

Policy and Procedures for the Ethics of Human Research at Laurentian University

The Tri-Council Policy Statement on "Ethical Conduct for Research Involving Humans" (see <http://www.sshrc.ca/english/programinfo/policies/ethics.htm>) establishes the procedures and standards for the ethics review of research involving human subjects. To be eligible for Council funds, Laurentian University and its Federated Colleges must certify compliance with the policy statement. **All researchers collecting data with human subjects¹ should become familiar with this policy.**

This document is meant to provide Laurentian University with Policy and Procedures under which research which involves human participants is to be conducted at the University and its Federated Colleges, in conformity with the *Tri-Council Policy Statement*. This document is a reflection of the state of research with human participants at the University at this particular time, and is subject to revision as that research is expanded, for instance into more biomedical and health-related fields, or in cooperation with the Aboriginal Community.

Definitions

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Human Subject means a living individual about whom an investigator conducting research obtains

- 1) Data through intervention or interaction with the individual, or
- 2) Identifiable private information.

Adverse Events are those occurrences during the course of a research project where a subject or another person has been subject to risk or harm. An adverse event may require a change in the research procedures to minimize the risk of reoccurrence of the event. **Adverse events must be brought to the attention of the REB immediately.**

Non-compliance means continuing disregard for the stipulations of the REB or a Departmental REB or the initiation of research procedures without the approval by the appropriate Board. **Non-compliance must be brought to the attention of the REB immediately.**

Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life.

¹ The Policy also applies to research with human remains, cadavers, tissues, biological fluids, embryos or foetuses, in conformity with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, August, 1998, 1.1. (Henceforth *Tri-Council Policy Statement*.)

Principles²

- Respect for Human Dignity
- Respect for Free and Informed Consent (Tri-Council Policy Statement: Section 2)
- Respect for Vulnerable Persons
- Respect for Privacy and Confidentiality (Tri-Council Policy Statement: Section 3)
- Respect for Justice and Inclusiveness (Tri-Council Policy Statement: Section 5)
- Balancing Harms and Benefits
 - Minimizing Harm
 - Maximizing Benefit

Research Requiring Review

All research that involves living human subjects requires review and approval by the appropriate Research Ethics Board (REB) in accordance with the Tri-Council Policy Statement, **before the research is started**. This includes research funded by grants, contracts and contributions, unfunded faculty research, graduate and undergraduate research and staff research. Research involving human remains, cadavers, tissues, biological fluids, embryos or foetuses must also be reviewed by the REB.

The only exceptions to this review process by the REB are:

- 1) Research about a living individual in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, or archival materials. Such research requires ethics review only if the subject and/or third parties are approached directly for interviews or for access to private papers, and then only to ensure that such approaches are conducted according to professional protocols and to Article 2.3 (Naturalistic Observation) of the Tri-Council Policy.
- 2) Quality assurance studies, performance reviews or testing within normal educational requirements.

For all funded projects (internal or external), ethics approval must be obtained before funds are released.

The Laurentian University Research Ethics Board

The Research Ethics Board (REB) is a Committee operating in both official languages, which reviews research applications and considers matters of policy related to research with human subjects. According to the Tri-Council Policy Statement on Research with Human Subjects, the REB must review all relevant research conducted by faculty, staff and graduate students. The University REB delegates the review of minimal risk research that is carried out by undergraduate students as part of their course work to **Departmental Research Ethics Boards**.³

² *Tri-Council Policy Statement, A. Context of a Research Ethics Framework, C, p5-6.*

³ For Departmental REB composition and guidelines, see page 8.

Composition

The University REB is composed of **one member from each** of the Departments/Schools whose faculty are heavily involved in research with human subjects. At present these are:

School of Commerce
School of Human Kinetics
School of Nursing
Department of Psychology
School of Social Work
Department of Sociology.

Those Departments whose faculty and students engage in research with human subjects on a less intensive basis, will have two representatives in total on the University REB at any time. See the section on Departmental Committees for further information.

In addition, the REB also includes a person with legal knowledge, an ethicist, and at least one community representative. A Native Human Services or Native Studies representative is also a member of the REB and is to help the REB to develop an appropriate policy regarding research with Native Communities.

