



**Laurentian**University  
Université**Laurentienne**

**LAURENTIAN UNIVERSITY RESEARCH ETHICS BOARD**

**TERMS OF REFERENCE**

2016

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## **Introduction**

**The Laurentian University Research Ethics Board (LUREB) Terms of Reference (TOR) presented here are an update of the previous Terms of Reference, dated March 15, 2013 to implement necessary revisions and to bring the new TOR in accord with the most recent update to the TRI-COUNCIL POLICY STATEMENT on Ethical Conduct for Research Involving Humans TCPS 2 (2014) .**

## Section 1

### Laurentian University Research Ethics Board (LUREB)

#### 1.1 Mandate of the Laurentian University Research Ethics Board (LUREB, also referred to as REB in this document)

All Canadian Universities must comply with Tri-Council Policy Statement (TCPS) regulations for continuing eligibility to receive and administer research funds from the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC), or “the Tri-Council Agencies.”

The mandate of LUREB is to review the compliance of research involving humans in accordance with the TCPS policies and other applicable legal and regulatory requirements with respect to consent and the protection of participant privacy and in keeping with the core principles as defined in TCPS 2. LUREB will review any proposed research project that will involve humans directly or indirectly. In doing so, LUREB will establish a “proportionate approach” to the review process.

#### 1.2 Enabling Body

The LUREB is established by resolution of the Board of Governors (BOG) of Laurentian University which has granted LUREB the mandate to review the ethical acceptability of research on behalf of the institution, including approving, rejecting, proposing modifications to, or terminating any proposed or ongoing research involving humans.

##### 1.2.1 Accountability and reporting relationship

The LUREB in its review and decision-making process must be sheltered from any external influence. In order to guarantee this independence and ensure LUREB is able to function effectively, the BOG of Laurentian University is expected to:

- Ensure the establishment of policies and procedures that support the independence of LUREB in its decision making so that LUREB may be free of inappropriate influence, including situations of real, potential or perceived conflicts of interest.
- Provide appropriate financial and administrative resources to the LUREB (e.g., research ethics administration staff) that will adequately support the effective and efficient operation of the LUREB.
- Provide funding for professional development of the members of the LUREB to appropriately perform their roles and responsibilities as outlined in the current TCPS policies.

The relationship between the BOG of Laurentian University and LUREB is through the Research Ethics Board Liaison Committee.

##### 1.2.2 Annual Report and Other Reports

LUREB will provide a written report annually to the BOG. This report will be sent to Senate for information. In the course of the year any urgent issues or issues deemed of sufficient importance to be addressed the BOG shall be brought by the chair of the LUREB or delegate to the attention of the chair of the Research Ethics Board Liaison Committee.

### **1.2.3 Conflicts of interest**

Laurentian University shall act in a transparent manner identifying and addressing conflicts of interest related to research. Its policies should address the roles, responsibilities and process for identifying, eliminating, minimizing or otherwise managing institutional conflict of interest relevant to research or all sources of potential for conflicts.

The BOG shall ensure that institutional policies and procedures shall also support and promote the independence of the LUREB in its decision making so that the LUREB may be free of inappropriate influence, including situations of real, potential or perceived conflicts of interest. In compliance with this principle, therefore, an institutional senior administrator (e.g., vice-president of research, director general or director of business development) should not serve on LUREB, nor directly or indirectly influence the LUREB decision-making process.

## **1.3 Scope of activities and approaches**

The role of the LUREB is to facilitate ethically acceptable research concerning human participants. The LUREB shall develop and implement policies and procedures concerning the role of the LUREB that comply with the terms of TCPS.

**1.3.1** The Canadian Research Tri-Council Policy Statement (TCPS) establishes the scope and principles that the LUREB will follow in the evaluation of a research proposal. The approach that will guide the work of LUREB in this respect will always remain in accordance with the core principles enunciated in the TCPS: Respect for Persons, Concern for Welfare, and Justice.

**1.3.2** LUREB will ensure that the consent process in approved research applications meets the provisions and standards outlined in the TCPS.

**1.3.3** LUREB will uphold the principles of fairness and equity in research participation in accordance to the principles in current TCPS and will be satisfied that the research protocol has provisions to respect the right to privacy and confidentiality.

**1.3.4** The LUREB may from time to time engage a consultant to provide expert advice by way of a written report.

**1.3.5** The REBLC shall review relevant policies, from time to time, to ensure their currency and relevance to national and other level policies and legislation and make recommendations to the LU BOG who has the final authority.

## **1.4 Composition**

**1.4.1** The membership of LUREB is designed to ensure competent independent research ethics review and reasonable workload. The membership is not based upon departmental or school representation but on the expertise needed to represent the different research activities conducted at Laurentian University.

