

Lakehead University Research Ethics Board (REB) Terms of Reference

Effective Date: *[proposed to be April 1, 2012]*

Approved by the Board of Governors

A) Introduction

The Lakehead University Research Ethics Board (REB) is responsible for overseeing all ethical matters related to research involving human participants undertaken for teaching and/or research purposes and conducted by Lakehead University faculty, staff, and/or students. Lakehead University endorses the principles set out in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2 (2010) (TCPS 2).

The guiding core ethical principles, as defined by the TCPS 2, are:

- respect for persons,
- concern for welfare, and
- justice

The application of the core principles ensures that a balance between providing the necessary protection of participants and serving the legitimate requirements of research is maintained.

The importance of research and the need to ensure the ethical conduct of research requires both researchers and REB members to navigate a course between the two main goals of providing the necessary protection of participants and serving the legitimate requirements of research.

B) Purpose

The purpose of the REB is:

- 1) 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. The Tri-Councils only provide funding to researchers and institutions that are compliant with this Policy.
- 2) to review the ethical acceptability of all research involving humans conducted under Lakehead University's jurisdiction or auspices, that is by faculty members, staff or students, regardless of where the research is conducted to ensure that research is compliant with the TCPS 2. 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.

- 3) to establish and communicate ethics policies, procedures and standard operating procedures that are consistent with the TCPS 2 and to ensure that they remain current.
- 4) to serve the research community as a consultative body and to contribute to education in research ethics.

C) Authority

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

Although established by the Board of Governors, the REB is independent in their decision-making. Lakehead University shall respect the authority delegated to the REB and may not override an REB decision to reject a research proposal. Information regarding the appeal process is found in Section E 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).

D) Reporting Relationship

The REB shall report annually to the Board of Governors through the President. When immediate reporting is required, the REB Chair will report directly to the President.

The REB Chair shall prepare by July 1 each year an annual report for the Board of Governors to be presented by the President. The report shall include the number of proposals reviewed/rejected and the submitting faculties, a generic description of ethics issues/concerns that have been addressed in the past year, and if necessary, recommendations concerning changes to the REB Terms of Reference.

E) 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 and be in accordance with the TCPS 2.

F) 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 without due notice if quorum is met.

Meeting Decisions

Business involving decisions related to research protocols shall be by consensus as declared by the Chair. In accordance with the TCPS 2, 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 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 and;
- 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.

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 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. Two community members who have no affiliation with the institution but are recruited from the communities served by Lakehead University.
3. One member with expertise 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).
7. Research Ethics and Administration Officer (Secretary to the REB and non-voting).
8. Director, Office of Research Services (non-voting).

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

Senior administrators or members of the Board of Governors shall not serve on the REB, nor 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. Their role is to provide leadership and to facilitate the REB review process, based on institutional policies and procedures and the TCPS 2. 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).

Chair Selection

The 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 Chair shall hold a tenured position with Lakehead University.

The Chair shall not serve in the positions of community member, member with expertise in the area of ethics, or member knowledgeable in relevant law.

Meeting Attendance

Where a member is absent for more than 50% of the face-to-face meetings 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.

Observers

At the Chair's discretion, observers may be admitted to REB meetings provided that they sign a confidentiality agreement and they do not have a conflict of interest with the specific meeting agenda. Observers may participate in discussions but will not be permitted to vote.

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.

G) 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.

H) Departmental Undergraduate Ethics Review

The REB delegates the ethical review of undergraduate research projects to Departmental Ethics Committees which are responsible for reviewing any undergraduate course-based research projects and honours theses that involve research on human subjects, and/or are a component of the pedagogical process.

Departmental Committees are responsible for referring to the REB any matter of ethical concern that the Departmental Committee is, by reason of disagreement or otherwise, unable to resolve, or is greater than minimal risk as defined by the TCPS 2.

Academic units regularly engaged in human subject 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 2 Course on Research Ethics (CORE). The committee must be registered with the Office of Research Services, 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 subject research are required to forward undergraduate research proposals involving human subject research to the REB for review.

Departmental 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.

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