The Director of Graduate Studies and Research is an Ex Officio member of the University REB.

The REB membership should represent the scientific, social scientific and humanities research disciplines, as well as knowledge of various aspects of the ethics of research with human subjects. The REB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that on the REB ⁴

Members of the Board are appointed for a set term (3 years, with the option of renewal) by the Vice-Presidents Academic, on the recommendation of the Director of Graduate Studies and Research.

The Board will elect a Chair each year.

Review of Proposals

Proportionate Review Process

Full Review

All research is presumptively in this category unless it meets certain exceptions, as described below. The term "full review" refers to a face-to-face review before the full REB. In such cases, the REB encourages researchers to participate in discussions about their proposals, but the researcher may not be present when the REB is making its decision.

⁴ Part 46.107. *Federal Policy for the Protection of Human Subjects*, Code of Federal Regulations, USA, Title 45, revised October 1998.

When the REB is considering a negative decision, all reasons for this decision will be made available to the researcher and a reply from the researcher will be requested. Researchers have the right to request, and the REB has the obligation to provide, reconsideration of decisions affecting a research project.

Application forms, Guidelines and pro forma consent forms are available on the Laurentian University Research Office Web site at http://www.laurentian.ca/admn/grad_study/research/forms.html, or can be obtained from the Research Office at L-808, Extension 3213.

Expedited Review

Research proposals will be reviewed by the chair of the REB (or a member delegated by the chair), and one additional member, if the research falls into certain categories defined as "minimal risk".

Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life. This definition requires a judgement by the chair and the member of the REB designated to review the proposal. In light of the proposed research, the judgement is based on such factors as:

- 1) the nature of the population studied (ie, children, institutionalized individuals, vulnerable populations, incompetent populations, aboriginal peoples) in light of the proposed research.
- 2) the nature of the information collected.-(i.e. information which, if known outside of the research, could reasonably place the subject at risk of civil or criminal liability or damage the subject's social standing, financial standing, or employability)
- 3) the use of physically or psychologically invasive manipulations.

Written Consent

According to the *Tri-Council Policy Statement*, "**Research governed by this Policy may begin only if prospective subjects, or authorized third parties, have been given the opportunity to give free and informed consent about participation...**" This consent should ordinarily be obtained in writing. Where there are **good reasons** for not recording consent in writing, the procedures used to seek free and informed consent shall be documented. As part of the informed consent process, subjects are to be given information on whom to contact in case they have questions regarding the study. The name of a member of the research team with contact information should be given to the participants, and also the name and contact information of the Research Officer at University.

Scholarly Review as Part of Ethics Review⁵

In all cases of research that poses more than minimal risk, the REB shall satisfy itself that the design of a research project is capable of addressing the questions being asked in the research. In cases of funded peer-reviewed research proposals, the review by the agency will constitute review of scholarly merit. In cases of research projects which have not been peer-reviewed (including contract or contribution research), if the REB itself is unable to determine the merit of the research, the individual will be requested to provide two names (one internal to the university and one external to the university) of arms-length experts in the field who could provide an assessment of the scholarly merit of the proposed research.

Research on Public Figures

In consideration of harms/benefits analysis of the proposal it is important for reviewers to note Article 1.5 (d) of the Tri-Council Statement: "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."

Community-based research

The REB will also serve as a liaison committee to review projects undertaken by members of the Laurentian University community that are conducted within the domains of other institutions (e.g. a school, hospital, social agency). For these research settings, the REB reviews the ethical soundness of faculty and student applications to be submitted to external agencies (e.g. The Sudbury District Board of Education, NEORCC, The Sudbury District Health Unit) whose Research Boards vet research proposals dealing with human subjects. Proposals should be submitted to the Research Office in time to be submitted for the next REB meeting prior to the external agency's deadline for the submission of proposals.

Multi-Centre Research

Where Cooperative or Multi-Centre Studies are brought to the REB for review, the Tri-Council Policy states that the REB shall have the authority to stipulate the requirements for acceptability, notwithstanding the requirements imposed by other centres. The REB may cooperate with other centres in the matter of Ethics Review, but may not take the acceptability of the proposal to other centres as certifying its acceptability to the REB.⁶

⁵ *Tri-Council Policy Statement, Analysis, Balance, and Distribution of Harms and Benefits*, Section 1C-c2, p. 1.6.

