Ethics Procedures for Reviewing Research Involving Human Participants

1.0 The Ethics Review Process

1.1 Overview of the Ethics Review Process

All research conducted at Trent University that is subject to ethics review must be approved by the University-wide Research Ethics Board (REB) or by one of its representative subcommittees. The purpose of the review is to help researchers achieve ethics compliance according to the standards established in the Tri-Council Policy Statement on the Ethical Conduct of Research Involving Human Participants (TCPS2, 2022). The REB shall conduct either a full or delegated review, depending on the level of risk, the status of the research, and the urgency of review[1]. Minimal-risk course-based research activities undertaken for pedagogical purposes only may be reviewed by a Faculty/Department/School Ethics Review Committee.

Research to be conducted with or in relation to Indigenous Peoples in Canada must be reviewed by REB members from the Chanie Wenjack School for Indigenous Studies. These members serve both the REB ethics review responsibility for the file AND the Indigenous ethics review process responsibility as well. The Indigenous ethics review responsibility/authority is given to these REB members by the Indigenous Education Council (IEC). This group includes community leaders from the surrounding First Nations communities and senior University administrators. The IEC is an Indigenous education advisory body at the University.

The Indigenous ethics review process is conducted to ensure that Indigenous research at Trent observes recognized ethical standards for conducting Indigenous research, including the Ethical Guidelines for Research outlined by the Royal Commission on Aboriginal Peoples to represent best practices, the TCPS2 (2022) Chapter 9: Research Involving the First Nations, Inuit, and Métis Peoples of Canada, and other emerging codes in Indigenous research.

All researchers must complete and submit the relevant ROMEO Application Form[2] for ethics approval by the REB. The review shall be conducted according to the principles and procedures set out in this document. If the REB refuses to approve the research or if the body requires amendment to the research as a condition of approval and the Principal investigator disagrees with the proposed amendments, the Principal Investigator may appeal the REB's decision to the Trent Ethics Appeal Board[3] which shall conduct an ethics review of both the Application and a review of the procedures followed by the REB. Research that is subject to ethics review and that is not approved may not be undertaken.

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[1] The types of review are described in Section 1.4.

[2] Applications are submitted on the Romeo system found through the "MyTrent" portal.

[3] The Trent Ethics Appeal Board is described in Section 1.9.

1.2 Governing Principles of the Ethics Review Process

I. Review procedures should ensure that there is accountability to Senate by way of documented correspondence between the researcher and the REB;

II. Reviews should be conducted, and structured feedback provided to the applicant, in an efficient and timely manner. The efficiency with which the REB works depends very much on the quality and completeness of the initial submission by the researcher. If the initial submission is complete,

- minimal-risk course-based research activities undertaken for pedagogical purposes take 2-4 weeks to review, inclusive of minor revisions
- faculty and student minimal-risk research protocols take 4-8 weeks to review, inclusive of minor revisions
- faculty and student above-minimal-risk protocols need at least 6 weeks to review. These protocols must be reviewed by the full REB and discussed at a monthly meeting. The REB may need to arrange peer-review and, depending on the nature of the risk and participant vulnerability, the full REB may elect to discuss the protocol revisions at a subsequent meeting.

III. Situations may arise where the loyalties of members of the REB may be divided or where their personal or professional interest may conflict with their duty to the REB. Members of the REB who are in a real or perceived conflict of interest with respect to protocols under review or to applicants thereof will exempt themselves from the review in question (Chapter 7, Section A, TCPS 2 (2022)).

1.3 Principle of Proportionate Review

The REB will use a proportionate approach, wherein proposals with greater foreseeable risks will be expected to provide greater justification as to how the exposure of participants to these risks is outweighed by any potential benefits. Potential harms are usually defined in terms of the magnitude of potential harm to participants and the probability of its occurrence. Both potential harms and benefits may span the spectrum from minimal through significant or substantial. A proportionate approach to ethics review thus starts with an assessment, primarily from the viewpoint of the potential participants, of the character, magnitude and probability of potential harms inherent in the research. The concept of minimal risk provides a foundation for proportionate review.

Minimal risk research means research in which the probability and magnitude of possible harms implied by participation in the research are no greater than those encountered by participants in the aspects of their everyday lives that relate to the research.

1.4 Types of REB Review

A proportionate review implies different levels of REB review for different research proposals. The status and the level of risk involved in the research shall determine whether the proposal undergoes delegated or full-board review.

(a) Delegated Review

This is the most common type of review. Research projects meet the criteria for Delegated Review when:

I. The project involves no more than minimal risk; or

II. The request is to renew an approved project in which there has been little or no change in the ongoing research; or

III. The request is to amend an approved project of no more than minimal risk; or

IV. Research conducted to address publicly declared emergencies.

Applications under delegated review shall be reviewed by a subcommittee of the REB. The subcommittee will be made up of an assigned member of the REB who Chairs this sub-committee, the Coordinator, Research Conduct and Reporting, and additional member(s) of the REB as warranted.