**1.4.2** The LUREB should be comprised of a Chair, Vice-Chair (or alternate), and a representative membership of at least five members composed of both men and women, Francophone members and Indigenous members.

Membership shall include:

expertise in relevant research disciplines, fields and methodologies;

knowledgeability in ethics;

knowledgeability in law;

knowledgeability in health research;

one person from the community;

one graduate student;

one representative of the Office of Research Services who will be an ex-officio, non-voting member. (TCPS2 2014 art. 6.4)

In addition, there will be a secretary / coordinator who works with the ex-officio member to provide support to the LUREB.

**1.4.3** In the event that the expertise to judge a particular research protocol is not found within the membership, LUREB shall call upon internal or external ad hoc advisors. Such advisors are consulted for a specific research ethics review and only for the duration of that review.

## Section 2

### Chair and Vice-Chair of the Research Ethics Board

#### **2.1 Election and Removal of the Chair and Vice-Chair**

The Chair and Vice-Chair will be elected by the membership of LUREB. The names of the Chair and Vice-Chair will be sent to the REBLC who will recommend the appointments to the Board of Governors. The terms of the Chair and of the Vice-Chair will be three years with staggered succession dates to ensure continuity of leadership. The Chair's term of office is renewable for a maximum of three successive terms in order to maintain the required expertise and to provide the necessary continuity of leadership. Removal of the Chair may be accomplished by a motion to such effect presented at a properly constituted meeting of the LUREB on which not fewer than 2/3 of the voting members of the Board voted in favour of the removal of the Chair. Removal of the Chair may be initiated by an advanced notice of a written motion to the members circulated with the materials for a regular or specially constituted meeting, a duly made and seconded motion to consider removal of the Chair, and a resolution on which no fewer than 2/3 of the voting members of the Board have voted in favour of the removal of the Chair. The successful resolution to remove the Chair from office will be conveyed with the numerical voting result and written reasons to the Chair of the REBLC.

#### **2.2 Role of the Chair**

The LUREB Chair is responsible for ensuring that the LUREB review process conforms to the requirements of the TCPS 2. The role of the Chair is to provide overall leadership for LUREB and to facilitate LUREB review processes based on institutional policies and procedures and this Policy. The Chair shall monitor LUREB's decisions for consistency and ensure that these decisions are recorded accurately and communicated clearly to researchers in writing as soon as possible by the Chair or his or her designate. In any situation where the Chair is unavailable, the Vice-Chair will assume the role of "Acting Chair." The University shall provide the necessary resources and adequate administrative support to enable the LUREB Chair to fulfill his or her responsibilities or for the Vice Chair if she/he must perform the "acting role" for any length of time.

The Chair shall be specifically responsible for:

**2.2.1** reviewing all proposals received (and pre-reviewed) by the Research Ethics Officer to determine whether a proposal qualifies for delegated review or should go to full review;

**2.2.2** signing proposal approvals, doing so only when he or she is satisfied that all relevant policies and procedures have been followed;

**2.2.3** seeking appropriate peer review of the proposed research ethics when the risk is more than minimal, and when there is insufficient expertise within the committee to evaluate a project;

**2.2.4** determining whether requests to change substantive elements of previously approved projects require full review, and if not, either to review them on behalf of LUREB or assign one or two committee members to evaluate the project;

**2.2.5** conducting any aspects of ongoing review delegated to the Chair by LUREB;

**2.2.6** communicating with researchers as required concerning their proposals;

**2.2.7** consulting as required with researchers and delegated (departmental) Ethics Boards;

**2.2.8** ensuring that the LUREB meets at reasonable, scheduled, publicized time intervals;

**2.2.9** appointing ad hoc LUREB members as required;

**2.2.10** consulting with the community representative in the event that the community member(s) cannot attend a meeting;

**2.2.11** consulting with the research ethics officer to identify and meet professional development and research ethics educational needs of the university community;

**2.2.12** participating in LUREB and University ethics-educational undertakings;

**2.2.13** ensuring that LUREB policies and procedures are reviewed regularly and updated as required;

**2.2.14** ensuring that issues arising with the present Terms of Reference (TOR) are noted for the purpose of future revision and that such revisions occur as required.

**2.2.15** chairing meetings in accordance with the most up to date Robert's Rules of Order.

### **Section 3**

#### **LUREB Members, Recruitment and Membership**

##### **3.1 Appointment of LUREB members**

**3.1.1** LUREB membership selection process shall be fair and impartial.

**3.1.2** There are three methods by which an LUREB member may be appointed:

- Open positions for the "required" expertise will be advertised within the university community. Interested individuals shall submit a letter of intent and a CV to the research ethics officer. The LUREB will examine all candidates and select new members.
- A list of LU schools and departments where human participant research is regularly conducted by faculty and students will be compiled. Each year the "next" units on this roster will be invited to recommend a member to the LUREB using their usual processes for LU committee appointment (e.g. election, volunteer, appointment). If the department/school at the top of the list is unable to identify an LUREB member, the next department/school on the list will be approached until a new member is found.
- Recruitment will be conducted among local communities served by Laurentian University.