⁶ From NCEHR Report to Laurentian University, May, 1999.

Review Procedures for Ongoing Research

The Tri-Council Policy Statement stipulates that: "**Ongoing research shall be subject to continuing ethics review. The rigour of the review should be in accordance with a proportionate approach to ethics assessment.**"

In cases of **greater than minimal risk research**, as part of the research proposal submitted for REB review, the researcher shall propose to the REB the continuing review process deemed appropriate for the project that is consistent with Article 1.13 of the Tri-Council Policy statement. In cases of **minimal risk research**, continuing review will consist of the submission of a succinct annual status report to the REB annually, or if the project is of less than one year in duration, at the end of the project.

This policy pertains to all faculty research and graduate student research. The REB shall be promptly notified when data collection for a project concludes. In the case of a master's student's research, the annual report form may be completed and signed at the time of the thesis defence.

Suspension of Research

The REB shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with its requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the REB's action and shall be reported immediately to the investigator, the Director of Graduate Studies and Research, and the funding agency.

Records

The REB shall maintain records regarding the review for the full term of the research activity plus at least seven years. Records shall consist of the original application, all correspondence with regard to the review and reporting of the ongoing review process, including adverse events reports and their follow-up.

Meetings and Attendance

The REB will meet monthly to review expedited review decisions and to review proposals that are deemed greater than minimal risk. For full reviews, a quorum will consist of 60% of the REB. Approval will generally be by consensus. If consensus cannot be reached, the members will vote and a 80% majority will be required for approval. If appropriate, reasons for the minority vote will be recorded. Minutes of these meetings will be available in the Office of Graduate Studies and Research.

The REB will submit an annual report to Senate by September 1, concerning the number of proposals reviewed in each category (expedited review, full review, continuing review), a generic description of ethics issues/concerns that have been addressed in the past year, and, if necessary, recommendations concerning changes to this policy or the procedures for conducting an ethics review.

Appeals

In cases when a researcher and the REB can not reach agreement through discussion and reconsideration, the decision will be reviewed by the REB from a cooperating University. An agreement is to be made with another University or Universities to provide this arms length appeals process.

Departmental Research Ethics Boards

In conformity with the Tri-Council Policy Statement, The Laurentian University REB is ultimately responsible for the ethical review of research involving human subjects conducted by its personnel. The REB delegates this authority to Departmental Ethics REBs in the case of the review of undergraduate students' course-related activities. There are two exceptions to this delegation:

- 1) Research conducted by undergraduate students which is part of a faculty member's own research program must be reviewed by the University REB.⁷
- 2) If a project is deemed greater than minimal risk by the departmental REB, it must be reviewed by the University REB.

If a Departmental REB is doubtful about the risk involved in a proposal, it will consult the University REB.

Structure and Process

Each Department/School at the University which engages in research with human subjects shall have access to a departmental or grouped departmental REB. Each of the following Departments/Schools whose undergraduate students regularly engage in research with human subjects are to have in place a Departmental REB:

- 1) School of Commerce,
- 2) School of Human Kinetics,
- 3) School of Nursing,
- 4) Department of Psychology,
- 5) School of Social Work, and the
- 6) Department of Sociology.

In addition, those Departments/Schools in which undergraduate students engage in research occasionally or on a limited basis must form groups with each other or with the five departmental REBs for the purposes of ethical review. A person from each of these departments/schools must be named by the Chair/Director to represent the Unit for matters regarding ethics, and to liaise with a standing departmental REB or with a newly formed group REB. The following groups have been suggested.

- 1) Sages femmes, orthophonie, and the School of Nursing
- 2) Economics, Political Science, Cultural Anthropology and the Department of Sociology
- 3) Biology, Chemistry, Physics, Physical Anthropology and Human Kinetics
- 4) History, Languages, Philosophy, Religious Studies, Native Studies, Women's Studies, Gerontology, in a separate group of Humanities research.
- 5) École des sciences de l'Éducation with the School of Commerce, Psychology or Sociology.
- 6) Native Human Services Program with the School of Social Work

⁷ *Tri-Council Policy Statement*, Section 1, Ethics Review, B3, Article 1.4c, p1.5.

