LAURENTIAN UNIVERSITY REB

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Frequently Asked Questions (FAQ)

Laurentian University REB

This FAQ and all policies on the REB forms as well as information displayed on the website are designed to handle the majority of general questions. If you need more information, for general questions and for REB meeting activities and timelines, please contact Pauline Zanetti at 705-675-1151 ext. 2436 or email pzanetti@laurentian.ca.

If you have questions prior to submitting your ethics application, or questions about your new submission, the status of your ethics application, REB policies and requirements, or continuing ethics review (reports, extensions and modifications) please contact Stephanie Harris at 705-675-1151 ext. 3681 or email sharris2@laurentian.ca.

Where is the Ethics Office located?

6th floor of the Parker Building.

What is the role of LU's REB?

LU's REB is a committee that reviews all research involving human participants, their identifiable data and human biological materials. Their review is based upon the perspective of protecting human subjects involved in research protocols. REB's role thus ensures compliance with the Tri-Council Policy Statement (TCPS). The committee is concerned basically with what happens to the participants before, during and after research has been completed.

REB membership consists of multidisciplinary faculty with various areas of expertise in research, graduate students, as well as community members.

How does LU's REB work?

The REB reviews all ethics research proposals involving human participants and their data. Sometimes this is done by a small group ("delegated review"), or as a full committee ("full review"), or the REB can seek additional external peer review expertise before deciding on a course of action.

Research proposals are sometimes accepted with only minor revisions while others require more substantial changes. In other cases, they may be deferred while external experts examine the proposals. Final determinations also may include rejecting the proposal, or suspending or terminating research in progress. While these determinations are rare, they are often based on a variety of circumstances related to research integrity or the use of unethical research practices.

FORMS, POLICIES AND THE APPLICATION PROCESS

Where can I find the appropriate application forms?

All forms are found on the Romeo Database at: https://romeo.laurentian.ca/romeo.researcher. Please refer to the Office of Research Services website at www.laurentian.ca/research for the step by step Romeo training module for Researchers.

Who can submit an ethics application to Laurentian's main REB?

All faculty members conducting research using human participants are required to seek ethics certification prior to beginning their research. All students from Ph.D. and Master's programs (and their supervisors) must also submit an ethics application prior to commencing their research if their research relies on human participants.

All fourth year thesis or other undergraduate students' ethics application should be submitted to their Departmental Ethics Committee if one exists. If one does not exist or if a fourth year thesis and undergrad students' ethics application are deemed more than minimal risk they should be submitted to the LU REB.

What is minimal risk?

According to the Tri-Council Policy Statement Guidelines, the standard of minimal risk is commonly defined as follows:

If potential participants 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 participant 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. The final decision on the level of risk always rests with the Chair of the REB.

What happens if my proposal is determined to be more than minimal risk?

The application is reviewed by the full committee at the following monthly REB meeting.

How long does it take for REB approval?

Delegated reviews will require a minimum of 20 working days but can take up to 12 weeks.

Full reviews (higher than minimal risk) require a minimum of five (5) weeks for evaluation. Please note, if it is deemed that an ethics application needs full review, it must be submitted to LU's REB **14 days before** their monthly meetings which are held every *first* Friday of each month.

What type of review will I have and can I request a delegated review?

Yes, you may request a delegated review directly on the main REB application form found in your Romeo Portal.

The type of review is based upon the pre-examination of your proposal conducted by the Ethics Officer and the Chair of the REB. To determine the status of the review, a proportional approach is applied (e.g. the balance of risks and benefits, topic being researched, participant selection criteria, etc.). The greater the risks are, the higher the precautions must be. Delegated reviews are based on minimal or below minimal risk. Full reviews are based on higher than minimal risk.

The notion of minimal risk is determined by the TCPS definition:

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. (TCPS article 1.4C).

If you believe that your proposal should be considered as minimal risk, complete the required section on the main REB application form and justify your request based on TCPS policies and guidelines. Please note that the default is full review by REB.

