Policy for Research Involving Human Participants

Category: Research Policy

Approval: Senate

Responsibility: Office of Research and Innovation

Date: January 19, 2021 Senate approved

1.0 Context for an Ethical Framework

Trent University has formulated a policy for the conduct of research[1] involving human participants[2], human remains, cadavers, tissues, biological fluids, embryos or fetuses. This policy applies to all Departments of the University. It is intended to protect the Researcher[3] and/or Principal Investigator, the Participant, and protect various rights and responsibilities of the respective parties to the research endeavor. Information provided by the Principal Investigator (PI) in compliance with these documents is confidential and will be retained in the files of the Office of Research and Innovation.

The Senate of Trent University affirms that researchers must respect the safety, welfare, and dignity of human participants in their research and treat them equally, fairly, and not as a means to an end. The University values the academic freedom of its researchers, and the ethics review process shall not censor researchers for supporting unorthodox views. However, academic freedom is complemented by the requirements that the rights of human participants be respected.

It is imperative that researchers conduct themselves ethically and respect ethical guidelines. This policy acknowledges the need for continuing interpretation and refinement of applicable policies to account for diversity and changes in research methods and perspectives, contexts and cultures. Thus, continued awareness and debate of the topic in the research community is essential. The University's principal reference for ethics review is the Tri-Council Policy Statement 2 (TCPS2 2018 version), with which the University has agreed to comply pursuant to the Memorandum of understanding between the University and the three agencies that make up the Tri-Council[4].

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[1] Research, for the purpose of this Policy is an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation.

[2] Human participants are persons who provide data or information to the researcher, other than information or data provided by that person in their professional capacity, or data or information already in the public domain.

[3] The Terms "Researcher" and "Principal Investigator" when used in this policy include: (a) Any member who conducts or advances research in that capacity or who accesses University students or staff as human research participants; (b) Any other person who conducts or advances research connected with the University; and (c) Any person who conducts research using University resources (whether research space, materials, equipment or human resources). The term "member" when used in this Policy includes faculty, emeritus faculty, contract faculty, staff, administrators, students, visiting or adjunct scholars, fellows and chairs, paid and unpaid research associates and assistants and any person in a like position.

[4] The TCPS2 2018 and the Memorandum of Understanding are on file with the Certifications and Regulatory Compliance Officer.

2.0 Ethics in the Design of Research Projects which Involve Human Participants

2.1 General Principles

A Research investigation that involves human participants should be designed to take account of the well-being of prospective participants. Human participants should be clearly, fairly, and fully informed of the research objectives, procedures, foreseeable risks, and potential benefits. Their decision to participate should be fully voluntary. Risks (if any) should never be excessively harmful, and the risk-to-benefit ratio should be taken into consideration in the design of the research. Participants' anonymity and confidentiality should be taken into consideration in the design of the research. Participants' anonymity and confidentiality shall be fully protected, unless this right is expressly waived or unless disclosure is authorized or required by law. The University shall fully support researchers' efforts to safeguard any commitments in regard to anonymity or confidentiality that have been made to human participants consistent with an approved research protocol.

Research design should be especially sensitive to ethical issues when the research involves not legally competent individuals and vulnerable populations (such as children, the elderly, ward clients, students in the researcher's courses, medical patients, prisoners, the homeless), as well as when it involves risky procedures, deception, or withholding of information. Research design should also be sensitive to values and perspectives unique to the cultural communities with which the research is to be conducted (e.g., Indigenous peoples).

Concerns regarding the ethical propriety of the research or the interpretation and application of the Senate policy should be addressed to the Chair, Research Ethics Board.

2.2 Informed Consent

(a) Principles of Informed Consent

Ethical research involving humans requires free and informed consent. To that end, all potential human participants (e.g., interviewees, research participants, community members, authorized third parties, etc.) have the right to full disclosure of all information necessary for making an informed decision to participate in a research project (TCPS2 2018, Article 3.2), including the following:

- Information that the individual is being invited to participate in a research project;
- A statement of the research purpose in plain language;
- The expected duration and nature of participation;
- The research methods to be used (e.g., medical procedures, questionnaires, participant observation, etc.);
- Any reasonably foreseeable risks or benefits;
- The storage, collection, encryption and final disposition of data;
- Their right not to participate, not to answer questions, and/or to terminate participation during data collection or at any time without prejudice (e.g., without academic penalty, withdrawal of remuneration, etc.);
- Their right to anonymity and confidentiality (except where disclosures are required by law);
- Any other issues of which the participants should be aware that are relevant to specific protocols and research projects;
- How the data from the research are to be used;
- Their right to receive a copy of the consent form for their records; and
- A statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm.