A list of all approved new members will be provided by the LUREB to the REBLC to recommend the appointments to the BOG for approval.

##### **3.2 Terms of Appointments**

**3.2.1** The term of office for LUREB members is 3 years, with optional renewal in order to maintain the required expertise of the membership.

**3.2.2** The term of a member beyond the regular term of appointment can be extended until a suitable candidate is identified and trained or in the case of a member who becomes chair with fewer than 3 years left in his/her term.

##### **3.3 Training and Expertise**

LUREB members must be provided with necessary training and ongoing education opportunities to effectively function in their review of research proposals that fall within the mandate of the LUREB. As a condition of membership, members are required to participate in self-education activities in research ethics such as the TCPS Course on Research Ethics.

### **3.4 Confidentiality and Conflict of Interest**

**3.4.1 Confidentiality:** Before entering into LUREB related activities, every LUREB member will review confidentiality policies and is required to maintain confidentiality in relation to the information they may become aware of while performing their duty.

**3.4.2 Conflict of Interest:** LUREB members shall declare any conflict of interest related to their position as soon as they become aware of it. Questions of Conflict of interest may be brought to and decided by the Chair of LUREB (in the case of the Chair of the LUREB, to the Chair of the REBLC).

**3.4.3 Community Member(s):** shall not be affiliated with Laurentian University and it is advisable that community members are not currently engaged in research or legal work as their principal activities. Their primary role is to reflect the perspective of the participant.

### **3.5 LUREB Members' Duties**

Each LUREB member's primary duty is the protection of the rights and welfare of the individual human beings who are serving as the participants of research. In order to fulfill his or her duties, LUREB members must be versed in regulations governing human participants' protection and policies relevant to human research participant protection.

#### **3.5.1 Attendance**

**3.5.1.1** LUREB members shall attend all regularly scheduled meetings as well as educational events. Within his or her discretion, the Chair may require a member to step down if he or she misses 3 or more consecutive scheduled meetings, or exhibits habitual absences or failure to complete delegated reviews in a timely and suitable fashion.

**3.5.1.2** LUREB members shall be available for the complete meeting. LUREB community members shall be entitled to reasonable compensation for their travel expenses to the LUREB meetings.

#### **3.5.2 Duties**

**3.5.2.1** All LUREB members are expected to review all distributed materials and be prepared to discuss each project and provide his/her input at convened meetings.

**3.5.2.2** LUREB members are expected to review the ethics proposal sent within the delegated review process in a timely manner (no more than 14 days after receiving the proposals).

**3.5.2.3** Member(s) knowledgeable in relevant law are expected to alert LUREB to legal issues and their implications, not to provide formal legal opinions nor to serve as legal counsel for LUREB.

**3.5.2.4** Member(s) knowledgeable in research ethics are expected to alert LUREB to potential ethics issues and options.

**3.5.2.5** LUREB ex-officio member's duties include:

Represent the university's administration to the REB and provide administrative and technical support to the LUREB.

## **Section 4**

### **LUREB Meetings**

#### **4.1 Frequency of Meetings**

The LUREB will meet at least 10 times a year to review proposals with occasional retreats and training

##### **4.1.1 Retreats**

The LUREB may hold one or more retreats or similar meetings during a year to discuss general issues arising from LUREB activities, to evaluate its terms of reference and standard operating procedures as well as to take advantage of educational opportunities.

#### **4.2 Notice of Meetings**

LUREB shall display on its website at least one month before the start of the academic year, a schedule of the LUREB meeting dates for the upcoming year.

#### **4.3 Informal Meetings**

Researchers and LUREB may have informal meetings with each other prior to the formal review process, in order to expedite and facilitate the review process. Such informal meetings cannot, however, substitute for the formal review process.

#### **4.4 Regular Meetings**

LUREB members may meet in person or by teleconferences or other means of electronic communications) to review proposed research that is not assigned to delegated review.

#### **4.5 Quorum**

Quorum shall be 50% of the total number of LUREB members provided the members participating in the meeting have adequate expertise to properly deal with the matters before the LUREB at the meeting.

#### **4.6 Decision by Consensus**

Routine LUREB decisions will be made by consensus whenever possible and, on an ordinary motion, by a 50% plus 1 majority vote when consensus is not achieved. A 2/3

vote by present members is required on motions to amend the LUREB Terms of Reference, or to expel a member, or suspend the rules. The chair shall vote only in the case of a tie vote.

