keep the file complete and up to date at all times. When the research project is finished, and the researcher(s) notifies the Research Services Office and the SLC REB, these files shall be “closed” and kept as records demonstrating compliance with the Tri-Council Policy. The files remain the property of SLC and cannot be removed from the Research Services Office by the researchers. These files shall be subject to audit by authorized representatives of SLC (research administrators), members of Appeal Boards, and funding agencies.

All research receiving ethical approval, whether through the normal or expedited process, as well as that receiving departmental level review shall require a proper file showing compliance with the

Tri-Council Policy Statement. Insufficient information in the file is grounds for refusing or delaying approval.

2.6 Research as a Component of Academic Courses

If human participants are involved in a teaching exercise (i.e., part of a student course and/or project), the activity may receive expedited review or may be reviewed by the REB or by a committee with delegated authority. Any committee established under delegated authority shall report the results of their ethics review to the REB for information and record-keeping purposes.

2.7 Continuing Ethics Review

Ongoing research shall be subject to continuing ethics review. The Chair of the REB must be promptly notified of any substantial change to the research plan or research protocol. Researchers will be asked to include monitoring mechanisms by which the public participating in the research may contact the Chair of the REB. Researchers may be asked to modify their studies in view of any problems that may have arisen during the study. More stringent monitoring mechanisms may be put in place depending on the level of risk involved in research projects.

Ethics certificates are issued for one year. If the project continues after one year the researcher must submit a completed "Annual Renewal and Amendment Form" to the REB. If no substantial change has been made to the research plan or research protocol, the Chair of the REB may issue a one-year extension. If in the opinion of the REB Chair, the research plan or research protocol has been substantially changed, resubmission and review by the REB is required.

The REB shall be promptly notified by the researcher when the project concludes.

2.8 Complaints

Complaints about the ethical propriety of ongoing research involving human participants will be considered by the REB. Should the REB conclude that a significant infringement of College policies or guidelines related to research involving human participants has occurred, the Principal Investigator will be notified and College support for the project, whether internal or involving an external funding agency, may be withdrawn. The Principal Investigator has the right to appeal such a decision to the Academic Council whose decision shall be final.

2.9 REB Conflict of Interest

If an REB is reviewing research in which a member of the REB has a personal interest in the research under review (e.g., as a researcher, supervisor or as an entrepreneur), conflict of interest principles require that the member not be present when the REB is discussing or making its decision. In cases of disagreement over conflicts of interest, both the REB member in alleged conflict and the researcher may present evidence and offer a rebuttal concerning the nature of the conflict of interest. The other members of the REB should make a final decision regarding how to proceed.

2.10 Review of Multi-Centred Research

The REB shall review all SLC research proposals involving human participants regardless of the location where the research is conducted. In multi-centred research, the researcher may wish to distinguish between core elements of the research (which cannot be altered without invalidating the pooling of data from the participating institutions) and those elements that can be altered to comply with local requirements without invalidating the research project.

2.11 Review of Research in Other Jurisdictions or Countries

Research by SLC researchers to be performed outside of the jurisdiction of SLC or outside of Canada shall undergo ethics review both by the SLC REB and the REB, where such exist, with the legal responsibility and equivalent ethical and procedural safeguards in the country or jurisdiction where the research is to be done.

3. Decisions of the REB on Research Involving Human Participants

3.1 Reconsideration

Researchers have the right to request, and the REB has an obligation to provide, reconsideration of decisions affecting a research project. When the REB is considering a negative decision, it shall provide the researcher with all the reasons for the decision and give the researcher an opportunity to reply before making a final decision.

SLC may not override REB decisions reached on grounds of ethics without a formal appeal mechanism.

3.2 Appeal

Researchers must apply to the Vice-President Academic to appeal a negative REB decision within two months of the date of the decision. A copy of the appeal letter should also be sent to the REB Chair. SLC shall use a duly constituted REB from another Ontario College of Applied Arts and Technology as its Appeal Board. Noncompliance with the substance of the Tri-Council Policy Statement is a reason for refusing to grant an appeal. Appeals may be granted only on procedural grounds or when there is a significant disagreement over an interpretation of the Tri-Council Policy Statement. The decision of the Appeal REB shall be final.

4. Report of the REB on Research Involving Human Participants

Certificates of Ethical Approval, signed by the Chair of the SLC REB will be issued to the Principal Investigator(s) and copies sent to the Vice-President Academic.

Any decisions by the Chair to approve minor amendments without full committee review will be reported to the committee at the next scheduled meeting.

An annual activity report from the REB will be made to the Applied Research Advisory Committee which will in turn bring the report to the Academic Council for consideration.

5. Administration

5.1 Administrative Support

The work involved in the ethical review process should be distributed appropriately among faculty members, staff, researchers, and administrators.

The Office of the Vice-President Academic will rely on the Research Services Office in providing administrative support to the REB including:

- a. Distribution of forms and materials necessary for submission of research proposals to the REB
- b. Collection of submissions and distribution of applications to REB members
- c. Keeping minutes of REB meetings
- d. storing submissions and related materials in a secure location
- e. Supporting the REB in its educational activities
- f. Acting as the point of contact for the Secretariat on Research Ethics (CIHR, NSERC and SSHRC), and for Health Canada

- g. Other duties related to the support of the REB in carrying out its mandate.

Deans will provide support to the REB, with respect to:

- a. educational activities
- b. ensuring that researchers requiring ethical review are submitting their projects to the REB
- c. advising their faculty members about the need to comply with the Tri-Council Policy Statement.

Individual Schools are expected to support and train students so that student research projects are ethical, and may be efficiently reviewed by the REB. Schools should establish a mechanism to screen student applications for ethical review prior to submission to the REB. The REB may return applications to the school if they do not conform to the requirements of the Tri-Council Policy. It is advisable that curriculum committees consider incorporating training in the ethical review process into the academic programs where it is needed.

5.2 College Support

SLC shall provide adequate resources and an annual budget to support the administrative processes and educational activities required by the REB so that the College as a whole remains in compliance with Tri-Council policy.

5.3 Sanctions

The Vice-President Academic shall have the sanction of refusing permission to open a research account or to access College controlled funds for researchers who do not comply with this policy.

The REB will report to the Vice-President Academic any cases that undermine SLC's compliance with the Tri-Council Policy and the President shall decide what sanctions or penalties to impose on the researcher(s) while respecting the collective agreement.

6. Acknowledgment

This policy is modeled after and includes much of the text of the Research Ethics Policy of the University of Ontario Institute of Technology.

7. Reference Cited

Boatright, J. Ethics and the Conduct of Business. 2nd ed. Prentice Hall, 1997, p329.