Departmental REBs will operate according to the Tri-Council Statement on "Ethical Conduct for Research Involving Humans", which is available at the following web site:

<http://www.sshrc.ca/english/programinfo/policies/ethics.htm>

The Departmental REB shall consist of at least two persons who are knowledgeable in the Tri-Council Policy and in research with human subjects who will be replaced with alternates when they are associated with the project under review. The Departmental REB is encouraged to include a student as an additional member.

REB members will be appointed by the Chair of the Department in consultation with their Dean and the Director of Graduate Studies and Research for a term of three years, renewable. One of the members of the Departmental Committee or another person will be named by the Chair of the Department in consultation with the Director of Graduate Studies and Research to the University REB. In the case of the grouped departmental REBs, two members in total from the group REBs will be members of the University REB on a two year rotation basis. A standard rotation schedule will be drawn up.

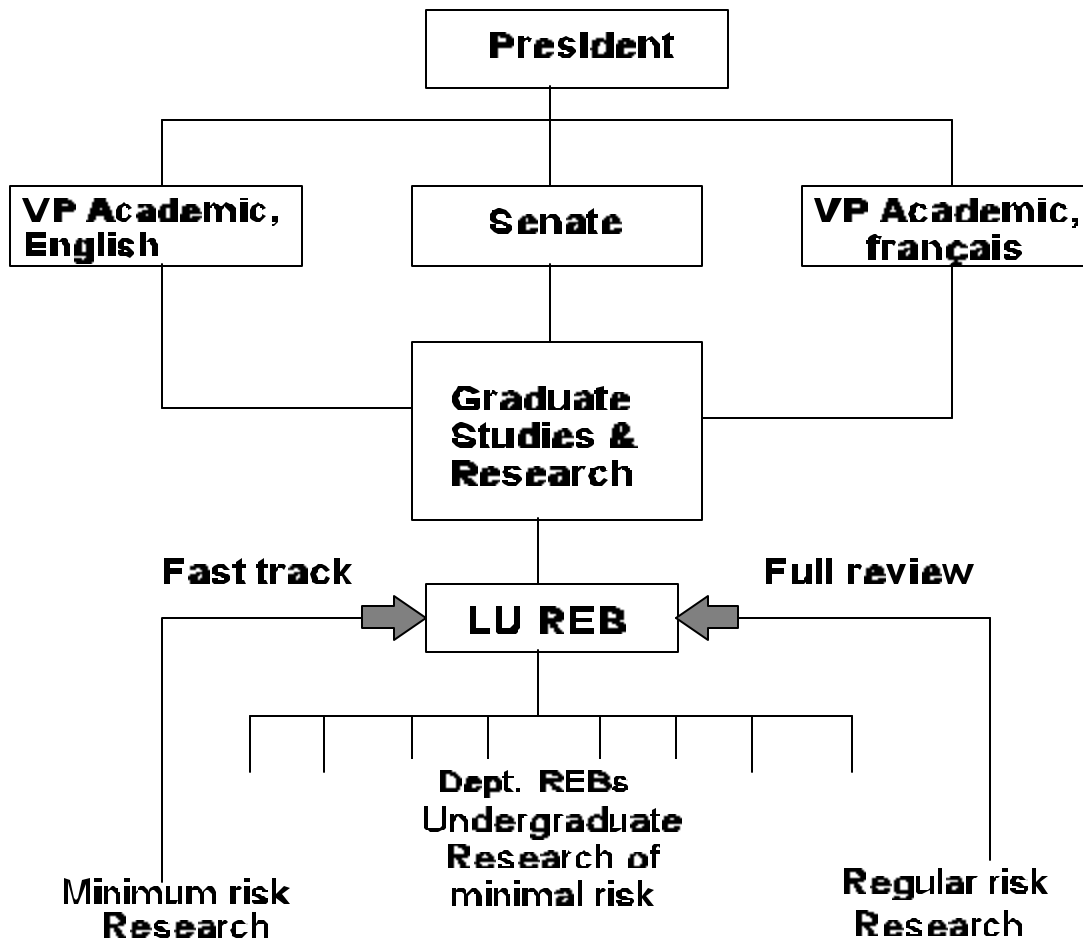
Reporting and Records

The Departmental REBs must maintain records⁸ of cases reviewed in accord with the stipulations of the Tri-Council Policy Statement, and must report periodically, but at least annually by June 1 to the University REB on their activities, including the cases reviewed, and any problems encountered. In addition, they are obliged to report immediately to the University REB any adverse events or non-compliance arising from cases under their jurisdiction. Members of the University's REB will be available as resource and support persons for the Departmental REBs.