(b) Delegated Review of Indigenous Research

All minimal-risk faculty and graduate student research applications that involve/impact Indigenous communities are delegated to the REB members from the Chanie Wenjack School for Indigenous Studies. These members serve both the REB ethics review responsibility for the file AND the Indigenous ethics review process responsibility as well. The Indigenous ethics review responsibility/authority is given to these REB members by the Indigenous Education Council (IEC). This group includes community leaders from the surrounding First Nations communities and senior University administrators. The IEC is an Indigenous education advisory body at the University.

c) The Scholarship of Teaching and Learning

Minimal-risk research examining teaching practices where faculty or students' coursework or course evaluations (either routine or research-specific) form part of the dataset and/or the intention of the researcher is to disseminate an examination of their teaching practices widely. These proposals are reviewed by the REB.

(d) Faculty/Department/School

Minimal-risk course-based research activities for pedagogical reasons. These are research activities presented as course assignments and/or lab activities that ask students to collect data from each other or from other persons by way of learning and practicing research techniques (e.g., interviewing, completing surveys, completing performance tasks, etc.). This data is not intended for publication. These protocols will be reviewed by a Faculty/Department/School ethics review committee whose members are not members of the REB and who must have the expertise and knowledge comparable to what is expected of a REB member.

(e) Full Review

All other research that is subject to review by the REB shall be reviewed by the full REB.

1.5 Scholarly Review as Part of the Ethics Review

For minimal-risk proposals, the REB focuses on ethical issues only and offers feedback on study design only in situations where that feedback:

a) can be justified in terms of an ethical concern that is presented clearly to the researcher, or
b) is offered as a collegial comment to the researcher. When this comment is presented to the researcher, it is made clear that the suggested change is not required for ethics approval.

In the case of research proposals that clearly present more than minimal risk, the design of the project must be peer-reviewed to ensure that it can address the question(s) being asked in the research. In this instance, the REB will concern itself with a global assessment of the degree to which the research might further the understanding of a phenomenon, and not be driven by factors such as personal biases or preferences. The REB will not reject research proposals on the grounds that they are controversial, challenge mainstream thought, or offend powerful interests or vocal interest groups. Sufficient peer review may be considered to be any one of the following:

a) Review by REB, if it is determined to have sufficient internal expertise to assess the design of the project;
b) Successful funding of a grant proposal by a funding agency (SSHRC, NSERC, CIHR) which is peer-reviewed; or
c) Ad-hoc independent external peer review reporting directly to the REB.

1.6 Review Procedure

Once the review is initiated, all official correspondence regarding the review between the researcher and the REB (feedback, revisions, etc.) must be conducted through ROMEO.

(a) General Considerations

The Principal Investigator is responsible for determining whether the proposed research is subject to ethics review. Questions about whether the proposed research is subject to review should be directed to the Chair of the REB or to the Coordinator, Research Conduct and Reporting, Office of Research and Innovation.

(b) General Procedures

The Principal Investigator must complete and submit the appropriate ROMEO Application Form. When received, the Coordinator, Research Conduct and Reporting will direct the application to the appropriate ethics review body. The REB will only consider applications from Principal Investigators who have proof of completion of the TCPS2 (2022) Course on Research Ethics (CORE) training within the previous four years. Proofs of completion of the TCPS2 CORE course are also required from student supervisors and all research team members who interact with participants.

The Principal Investigator shall:

I. Complete and file the appropriate ROMEO Application and Event Forms depending on the type of the proposed research;
II. Only proceed with the research once advised by the REB that the research has been reviewed and approved;

III. Advise the REB of any change to a research procedure or the level of risk to human participants by submitting a Protocol Amendment through ROMEO, and wait for approval before implementing those changes;
IV. Report any adverse event (unanticipated negative consequences or results affecting participants) to the REB (c/o the Coordinator, Research Conduct and Reporting, Office of Research and Innovation), within a period of no more than 3 days subsequent to their occurrence;
V. For the duration of the research, submit annual reports to the appropriate ethics review body regarding the status of the research;
VI. Advise the ethics review body in writing when the research is completed or abandoned.

Research protocols are approved for one (1) year and are renewable for the following three (3) years for a maximum of four years before a resubmission to the REB is required. Annual Progress Report forms need to be submitted annually to maintain approval status.

Failure to comply with any of these policies and procedures may be considered Scholarly Misconduct, under Trent University's Policy on Research and Scholarly Misconduct.

(c) Special Procedures

The REB recognizes that according to the TCPS2, the ability to give consent is determined by competence, not age (supported by Canadian case law). In practice, the REB advises researchers who are conducting minimal-risk research with children older than age 12 to plan to ask for the potential participant's consent. If the researcher has concerns about the potential participant's competence, they should explain their concern to the REB and submit their plan to seek the participant's assent and parental/guardian consent. If the potential child participant is younger than 12, the REB will ask that the researcher submit their plan to seek the participant's assent (in age-appropriate language) and their parent/guardian consent.

