



Research Ethics: Research involving Human Subjects Trent University Research Ethics Board (REB) Protocol

All research conducted under the auspices of Trent University by faculty, staff, or graduate students, funded or unfunded, that involves human subjects requires approval in advance from the Research Ethics Board.

In the case of undergraduate student research with human subjects, departments/programs shall review student research proposals according to departmental ethics criteria as approved by the Research Ethics Board. In the case where a department/program has not ethics review procedures, they are mandated to develop these so that undergraduate research proposals involving human subjects can be reviewed. Assistance can be provided by the Research Ethics Board to departments/programs in developing such procedures.

Research projects which involve human remains, cadavers, tissues and biological fluids, embryos or fetuses must be forwarded to the Research Ethics Board.

Trent University is responsible for the ethical conduct of all research undertaken by its faculty, staff, graduate and undergraduate students. In instances where research is conducted off site (i.e. Peterborough Regional Health Centre, local elementary or secondary schools, community services, etc.) ethical review is required by the Trent University Research Ethics Board and the governing body which has jurisdiction of the site of research. Where research is to be conducted outside of Canada, the researcher is required to secure ethics certificates as regulated and provide proof of ethical certification to the Trent University Research Ethics Board prior to starting any research program involving living human subjects.

Trent University Procedures:

The Trent University Research Ethics Board is a standing committee of Senate, reporting and accountable to Senate. The Research Ethics Board will advise Senate and the Associate Vice-President, Research on all matters of research involving human subjects at Trent University.

The role of the Research Ethics Board is to review proposals by members of the university, and others who conduct research involving human subjects at Trent, to determine conformance with the whole of the Tri-Council Policy Statement, Ethical Conduct for Research Involving Human Subjects". This document should serve to safeguard the rights and welfare of human subjects and participants. Accordingly, the scope of the Tri-Council Policy Statement and the required ethics review normally applies only to research involving human subjects who are living. Ethics review is usually not required for research based on materials in the public domain, where interaction with the living human subjects is not involved. The University also re-affirms its support of basic guiding values established by the academic community, including a commitment to academic freedom, fairness, and the proportionate approach to ethics assessment and the work of the Research Ethics Board will reflect these values and commitments. In all cases, the Research Ethics Board is to strive to balance the principals of protection of the rights of human subjects and of researchers. In the absence of clear evidence of more than minimal risk to human subjects, constraints on research should likewise be minimal.

RESEARCH ETHICS BOARD (REB)

Terms of Reference

An independent Board of the Research Policy Committee

- The Research Ethics Board (REB) will operate in accordance with the Tri Council Policy Statement on "Ethical Conduct for Research Involving Humans".
- All research conducted under the auspices of Trent University by faculty, staff, or graduate students, funded or unfunded, that involves human subjects requires approval in advance from the REB. Research with human subjects at Trent University, but conducted by others, also requires prior approval. Proposals for undergraduate student research with human subjects shall be reviewed by the departments/programs involved in accordance with criteria approved by the REB.
- The REB shall review proposals by members of Trent University, and others who conduct research with human subjects at Trent, to determine compliance with the Tri-Council Policy Statement. The REB may approve, reject, propose modifications to or terminate any proposed or on-going research involving human subjects which is conducted within, or by members of, Trent University, using the considerations set forth in the Tri Council Policy Statement as the minimum standard.
- In cases where researchers and the REB cannot reach agreement through discussions and reconsideration, an appeal against a decision of the Research Ethics Board may be directed to the Research Ethics Appeal Board.

- The REB will act in an advisory capacity to the Research Policy Committee, the Associate Vice-President, Research, and to members of the University conducting research with human subjects on all matters of research involving human subjects at Trent University and other related matters of ethics in research.