#### **4.7 Researchers' Presence when their proposal is reviewed**

Research applicants (and in the case of students, the supervisor) may attend where a full review is required to participate in discussions about their proposals, but those researchers cannot be present when LUREB is making its decision.

#### **4.8 Impartiality and efficiency**

LUREB shall function impartially, provide a fair hearing to the researchers involved, and provide reasoned and appropriately documented opinions and decisions. LUREB should make its decisions on the ethical acceptability of research in an efficient and timely manner, and shall communicate recommendations, approvals and refusals to researchers in writing, in print or by electronic means, in accordance with their procedures.

#### **4.9 Reconsideration Process**

When LUREB is considering not to approve a proposal, it will provide the researcher with all the reasons for doing so and give the researcher an opportunity to reply before making a final decision.

#### **4.10 Content of the Minutes**

The minutes of each regular meeting shall clearly reflect LUREB's decisions, contain a summary of the discussions, the rationale for LUREB's decisions, and any dissenting opinion(s).

The portion of LUREB meetings pertaining to the discussion of cases is held *in camera*. The minutes of the LUREB are confidential but a summary of the minutes will be posted on the LU intranet.

#### **4.11 Access to personal portions of the Minutes**

Every researcher has access to the portion of the minutes that relates to his/her proposal. However, the LUREB may, from time to time, declare an *in camera* session to discuss a sensitive matter. The minutes for an *in camera* session will be maintained separately and confidentially, with the final decision recorded in the regular meeting minutes.

## **Section 5**

### **Appeals and Reviews**

Where researchers do not receive ethics approval, or receive approval conditional on revisions that they believe will compromise the feasibility or integrity of the proposed research, they are entitled to reconsideration by LUREB. If the researcher remains dissatisfied with the outcome of the reconsideration, he or she may appeal using the established appeal mechanism in accordance with institutional procedures. Researchers

may request, and LUREB shall provide reconsideration of decisions affecting a research project within one calendar month.

### **5.1 Review of Department (Delegated) REB Decision**

A researcher may request that a departmental (delegated) REB decision be reviewed by the LUREB, in which case the proposal will undergo full review. Such request must be made in writing, detailing the reasons for the request, and should be directed to LUREB's Chair.

### **5.2 Review of LUREB Decision**

Researchers may request that LUREB reconsider a decision that affects their project. They must do so in writing, detailing the reasons for their request within one calendar month of received LUREB's decision. Such requests shall be directed to the chair of LUREB.

### **5.3 Appeal of LUREB Decisions**

In cases when researchers and LUREB cannot reach agreement through reconsideration, the institution shall provide access to an established appeal process for the review of a LUREB decision where such institutional appeal process has been established by the institution and adopted by the LUREB. The appeal must be made in writing to the Chair of the LUREB and set out the reasons for the appeal as well as the specific provisions of the TCPS or of this policy that the appeal is based upon.

### **5.4 Mandate of the appeal body**

The mandate of the appeal body is to do the following:

- conduct a full review of the application and associated documentation in order to reach an independent decision;
- render a final and binding decision, by majority vote, which may either uphold the original decision; modify the original decision; or impose specific conditions for approval of the project;
- communicate the decision to the researcher and the Chair of LUREB;
- delegate to LUREB the responsibility for implementing and monitoring the final decision of the appeal body.
- The outcome of such an appeal is final.

## **Section 6**

### **Administrative Support**

#### **6.1 University Undertaking**

The LU BOG undertakes to provide appropriate human, administrative and financial resources to LUREB so that it can discharge its mandate including support for professional development of its members.

Laurentian University will indemnify and save members of the LUREB from any and all liability associated with the exercise of the members' duties while serving on LUREB.

## **6.2 Needs of LUREB**

The Chair of LUREB will submit annually an anticipated operational budget to the Vice-President, Research, and outline the human resources, administrative and financial needs necessary to support the work of LUREB. The request from the Chair of the LUREB will be taken into account by the Vice-President and there will be a dedicated budget line for the LUREB.

## **6.3 Records**

The Office of Research Services will maintain records regarding LUREB reviews and decisions for the full term of the research activity plus 7 years. Records will consist of the original proposal, the consent form, correspondence with regard to the review and reporting of the ongoing review process, including adverse events reports and their follow-up.

## **Section 7**

### **Approval, Ratification and Revision**

#### **7.1 Revision of the Terms of Reference**

The current LUREB Terms of Reference will be reviewed every three years or when the TCPS policy is revised.

#### **7.2 Approval and Ratification of the Terms of Reference**

Current and future updates of Terms of Reference will be presented to the BOG of Laurentian University through the REBLC for approval and to Senate for information.