



Policy Framework for Research Ethics Involving Humans at Lakehead University

Category: Research;

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

Approval Authority: Board of Governors;

Established on: March 30, 2012;

Amendments: None;

Most Recent Review: September 10, 2020; September 9, 2021; September 29, 2022;

Introduction and Background

In keeping with its objects and purposes, the Board of Governors of Lakehead University, on behalf of the institution, is committed to the ethical integrity of all research involving humans conducted in its jurisdiction or under its auspices, by its faculty, staff or students, regardless of where it is conducted.

The Board acknowledges there is potential risk for participants and society involved with the conduct of research. On behalf of Lakehead University, the Board endorses the Tri Council Policy Statement: Ethical Conduct for Research Involving Humans 2 (TCPS 2) as the policy and compliance guide for the ethical conduct of research involving humans at the University.

Governance of Research Ethics at Lakehead University

The Board of Governors will exercise its overall governance, risk management and oversight duties (including compliance monitoring and reporting) with respect to research involving humans in alignment with the TCPS 2, as set out below.

1. Through this Policy Framework, establishing an independent Research Ethics Board (REB) the mandate of which shall be clearly stated as, "To review the ethical acceptability of research involving human participants", in keeping with the scope and application of this mandate, as set out in TCPS 2.
2. In establishing the REB, delegating the authority and duty to independently review the ethical acceptability of research involving human participants (initially and ongoing) including: approving, rejecting, proposing modifications to, or terminating any proposed or ongoing research involving human participants; and providing for an appeals process, in keeping with mandatory provisions and policy guidelines in TCPS 2.
3. Identifying the Chair of the REB as responsible for ensuring that the REB process conforms to the requirements of TCPS 2 and accounts to the Board of Governors through a reporting process set out in this Policy Framework and in the Terms of Reference of the REB.
4. Providing for the necessary financial and administrative resources to support the REB in keeping with the mandate as stated in 1 above, and the requirements of TCPS 2.
5. The Board establishes the [Terms of Reference for the REB](#) that clearly state the mandate, authority, and accountability for the REB, in accordance with the TCPS 2 Policy, in keeping with the following:
 - a) With respect to the REB's mandate as stated in 1 above, the Board of Governors acknowledges and ensures the independent authority of the REB with respect to its mandate. For process integrity purposes, the REB shall exercise its mandate independent of and free of undue influence from the Board of Governors, Senate, faculty or senior administration in keeping with the Conflict of Interest definition* set out in the Glossary and discussed in Chapter 7 of the TCPS 2, and as required by applicable law.
 - b) Requiring that the REB carry out its mandate using a process that provides for the core principles of respect for persons, concern for welfare, and justice. The REB will carry out its mandate with a level of scrutiny proportional to foreseeable risks, potential benefit, and ethical implications of each project, and with due attention to research ethics and law, the perspective of the participant, and

- appropriate expertise for review, in keeping with the TCPS 2 policy and application guidance.
- c) Requiring the Chair of the REB to report to the Board of Governors annually or when otherwise requested or required, on the integrity of its ethical acceptability review process (initial and continuing). Such reporting shall include the provision and use of an established appeals process. Such reporting shall be in keeping with this Board Policy Framework, with particular reference to 5b. above, and the approved Terms of Reference of the REB. Such reporting shall demonstrate or reference compliance with the mandatory provisions in the TCPS 2. The report will also identify any issues regarding process integrity of research review at Lakehead University that may require discussion with the Board of Governors.
 - d) Requiring that the Board of Governors be informed immediately of any internal or external challenge to the integrity of research ethics at Lakehead University or compliance with the TCPS 2.
 - e) Requiring the Chair of the REB to report to the Board of Governors any suggestions for change to the Terms of Reference for the REB in advance of effecting or acting on any such suggested or requested change.

Public Accountability and Reporting

On behalf of Lakehead University, the Board of Governors shall publish an Annual Report summarizing the institution's activities and initiatives relevant to research involving humans, its research ethics administration, and relevant research ethics education and training.

Monitoring and Review of Board of Governors Research Ethics Policy Framework

The Board of Governors will review this Board Policy Framework and make any necessary changes, annually or when issues or challenges arise that require its review.

* Conflict of Interest is defined in the TCPS2 Glossary as, "The incompatibility of two or more duties, responsibilities, or interests, (personal or professional) of an individual or institution as

they relate to the ethical conduct of research, such that one cannot be filled without compromising the other."

Review Period: 3 years;

Next Review Period: 2024-2025;

Related Policies and Procedures: Terms of Reference for Research Ethics Board;

Policy Superseded by this Policy: None.

The University Secretariat manages the development of policies through an impartial, fair governance process, and in accordance with the Policy Governance Framework. Please contact the University Secretariat for additional information on University policies and procedures and/or if you require this information in another format:

Open: Monday through Friday from 8:30am to 4:30pm;

Location: University Centre, Thunder Bay Campus, Room UC2002;

Phone: 807-346-7929 or Email: univsec@lakeheadu.ca.