



Terms of Reference for Research Ethics Board (REB)

Jurisdiction: Vice President, Research and Innovation; Board Audit and Risk Committee;

Approval Authority: Board of Governors;

Established on: April 1, 2012 (approved by Board Executive Committee on March 30, 2012);

Amendments: October 2015; June 2016.

A. Introduction

The Terms of Reference for the Research Ethics Board (REB) at Lakehead University are established by the Board of Governors in the Board of Governors Policy Framework on Research Ethics Involving Humans at Lakehead University (the Board Policy Framework).

In the Board Policy Framework, on behalf of Lakehead University, the Board of Governors has endorsed the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2 (TCPS 2) 2014 as the policy and compliance guide for the ethical conduct of research involving humans at the University.

The Lakehead University Research Ethics Board is established to fulfill the ethical responsibilities concerning research involving human participants in accordance with the standards developed by the Tri-Councils [Canadian Institute of Health Research (CIHR), Natural Sciences and Engineering Research Council (NSERC) and Social Sciences and Humanities Research Council (SSHRC)] and contained in the TCPS 2 2014. The Tri Councils only provide funding to researchers and institutions that are compliant with this Policy.

The REB is built upon the guiding core ethical principles as discussed by the TCPS 2 2014, of: respect for persons, concern for welfare, and justice. The application of these core principles is intended to maintain balance between the necessary protection of participants and the legitimate requirements of research.

Recognizing the importance of research and the need to ensure the ethical conduct of research at Lakehead University, the independent functioning of the REB requires REB members and researchers to navigate a course between the two main goals of providing the necessary protection of participants and serving the legitimate requirements of research through a transparent and accountable process for review of the ethical acceptability of research.

B. Mandate, Authority and Accountability

- 1) The mandate of the REB is to review the ethical acceptability of all research involving humans conducted under Lakehead University's jurisdiction or auspices by faculty members, staff or students, regardless of where the research is conducted in accordance with the TCPS 2 2014. This includes approving, rejecting and proposing modifications to protocols, or terminating any proposed or ongoing research involving humans that is deemed to be non-compliant with the TCPS 2 2014.

In support of fulfilling this mandate, the REB:

- establishes and communicates policies regarding the ethical conduct of research with human participants, along with guidelines and standard operating procedures that are consistent with the TCPS 2 2014 throughout the research process;
- contributes to education in research ethics that falls within the REB's mandate; and
- serves the research community and stakeholders as a consultative body regarding matters that fall within the REB's mandate.

2) Authority

The Board of Governors of Lakehead University has established the REB to ensure competent and independent research ethics review (TCPS 2 2014 Article 6.4). The REB will review the ethical acceptability of all research involving humans conducted within the University's jurisdiction or under its auspices, by their faculty, staff or students, regardless of where the research is conducted, in accordance with the TCPS 2 2014.

The REB is independent of the Board of Governors, Senate, and Senior Administration in its decision-making with respect to its mandate under the TCPS 2 2014. All other entities and offices shall respect the independence, accountability and authority delegated to the REB and may not override an REB decision to approve or reject a research proposal. Information regarding the appeal process is found in Section C of this document.

An REB approval applies to the ethical acceptability of the research and does not, in itself, constitute authorization for the research to proceed (such reasons may be administrative or resource-based in nature).

3) Accountability

In keeping with TCPS 2 2014, and the Board of Governors Policy Framework, the REB Chair is responsible for ensuring that the REB process conforms to the requirements of TCPS 2 2014 (Article 6.8). The REB and the REB Chair are accountable to the Board of Governors for the integrity of its research ethics review process. For oversight and risk management purposes, beyond an Annual Report to the Board of Governors, when immediate or incidental reporting is required, the REB Chair will notify the President who will notify the Chair of the Board of Governors. For day-to-day administrative matters, the Chair of the REB will report to the President.

In keeping with the Board of Governors Policy Framework on Research Involving Humans, the REB Chair shall prepare an Annual Report to the Board of Governors. The Annual Report shall include the number of proposals reviewed, approved, and rejected, the submitting Faculties, a generic description of research ethics issues/concerns that have been addressed in the past year, and frequency of use of the REB appeals process. The Report shall also demonstrate compliance with the mandatory provisions in the TCPS 2 2014 and identify any issues regarding process integrity of research review (initial and continuing) at Lakehead University. Concerns or 3 suggestions regarding the REB Terms of Reference should also be included for discussion with the Board of Governors at this time.

C. Reconsideration and Appeal Process

Lakehead University's Research Ethics Appeal Board shall be Laurentian University's Research Ethics Board. Laurentian University's Research Ethics Appeal Board shall be Lakehead University's Research Ethics Board. The specific terms and procedures for filing an appeal shall be outlined in an inter-institutional agreement between both Universities in accordance with the TCPS 2 2014 and in alignment with the Lakehead University Board of Governors Policy Framework on Research Ethics Involving Humans.

D. REB Meetings and Membership

Meeting Schedule and Notice

The REB will schedule meetings monthly from September through May. Additional meetings will be held whenever necessary. Seven (7) days notice shall be given for all meetings except that a meeting may be held at any time, if required, without due notice if quorum is met.

Meeting Decisions

Decisions related to the REB's mandate shall be by consensus as declared by the Chair. In accordance with the TCPS 2 2014, in the event that a minority within the REB membership considers a research project unethical, even though it is acceptable to a majority of members, an effort should be made to reach consensus. Consultation with the researcher, external advice, peer review or further reflection by the REB may be helpful.

