



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; October 3, 2019; October 1, 2020,
November 25, 2021

A. Introduction

The Terms of Reference for the Lakehead University Research Ethics Board (REB) 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 (TCPS2), as amended from time to time, as the policy and compliance guide for the ethical conduct of research involving humans at the University.

The Lakehead University REB is responsible for fulfilling 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 TCPS2. 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 TCPS2, 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.

The need to ensure the ethical conduct of research at Lakehead University, and the independent functioning of the REB requires REB members and researchers to navigate a course between two main goals: 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.

B. Mandate, Authority and Accountability

1) Mandate

The mandate of the REB is to review the ethical acceptability of all research involving humans conducted under Lakehead University's jurisdiction or auspices. This includes research undertaken by faculty members, adjunct professors, staff, postdoctoral fellows, or students, regardless of where the research is conducted in accordance with the TCPS2. This also includes research that is reviewed by the Lakehead University REB in accordance with the REB Reciprocity Agreement signed between the Thunder Bay Regional Health Sciences Centre and Lakehead University.

This mandate includes approving, rejecting and proposing modifications to protocols, continuing review of protocols, or terminating any proposed or ongoing research involving humans that is deemed to be non-compliant with the TCPS2.

To fulfill this mandate, the REB:

- establishes and communicates policies, guidelines, and standard operating procedures regarding the ethical acceptability of research with human participants, along with guidelines and standard operating procedures that are consistent with the TCPS2 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 (TCPS2 2018 Article 6.4) in accordance with its approved mandate.

The REB is independent of the Board of Governors, Senate, and Senior Administration in its decision-making with respect to its mandate under the TCPS2. 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 TCPS2, and the Board Policy Framework, the REB Chair is responsible for ensuring that the REB process conforms to the requirements of TCPS2 2018 (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. However, 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 REB Chair will report to the President.

In keeping with the Board Policy Framework, the REB Chair shall prepare and submit 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 TCPS2 and identify any issues regarding process integrity of research review (initial and continuing) at Lakehead University. Concerns or suggestions regarding the REB Terms of Reference should also be included for discussion with the Board of Governors at this time.

These REB Terms of Reference shall be reviewed at least every three (3) years or sooner in order to ensure compliance with changes to the TCPS2.

When an official agreement (e.g. reciprocal agreement) is in place with a third party, the REB follows the reporting structure for such third party outlined in the agreement for studies falling under that agreement.

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 TCPS2 and in alignment with the Board Policy Framework.

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.

Five (5) business days' notice shall be given for all meetings except that a meeting may be held at any time, if required under exigent circumstances, without due notice if a quorum is established.

Where a member is absent for more than 50% of meetings per academic year, the REB Chair 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, participation by member(s) by the use of technology (e.g., phone or virtual) is acceptable.

Remote Participation using Electronic Technology

Meetings shall normally be held in person but may be held by teleconference, videoconference, or other technological means, when circumstances warrant, at the discretion of the REB Chair. Any member joining a meeting by such electronic means shall be provided with all meeting materials for prior review and be included in determining quorum for the meeting.

Meeting Decisions

Decisions related to the REB's mandate shall be by consensus as declared by the REB Chair. In accordance with the TCPS2, 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 (TCPS2 2018 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.
- In addition, the presence of a member knowledgeable in the relevant law is required when reviewing biomedical research.

Decisions requiring full review should only be made when the members in attendance at that meeting have the specific expertise, relevant competence and knowledge necessary as determined by the REB Chair; this is to ensure that an adequate research ethics review is conducted 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 (TCPS2 2018 Article 6.9). Decisions made without a quorum are not valid or binding upon the REB.

Composition and Appointment of Members

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

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; at least one community member must self-identify as Indigenous.
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 area of expertise includes Indigenous knowledge (i.e., governance, culture, community relations, economies, politics, research methodologies and ethics, and the law).
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 internal legal counsel or risk manager).

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.

Recruitment and Appointment of New REB Members

Annually, the REB assesses the need for expertise (based on attrition and vacancies) in the relevant research disciplines in order to ensure competent independent research ethics

review (TCPS2 2018 Article 6.4). The REB shall seek new members through an open call and direct recruitment within Lakehead University; the open call will specify the research disciplines, fields and methodologies that are being sought to ensure compliance with these TOR. Expressions of interest to serve on the REB, supported by the member's Faculty Dean, will be reviewed by the REB and final recommendations shall be made by consensus. Each member shall be appointed to formally fulfill the requirements of only one of the above categories.

New members will be recommended to the President by the REB and new REB members shall be appointed by the President.

Terms

Appointments are for three-year terms, renewable once. An exception to the term of an appointment can be made for the members elected to the REB Chair and/or REB Vice-Chair positions; this will enable a member to serve 3 years as REB Vice-Chair, then 3 years as REB Chair to ensure continuity of leadership on the REB.

REB Chair

The REB Chair is responsible for ensuring that the REB review process conforms to the requirements of the TCPS2. Their role is to provide leadership and to facilitate the REB review process, based on institutional policies and procedures and the TCPS2. The REB 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 REB Chair or his or her designate (TCPS2 2018 Article 6.8). The REB Chair shall hold a tenured position with Lakehead University.

REB Vice-Chair

The REB Vice-Chair also holds responsible for ensuring that the REB review process conforms to the requirements of the TCPS2. The REB Vice-Chair will fulfil the role of the REB Chair when the REB Chair is either not available, or there is a conflict of interest

declared by the REB Chair. Ideally, the REB Vice-Chair will move into the REB Chair position when the REB Chair either leaves the REB or completes their term.

REB Chair and REB Vice-Chair Selection

The REB Chair and REB 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. The REB Vice-Chair will hold a tenured position with Lakehead University.

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

Conflicts of Interest

Any REB member who has a personal/professional interest or a real or perceived conflict of interest with an issue, project or proposal under review (for example, as Principal Investigator, Co-Investigator, Supervisor, student, funder) must declare a conflict of interest and shall not be present when the REB is conducting its discussions or deliberations.

E. Research Ethics Administration and Compliance Support

Through the Office of Research Services, the REB will be provided human resources, office space and support services from the Office of Research services, subject to budgetary approval, in order to fulfill the REB mandate and duties described above; such support may include resources for educational activities and professional development for REB members.

The director, office of Research Services, is the senior advisor to the REB in all matters associated with its mandate, compliance monitoring, and reporting (ex-officio non-voting).

The Manager, Research Ethics and Contracts Officer provides guidance and support to the REB (ex-officio, non-voting).

The Research Ethics Coordinator is the Secretary to the REB.

In accordance with the TCPS2 (Chapter 7: Conflicts of Interest), employees of Lakehead university who are 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.

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 with human participants, and/or are a component of the pedagogical process.

Delegation to URECS is not appropriate 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 UREC is, by reason of disagreement or otherwise, unable to resolve, or is greater than minimal risk as defined by the TCPS2.

Academic units regularly engaged in human participant research are to maintain an active UREC charged with the review and monitoring of undergraduate research. Each UREC shall consist of a minimum of three faculty members who have completed the TCPS2 Course on Research Ethics (CORE). Each UREC must be registered with the REB, keep formal records of their deliberations and decisions, and submit a list of approved projects 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.