Researchers conducting above-minimum risk research with children will be expected to conduct a harm-benefit analysis and present an appropriate plan for obtaining assent/consent.

(d) Meetings

The REB shall meet regularly to review applications for approval. All members are expected to attend the meetings; however, quorum for meetings shall be a majority of the voting members. The REB shall keep minutes of its meetings. In the event a member is not able to attend a meeting, the member is expected to review and submit comments to the committee via the Romeo system. If a protocol is submitted for review and the REB determines that there is not sufficient expertise to review the protocol, an alternate subject-area specialist, selected by the REB Chair will be consulted for the duration of the review.

1.7 Faculty, Department, School Ethics Review Committees

All Departments shall establish, under the authority of the REB, an ethics review committee(s). Faculty/Departments/Schools may establish an ethics review committee if the level of research activity within the unit warrants doing so. The REB encourages Faculty/Departments/Schools to establish joint review committees with other Faculty/Departments/Schools.

Faculty/Department/School Ethics Review Committees shall:

a) Establish review procedures according to the guidelines set out above and approved by the REB;

b) Review minimal-risk course-based research activities for pedagogical reasons that are subject to ethics review according to the policies and review criteria set out in the Trent University Policy for Research Involving Human Participants; and

c) Report to the REB by May 30th of each year on the research proposals reviewed and the decisions made for the 12-month period ending April 30th. The report should include the names of the Principal Investigator and supervising faculty member, the assigned ROMEO file number, and the research title).

1.8 Decisions

Following a review of the protocol, the REB may:

a) Approve the protocol;
b) Approve the protocol subject to minor revisions to be approved by the Chair of the REB or delegate member of the REB;
c) Approve the protocol pending major revisions to be reviewed by the full REB or delegate member of the REB;
d) Not approve the protocol;

All decisions require consensus among those members of the REB who review the protocol. By consensus, the REB seeks not only the agreement of most members, but also to resolve and mitigate the objections of the minority to achieve the most agreeable decision.

The Chair will convey the decision of the ethics review body in writing to the applicant.

Resubmissions following decisions may include a written request for reconsideration of REB requirements and/or decisions, explaining the reasons for seeking such reconsideration.

1.9 Appeals of Decisions: Trent Research Ethics Appeal Board (EAB)

See: Trent Research Ethics Appeal Board Terms of Reference and Guidelines

1.10 Review of Research Performed in Emergency Health Situations

Subject to applicable legislative and regulatory requirements, research involving emergency health situations shall be conducted only if it addresses the emergency needs of the individual(s) involved, and then only in accordance with criteria established in advance of such research by the REB. The REB may allow research that involves health emergencies to be carried out without the free and informed consent of the participant or of the authorized third party if ALL of the following apply:

- A serious threat to the prospective participant requires immediate intervention; and
- Either no standard of efficacious care exists, or the research offers a real possibility of direct benefit to the participant in comparison with standard care; and
- Either the risk is not greater than that involved in standard efficacious care, or it is clearly justified by the direct benefits to the participant; and

- The prospective participant is unconscious or lacks the capacity to understand risks, methods, and purposes of the research; and
- Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and
- No relevant prior directive by the participant is known to exist.

When a previously incapacitated participant regains capacity, or when an authorized third party is found, free and informed consent shall be sought promptly for the continuation of the project and for subsequent examinations or tests related to the study.

2.0 Education and Dissemination

Trent University is committed to the provision of an education process and outreach service on ethics. To that end, the University is committed to the dissemination of information on the guiding ethical principles and the requirements of its ethics review process to faculty, students, staff, and the community. This shall be accomplished by the following means:

a) Meetings and presentations to relevant faculty members – specifically:
    - The members of the various ethics review committees (including the REB);
    - The Vice-President whose responsibilities include research; and
    - Chairs and Directors of academic Departments, Schools, and Programs.
b) Open sessions in the Departments and Schools – designed to address a broader audience, including all faculty, staff, and graduate students. These sessions are regular features, typically offered at the outset of the academic year, and prior to granting council submission deadlines;
c) A website - to provide policy and process information to the University community, including:
    - Where to get help;
    - Guidelines and a summary of the presentations made in the open sessions;
    - Tri-Council Policy Statement Ethical Conduct for Research Involving Humans, TCPS2 2022;
    - Frequently Asked Questions and responses;
    - Ongoing information about and links to developments in research ethics;
    - Trent's ethics review policies and process;
    - Definitions and examples of minimal risk research
    - The Senate Policy for Research Involving Human Participants;
    - Appropriate language for consent forms; and
    - Ethics application submission deadlines

Questions about any of the above information can be addressed to the Chair, REB, Coordinator, Research Conduct and Reporting, Office of Research and Innovation.

3.0 Other Relevant Documents

- Human Participant Research At Trent (ORI Website)
- Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans
- Trent Policy on Research Involving Human Participants
- Trent Research Data Management Strategy

- Trent Guidelines for Research Involving Student Participants (2021)
- Outline of a Standard Consent Form
- Research Ethics and SOTL by Dr. Devon Stillwell