Quorum

Quorum is met when the minimum requirements of membership representation are present (TCPS 2 2014 Article 6.9, 6.4). The minimum requirements are as follows:

- At least two members with expertise in relevant research disciplines, fields and methodologies covered by the REB;
- At least one member knowledgeable in ethics; and
- At least one community member who has no affiliation with the institution.

The presence of a member knowledgeable in the relevant law is only mandatory when reviewing biomedical research.

When there is less than full attendance, decisions requiring full review should be adopted only when the members in attendance at that meeting have the specific expertise, relevant competence and knowledge necessary as determined by the Chair to provide an adequate research ethics review of the proposals under consideration.

Ad hoc advisors, observers, research ethics administration staff and others attending REB meetings should not be counted in the quorum. Nor should they be allowed to vote on REB decisions (TCPS 2 2014 Article 6.9). Decisions made without a quorum are not valid or binding.

Composition and Appointment of Members

The membership of the REB is designed to ensure competent and independent research ethics review.

Annually, the REB determines the need for expertise in relevant research disciplines in order to ensure competent independent research ethics review (TCPS 2 Article 6.4). Members shall be appointed by the President on the recommendation of the Chair of the Research Ethics Board. The REB may consult with Faculty Deans, Department Chairs and the Office of Research Services in maintaining appropriate REB membership. Appointments are for three-year terms, renewable once.

The complement of the REB will be determined by the ongoing needs of the University, but should include:

1. Minimum of six full time faculty members who have expertise in relevant research disciplines, fields and methodologies covered by the REB.
2. Minimum of two community members who have no affiliation with the institution but are recruited from the communities served by Lakehead University with preference that one of the community members be of Aboriginal origin.
3. One member with knowledge in the area of ethics. This can be someone who has a teaching or research specialization in ethics, or someone who has had extensive experience in the area of research ethics.
4. One full time faculty member whose research involves Aboriginal people.
5. A minimum of one member with a biomedical background.
6. One member knowledgeable in the relevant law (but the member should not be Lakehead University's legal counsel or risk manager).

The Director, Office of Research Services, is the senior advisor to the REB in all matters associated with its mandate, compliance monitoring, and reporting.

The Research Ethics and Administration Officer is the Secretary to the REB.

Each member shall be appointed to formally fulfill the requirements of only one of the above categories.

In accordance with the TCPS 2 2014 (Chapter 7: Conflicts of Interest), senior administrators or members of the Board of Governors shall not serve on the REB, or directly or indirectly influence the REB decision-making process.

Ad hoc advisors may be consulted in the event that the REB lacks the specific expertise or knowledge to review the ethical acceptability of a research proposal competently.

Chair

The REB Chair is responsible for ensuring that the REB review process conforms to the requirements of the TCPS 2 2014. Their role is to provide leadership and to facilitate the REB review process, based on institutional policies and procedures and the TCPS 2 2014. The Chair should monitor the REB'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 (TCPS 2 Article 6.8). The Chair shall hold a tenured position with Lakehead University.

Vice Chair

The REB Vice Chair also holds responsible for ensuring that the REB review process conforms to the requirements of the TCPS 2 2014. The Vice Chair will fulfil the role of the Chair when the Chair is either not available, or there is a conflict of interest declared by the Chair. Ideally, the Vice Chair will move into the Chair position when the Chair either leaves the REB or completes their term.

Chair and Vice Chair Selection

The Chair and Vice-Chair shall be appointed by the President based on the recommendation of the REB normally from among the appointed members and shall serve, normally, for a term of three years, once renewable. Preferably, the Vice-Chair will hold a tenured position with Lakehead University, however it is not necessary.

The Chair and Vice-Chair shall not serve in the positions of community member.

Meeting Attendance

Where a member is absent for more than 50% of meetings per academic year, the Chair of the REB shall review whether that member should continue to serve on the REB in a report to the President. Unexpected circumstances such as emergencies may prevent individual member(s) from attending the REB meeting. In these exceptional cases, input from member(s) by the use of technology (e.g., phone or video link) is acceptable.

Conflicts of Interest

Any REB member who has a personal/professional interest or a real or perceived conflict of interest with a research proposal under review (as Principal Investigator, Co-Investigator, Supervisor, student, funder) shall not be present when the REB is making its decision.

E. Administrative Support

Secretary: Research Ethics and Administration Officer

Administrative Office: Office of Research Services

The REB will be provided human resources, office space and support services from the Office of Research Services in order to fulfill the REB duties.

F. Departmental Undergraduate Ethics Review

The REB delegates the ethical review of undergraduate research projects of minimal risk to Undergraduate Research Ethics Committees (URECs) which are responsible for reviewing any undergraduate course-based research projects and honours theses that involve research on human participants, and/or are a component of the pedagogical process.

Undergraduate level review cannot be used when a student's project is part of a faculty member's own research program. Such research must receive ethics approval from the Lakehead University Research Ethics Board.

URECs are responsible for referring to the REB any matter of ethical concern that the undergraduate research ethics committee is, by reason of disagreement or otherwise, unable to resolve, or is greater than minimal risk as defined by the TCPS 2 2014.

Academic units regularly engaged in human participant research are to maintain an active undergraduate research ethics committee charged with the review and monitoring of undergraduate research. This committee shall consist of a minimum of three faculty members who have completed the TCPS 2014 Course on Research Ethics (CORE). The committee must be registered with the REB, and keep formal records of their deliberations and decisions. A list of approved projects must be submitted to the REB twice annually, in January and July. Departments not regularly involved in human participant research are required to forward undergraduate research proposals involving human participant research to the REB for review.

For additional information, please refer to the Undergraduate Research Ethics Committee (REC) Terms of Reference document approved by the REB in December 2014.