How do I know if my protocol should go for delegated or full review?

If you still have difficulty making this assessment, please contact Stephanie Harris (sharris2@laurentian.ca or at ext. 3681). The default position according to TCPS guidelines is full review.

What types of research need to have ethics approval?

All research conducted at Laurentian that involves human subjects or their identifiable data, whether funded or not, must obtain ethics certification prior to starting the research.

Ethics approval required:

- All research with human beings requires review and approval by an REB in accordance with the TCPS, before the research is started, except as otherwise stipulated.
- Research involving secondary data, human remains, cadavers, tissues, biological fluids, embryos or fetuses shall also be reviewed by the REB. The opinion of the REB should be sought whenever there is any doubt about the applicability of this Policy to a particular research project.

Ethics approval not required:

Research about a living individual involved in the public arena, or about an artist, based exclusively on <u>publicly available</u> information, documents, records, works, performances, archival materials or third-party interview, is not required to undergo ethics review.
 Such research only requires ethics review if the subject is approached directly for interview or for access to private papers.

- REB review is generally not required for research involving public policy issues, the
 writing of modern history, or literary or artistic criticism, even though all of these might
 well involve human subjects.
- Research for a critical biography about someone deceased should not require REB review because the term "research participants" refers to living individuals.
- Quality assurance studies, performance reviews or testing within normal educational requirements also should not be subject to REB review.
- Research involving observation of participants in, for example, political rallies, demonstrations or public meetings should not require REB review since it can be expected that the participants are seeking public visibility.

The <u>REB is responsible for deciding if projects are excluded from review.</u> We recommend that you consult with the Ethics Officer or submit your proposal if you are not sure. No exemption will be provided on partial information (emails, phone conversation, intentions etc.).

What types of human research are exempt from REB review?

<u>Laurentian's REB is responsible for determining what projects can be exempted from review.</u> If you are not sure, contact the Ethics Officer at Laurentian University (L-619, ext. 3681).

In general, the Laurentian Ethics Board may exempt from review the following type of projects:

- Research about a living 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;
- Research involving the observation, assessment, or recording of public behaviour where such research involves the observation of participants in, for example, political rallies, demonstrations, public meetings or similar activities in which it can be expected that participants are seeking public visibility and therefore observation and possible recording.
- Quality assurance studies, performance reviews of an organization or its employees or students within the mandate of the organization, or testing within normal educational requirements, unless they contain an element of research in addition to assessment.

Note that these studies may require the administrative review of the Research Ethics Office.

What about naturalistic observation or conducting interviews with family or close friends?

As naturalistic observation is defined as research based on observations of participant behaviour in a natural environment where participants are not aware that they are being

observed and consequently, have not given consent, this type of research is subject to REB review. If you are interviewing friends and family, you may need ethics review.

SAMPLE MATERIALS AND INFORMATION

Where can I download the latest version of the TCPS?

You may obtain the latest TCPS here (English versions): Tri-Council Policy Statement

Can the Ethics Officer provide me with support to help me draft consent forms and information letters?

Yes, please contact the Ethics officer by email at sharris2@laurentian.ca or by telephone at extension 3681.

PARTICULAR TOPICS

Why is my project subject to ongoing monitoring by the REB?

Most research protocols only require annual reports. Some protocols include more than minimal risks and require more safeguards for the participants. In this context, Laurentian's REB has the authority to require review more frequently than the time frame approved when:

- the risks presented by a protocol warrant it
- the REB wishes to ensure quality assurance
- the REB is concerned with the degree of vulnerability of participants.

What is ongoing review?

All ethics approvals are good for one (1) year minus one day from the date the ethics certificate is issued unless the termination of the project, as determined by the researcher(s), occurs before one year.

If the research ends within the year of approval, researchers are expected to submit their final report (using the appropriate form in the Romeo Portal - for support please contact the Ethics Officer at sharris2@laurentian.ca or by telephone at ext. 3681).

If the research is not finished within the year of approval, the researcher must request an annual extension.