Composition

3 faculty (normally one each from humanities/social sciences, psychology, physical/biological sciences) - one to Chair
 1 (other) faculty member, knowledgeable in ethics
 1 community representative
 1 graduate student
 Co-ordinator of Research & Graduate Studies (secretary, non-voting)

RESEARCH ETHICS APPEAL BOARD (REAB)

Terms of Reference

An independent Appeals Board of the Research Policy Committee to be convened in the case of an appeal

- To provide an independent appeal process in the case of an appeal from a decision of the Research Ethics Board
- Decisions of the Research Ethics Appeal Board are final, subject to further procedures as may be provided through collective agreements

Composition

An Associate Dean of Arts and Science (Chair)
 Chair (or designate) of department of the appellant
 2 faculty with previous experience on the Research Ethics Sub-Committee
 Co-ordinator of Research & Graduate Studies (secretary, non-voting)

UNDERGRADUATE DEPARTMENT CHAIRS/DIRECTORS

Terms of Reference:

Responsibilities of Departments

1. To submit to the Research Office a written description of the procedure used for providing ethics review for undergraduate theses conducted through the department.

The following should be included:

- a) If the department has a constituted Research Ethics Board (REB), a description of how it is constituted (e.g., as a standard departmental committee, ad hoc, size of membership, etc).
 - b) How thesis projects considered greater than minimal risk are handled.
 - c) How thesis projects that are part of the thesis supervisor's research are handled.
2. To submit to the Research Office a written report on any subsequent revisions to this procedure, as soon as possible following its revision.
 3. To submit copies of any departmental documents used by students to prepare and submit ethics applications (e.g., application forms, policy statements, instructions, etc.)
 4. At the beginning of each academic term, to notify the Research Office of the names and contact information for members of the departmental REB.

Responsibilities of Departmental Research Ethics Boards

1. To ensure that all members of the REB have read and are aware of the Tri-Council Policy Statement *Ethical Conduct for Research Involving Humans*.
2. To issue a written report to the Research Office at the end of each Academic Term containing the following information about each approved thesis project:
 - a. Project name
 - b. Student investigator
 - c. Faculty supervisor

REB PROCEDURES:

Applications for Ethical Review of Proposed Research forms can be downloaded from the Research website <http://www.trentu.ca/research/forms.html>

Applications are due on the last Monday of each month without exception. Late applications will be held until the next month. All applications are to be submitted with one original and three complete copies. Applications normally take 4-6 weeks to review. The normal protocol for processing applications is as follows:

- 1) All applications are assigned a REB number which is to be quoted on all correspondence related to the application and the proposed project;
- 2) Applications are recorded in the REB database and then circulated to the members of the REB

- 3) The REB meets to discuss the applications and assign the applications to one of the following categories:
- a. Approved (no revisions required) Ethics approval normally applies for a period of one (1) year. Please note that fundamental changes to a previously approved research project involving human subjects must be reported to the REB for review.
 - b. Approved for initial stage only (Normally, this refers to (i) the stage where research instruments are to be developed and re-evaluation is required before the instruments are taken into the field and used on human subjects, or (ii) to the first stage of a multi-phased research project in which research instruments will be developed at a later date and are depended on first-stage results/data
 - c. Delayed Approval (Applies when the REB identifies points within the application which require clarification, amendment, expansion, etc.) Normally, once the concerns are satisfactorily addressed, the Chair of the REB has the authority to grant ethics approval.
 - d. Not approved (The REB is not able to approve the application. Normally reasons will be provided)

Research Projects Monitoring Process:

1. All projects approved by the REB must include the REB reference number of all materials related to the project where appropriate.
2. Researchers are required to fill out an annual status report for all their research projects that received ethics approval and forward the report to the Office of Research. The status report can be used to close the ethics file on a project or to extend the ethics approval if necessary. In the case of undergraduate research, Department Chairs are required to submit an annual report to the Office of Research.
3. Random Audit: The REB, in collaboration with the Office of Research reserves the right to randomly monitor active research projects previously approved by the REB to ensure compliance with the Tri-Council policy and the policies of the REB.

COMPLIANCE

All projects involving humans subjects must be approved prior to any contact with the human research subjects with out exception. All projects, whether funded or unfunded must abide by the protocols for ethical review identified by Trent University.