*Gabrielle Miller,
Research Office
May 31, 2000*

⁸ "As with other levels of review, proper accountability demands appropriate record keeping."
Tri-Council Policy Statement, B3, Article 1.4c, p1.5.

Appendix 1
Structure for Ethics Review Process at Laurentian University



**see the University and Tri-Council policies for the definition of minimal risk

Appendix 2: Timelines⁹

Meetings:

The Laurentian University Research Ethics Board meets on the first Friday of each month.

Due to holidays during the Summer months (July and August), the schedule may not be adhered to completely. Please consult the Research Office (675-1151 ext. 3213), or e-mail gmiller@nickel.laurentian.ca for current information during these months.

For the departmental meeting schedules, please consult the appropriate Department. Remember that only undergraduate research which is of **minimal risk can** be dealt with by departmental review.

Full Review:

Proposals which require **full review are to be submitted at least one week before** the date of the monthly meeting. Applications received after that deadline will be brought forward to the next monthly meeting.

Guidelines, Instructions and applications are available on the Ethics Board's web site at http://www.laurentian.ca/www/admn/grad_study/research/ethics.html. Applications are to be brought or e-mailed to the Research Office by the deadline.

Review will be done as quickly as possible, and applicants will be informed of the results of the review (usually by e-mail) within a few days of the meeting. In quite a few cases, some changes are recommended by the REB. If there are any unanswered questions, the review may take longer.

Applicants who wish to do so are invited to come to the meeting to discuss their proposal. This is particularly helpful if there are unusual or complicated aspects to the proposal, which would take much longer to settle by normal written correspondence. Applicants who wish to come to the meeting must make arrangements with the Research Office before the meeting.

Expedited Review:

For criteria, see the appropriate section of the Policy. If, after consulting the criteria, applicants consider that their proposal will fall under expedited review process, they are to e-mail a copy or bring two copies of the proposal to the Research Office. The Research Officer will consult if necessary, and send the proposal out for review. Expedited Review is usually done quickly, and can take less than a week.

Reports:

Forms for annual/scheduled reports as well as for reports on problems encountered in the course of the research are available on the Ethics Board web page. Reports are to be submitted to the Research Office.

⁹ This is subject to change. Please consult the Research Ethics web page for current information.

Appendix 3: Compensation for the Chair and members of the Laurentian University research Ethics Board and for the Departmental REBs.

Although Senate is not able to make budgetary allocations for the compensation of the Chair and members of the Boards which provide review of research involving human participants, the University has the obligation to take the role and responsibilities of such members most seriously. According to the Report of the National Council on the Ethics of Human Research, which visited the University in February 1999, to evaluate the ethics review process, and progress towards bringing it into conformity with the Tri-Council Policy,

“The Administrators whom we met seemed to be sensitized to the issues related to the review of research employing human subjects. They were aware that the enlarged mandate of the Central Ethics Committee would require greater administrative and financial resources. The Administrators seemed open to the idea of allocating the necessary funds for the good functioning of the of Ethics Review process. They were equally aware of the heavy responsibility undertaken by the Chair of the Committee, and of the participation by members of the Committee, and seemed ready to consider such responsibilities in their decisions regarding promotion, reductions in workload, etc. The Administrators seemed ready to show their support for the Ethics Committee and recognize the necessity to support changes in the university culture regarding ethics review.”¹⁰

The Task Force recommended that a workload reduction be given to the Chair, and that members be given appropriate credit for their work on this Board by their Departments/Schools and Faculties.

¹⁰ Letter from Richard Carpentier, Director General, National Council on Ethics in Human Research., to Dr. Frank Smith, Director, School of Graduate Studies and Research, on 27 April 1999.