It is the researcher's responsibility to keep track of these reporting dates. Consequences for non-compliance may involve suspension of a thesis defense, revocation of a degree, suspension of access to research funds, and termination of the research.

What if I have to modify my already-approved research proposal?

If a researcher wants to modify their pre-approved research (e.g., adding or removing a questionnaire or task, adding team members or modifying recruit procedures), they must

advise the REB and complete a research modification request form with supporting documents as necessary. The request for modification will also be considered as an annual report.

If more than three (3) renewals or changes are requested since the original approval of the project, a full new REB application form must be completed. This is to ensure ethical integrity through the various versions.

NOTE: The Annual Report, Extension and Modification Request Form is one form and is found in Romeo by clicking on "Applications: Post-Review". From there, researchers need to find the file in question and click on "Events" after which a new screen will appear with the form highlighted at the top of the screen. For additional support please contact the Ethics Officer at sharris2@laurentian.ca or by telephone at extension 3681.

Can partial funds be released prior to REB approval to pay my students or to purchase equipment, prior to involving human participants?

Yes, partial funds may be released for activities not involving human participants. Please complete the Release of Research Funds Prior to Ethics Approval Form. On the form, explain the reasons why you are requesting partial release of funds and describe the schedule of activities related to the use of the released funds. You also must commit to a date to submit your proposal for ethics review. To access this form, please contact Stephanie Harris at sharris2@laurentian.ca or by telephone at ext. 3681.

Signature of the Chair of the Ethics Board and of the Vice President/Research is required to release funds prior to REB review. Please note that we generally do not release more than 25% of the total amount of research funds awarded.

I am a student and my project is part of academic research, do I need to submit to the REB?

If human participants are involved, yes. Note that student researchers <u>must have</u> a faculty member supervise their research project. The supervisor's signature must be included with the application in Romeo indicating that they agree with the content of their student's ethics proposal.

Course-based research: My class is doing research involving human participants. Can I submit only one application for the entire class?

Yes, an entire class can be covered by only one application form completed by the professor-instructor, if the research is deemed as minimal risk and if the research protocols can be established as basically the same for all students. The professor-instructor will have to make a final report at the end of the term that will include a short description of what was done and also report any anomalies or incidents. The duration of the approval is related to the duration of the course and can't exceed one year, however is eligible for annual renewal.

Do I need to have a consent form or an information letter for REB review?

Generally, we recommend that a letter of information/recruitment as well a separate written consent letter be drafted for REB review.

The information letter, written in lay language, informs participants about the research, what will be required of them, and has contact information.

The consent form (copy), also written in lay language, can be kept by the participant for future contact information and as proof of having understood and participated in the research. Most of the protocols will require a consent form as the expression of the free and informed consent process.

There are many types of research and many ways to seek free and informed consent. If you are interviewing officials in their public duties, you won't necessarily have to get the same level of consent than if you are interviewing vulnerable populations.

Public officials: a letter of information may be used as the expression of the consent as long as it contains your contact information, rights to withdraw, assurances with regards to publication of statements, contact information for the Research Ethics Board and the date and time for the meeting. If the official agrees to the interview, this is the same as consent. You still need to document the consent process, however.

Surveys: Surveys that are sent via mail or are to be completed online sometimes do not require separate written consent as the act of completing and returning the survey is a reflection of consent. However, participants must be informed of their rights such as to withdraw from the research or not to have the obligation to answer to all questions, and how their confidentiality will be maintained.

Vulnerable populations: Special precautions must be taken for particular vulnerable populations. The higher their vulnerability, the higher the precautions and safeguards needed.

Written consent: Written consent may not be necessary for people who do not have a culture of the written word. However, researchers need to document how they obtain consent in such cultures. Ensure this is detailed in your main REB application form.

Internet: If you are using the internet to collect data (e.g., chatrooms or survey instruments) special provisions may apply for consent. Participants who are asked to answer questions or to fill out a questionnaire should have to read the equivalent of a consent form including:

- the aims of the research project, its components;
- the statement of risk if any;
- measures taken to ensure confidentiality or anonymity to the respondents;
- the right not to participate in the project or not to complete the questionnaire as a whole.
- thereafter, there could be a paragraph to the effect that the person has read the information and that they accept to participate in the project, namely to complete the questionnaire.

 although participants did not sign as a consent form, information relevant to their participation is transmitted, and answering questions/completing the questionnaire can be interpreted as consent.

If you are using tools such as SurveyMonkey or other US-Based survey platforms, participants must be aware that under the Patriot Act, absolute confidentiality cannot be ensured for information stored on USA-based servers. The REB discourages the use of American-based online survey software tools (e.g., SurveyMonkey) for use in research where confidentiality to participants is promised. Data stored on servers based in the USA are subject to the United States Patriot Act, to which US law enforcement agencies have potential discretionary access.

Alternatively, the REB would encourage use of online survey software that is hosted securely in Canada such as RedCap, LimeSurveys, and Google Surveys through your Laurentian Google Drive.

What are Primary and Secondary Data?

Primary data collection involves direct contact with, or observation of one or more people for the purpose of collecting data from or about them.

Secondary data collection involves accessing information that has already been and originally obtained for a different purpose or research project, about human participants, either individually or in aggregate form. Secondary data that contain personal identifiers is subject to ethical review. Secondary data that do not contain personal identifiers are exempt from these requirements. Researchers are encouraged to consult with the REB to determine if their research requires REB review. Laurentian's REB is responsible for determining what projects can be exempted from review.

Secondary data - whether it contains personal identifiers or not - may be used only when original consent was obtained which allows the information to be used in this manner.

In which circumstances does secondary data require ethics approval?

Laurentian's REB requires ethics review of all research protocols/studies that involve the use of secondary data, especially where identifying information is involved.

Laurentian's REB will allow researchers to access identifying information if they demonstrate that:

- identifying information is essential to the research; and
- they will take appropriate measures to protect the privacy of the individuals, to ensure the confidentiality of the data, and to minimize harms to subjects;
- individuals to whom the data refer have not objected to secondary use.

Laurentian's REB also may require that a researcher's access to secondary use of data involving identifying information be dependent on:

• the informed consent of those who contributed data or of authorized third parties; or

- an appropriate strategy for informing the subjects; or
- consultation with representatives of those who contributed data.

Full Reviews for secondary data will be required in highly sensitive situations such as when identifiable data will be published or other instances when there is a significant risk of breach of confidentiality.

As per TCPS Policy, the REB may require the researcher/research team to seek consent to use the stored data from those who made the contribution.

Laurentian's REB recognizes that it may be difficult or economically unfeasible to contact all subjects in a study group to obtain informed consent. This can occur when the group is large or its members are deceased, geographically dispersed or difficult to track. It is the obligation of the researcher/research team to identify ways in which the rights of the participants and the confidentiality of their information will be maintained.

Delegated reviews for secondary data: when research protocols/studies involve the secondary use of data that does not include any identifying information, and where risk to research participants is considered minimal, the REB review can be delegated or exempted. <u>Laurentian's</u> REB is responsible for determining what projects can be exempted from review.

Data linkage precautions: Researchers should pay particular attention to the use of databases and be sensitive to the possibility of identifying individuals through databases. As per TCPS policy;

- The REB is required to appraise the possibility of identification, in particular with regard to the extent of the harm or stigma which might be attached to identification.
- The REB and the researcher should also be aware of legal provisions that affect the database(s) to be used in the research.
- Laurentian's REB requires that researchers identify the context in which the database
 was created, such as a confidential relationship, and the expectations of the groups or
 individuals at the time of the collection of the data with regard to its use, retention and
 disclosure.
- Re-contacting original research participants: Researchers who wish to contact
 individuals to whom data refer shall seek the authorization of the REB prior to contact.
 The researcher must provide compelling reasons why follow-up contact and/or
 interviews with former study participants are required.

Multi-Institutional Research and ethics approvals.

The multiplication of REB reviews in a multi-institutional research context can multiply the difficulties and also can be very time consuming. In an attempt to simplify such research initiatives, Laurentian's REB agrees to consider the REB decisions of other universities within its review process.

When the principal Investigator (PI) of the research project is from Laurentian University, Laurentian REB policies and procedures shall be given priority.

When Laurentian investigators are collaborating with a research team from other institutions, they must submit an ethics application to Laurentian's REB. Whether they are the Principal Investigator or not, Laurentian collaborators can request a delegated review, even if the project required full review at the external institution. LU collaborators will have to provide Laurentian's REB with evidence of the approval and with the documentation of the external REB's decision.

Please note that Laurentian's REB is not obliged to accept another's institution's decision. Principles of institutional accountability require each local REB to be responsible for the ethical acceptability of research undertaken within its institution. In multi-centered research, however, when several REBs consider the same proposal from the perspective of their respective institutions, they may reach different conclusions on one or more aspects of the proposed research.

To facilitate the coordination of ethics review, when submitting a proposal for multi-centered research, the researcher may wish to distinguish between core elements of the research — those that 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.

REBs also may wish to coordinate their reviews of multi-centered projects and to communicate any concerns that they may have with other REBs reviewing the same project. The needed communication would be facilitated if the researcher provides information on the institutional REBs that will consider the project.

Research conducted within local school boards.

As many school boards require an ethics approval prior to examining and accepting research proposals, we recommend that you submit first to Laurentian's REB. Most of the School Boards now have their own REB guidelines and committees.

To access research participants through school boards, you must be aware of School Board policies for access to directors, principals, teachers, parents etc. Allow yourself enough time in these types of research to go through both Laurentian's REB and the School Board REBs. Some Boards will allow you to do both at the same time while others will require Laurentian's REB accreditation first. If the School Board REB requires modifications to the proposal, these must also be submitted to the Laurentian REB.

We suggest seeking Laurentian ethics approval first before going to the school boards.

Funded research with human participants. I'm applying to a major agency - do I need to submit to ethics before applying for the funding?

If you are applying to a funding agency such as NSERC and SSHRC, you won't be asked to provide evidence of ethics approval prior to being awarded. CIHR often will request evidence of ethics approval before accepting to evaluate the research proposal, however.

Generally, after you have been granted an award, the councils set a six months deadline to obtain ethics approval or the funds will be returned to the Councils.

Note that your account may be opened much more rapidly if you submit an application before you are awarded the grant, and your proposal has been approved by the Research Ethics Board. All conditions (including certifications) must be met before an account will be opened.

May I use deception or incomplete disclosure in my project?

Although discouraged under the federal guidelines, in certain circumstances and if justified, the REB will consider applications involving incomplete disclosure or deception along with the submission of a debriefing script.

Further to informing participants about their experience with respect to the primary study intent, the debriefing script should include a reminder that participants are free to request - without consequence - complete withdrawal of their data from the sample, if possible, and indicate the timeframe within which they can request their data withdrawal. Typically, withdrawal of data can be done up until the point of dissemination of findings (e.g., publication, conference presentation).

In all protocols involving students in the Psychology department, submission of a debriefing script to the REB is required. The Board recommends that debriefing takes place as soon as possible once the participant has completed their participation in the study.

I am conducting research in a foreign country. Is my Laurentian ethics approval valid or do I need further approvals?

You may need to obtain approval from an institution in that country. Please make sure that you obtain any relevant approvals in that jurisdiction.

Do institutional surveys require review by Laurentian REB?

It depends. A survey is considered to be an "institutional survey" when one is trying to obtain information about institutions or organizations by surveying one or more of its representatives. If the survey is used to collect only factual information that is publicly available, then an ethics review may not be necessary.

If the survey includes any questions asking for opinions or interpretation by the participant, then ethics review is required. If you have any doubt about whether or not your project requires ethics review, please submit a preliminary application to the Research Ethics Board for assessment using the online REB application form.

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