Evidence of consent shall be contained in either a signed consent form or in documentation by the researcher of another appropriate means of consent. The manner in which a Principal Investigator obtains informed consent may be restricted as a result of the nature of the research, status of the participants, and culture-specific norms. Principles of informed consent must be met; however, the reviewing bodies shall be flexible in how that consent is obtained where circumstances warrant. The following three methods of informed consent are common:

- Informed Consent Form: The traditional informed consent form is the standard for research involving human participants and it is the one routinely required to be used. It details the principles outlined above and requires the participant's or their representative'(s) signature(s).
- Letter: Where the traditional informed consent form is not appropriate (e.g., interviews with artists or government officials, mass mailed questionnaires, etc.), the researcher may seek permission by means of a communication signed by the Principal Investigator inviting participation. This letter must incorporate the principles of informed consent outlined above.
- Verbal Statement: Researchers relay the principles outlined above verbally, the script of which must be provided to the Research Ethics Board for review and indicated on the consent form.

(b) Informed Consent and Research Involving Individuals Lacking Capacity to Decide for Themselves
The following conditions must be observed when involving individuals who lack capacity to decide for themselves as human participants in research: (TCPS2, Article(s) 3.9, 3.10, 3.11):

- The researcher involves participants who lack the capacity to decide on their own behalf to the greatest extent possible in the decision-making process. This includes the ability to decline to participate even if their authorized third parties have provided consent to participate on their behalf;
- The researcher seeks and maintains consent from authorized third parties in accordance with the best interests of the persons concerned;
    - If authorization for participation was granted by an authorized third party, and a participant acquires or regains decision-making capacity during the course of the research, the researcher shall promptly seek the participant's consent as a condition of continuing participation;
- An individual or their authorized third parties' consent to participate is consistent with any signed research directive, should it exist, indicating their preferences about future participation in research in the event that they lose capacity or upon death;
- The authorized third party is not the researcher or any other member of the research team; and
- The researcher demonstrates that the research is being carried out for the participant's direct benefit, or for the benefit of other persons in the same category. If the research does not have the potential for direct benefit to the participant but only for the benefit of the other persons in the same category, the researcher shall demonstrate that the research will expose the participant to only a minimal risk and minimal burden and demonstrate how the participant's welfare will be protected throughout the participation in research.

2.3 Conflict of Interest

Any conflict of interest that exists or may appear to exist as it related to any of the researchers must be described, even though this need not preclude the continuance of the research. A conflict of interest may exist if there is potential or perceived financial and/or material benefit or when researchers partner with organizations whose primary motive is profit.

3.0 Research that is Subject to Ethics Review

All University-based research involving human participants, whether funded or non-funded, faculty or student, scholarly, commercial, or consultative, is subject to the ethics review process. Research subject to review includes, but is not limited to, experiments, surveys, questionnaires, and interviews.

3.1 For Clarity, the following specific situations are subject to ethics review:

I. Research involving human remains, cadavers, tissues, biological fluids, embryos or fetuses, which shall also be reviewed by the Biosafety Committee;
II. Where the research involves interaction with an individual in public life or an artist as a research participant by way of request for an interview or for access to private papers, the ethics review shall focus only on whether these requests will be made in accordance with appropriate ethical and professional standards;
III. Any work of research that initially did not involve human participants, but due to necessity has changed to involve human participants, must submit to an ethics review. Failure to do so puts the researcher in a violation of Trent University's "Policy on Research and Scholarly Misconduct";
IV. Research that involves multiple institutions and/or multiple Research Ethics Boards (TCPS, Chapter 8); and
V. Multi-jurisdictional research: a research project that researchers working under the auspices of Trent University conduct in another province, territory or country.

3.2 For Further Clarity, the following specific situations are not subject to ethics review:

I. Research about a living individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials, is not required to undergo ethics review. Such research requires ethics review only if the participant is approached directly for interviews relating to their private life, or for access to private papers;
II. Quality assurance studies, performance reviews or testing within normal educational requirements are not subject to ethics review. This means that studies related directly to assessing the performance of an organization or its employees or students, within the mandate of the organization or according to the terms and conditions of employment or training, are not subject to ethics review. However, performance reviews or studies that contain an element of research in addition to assessment (e.g., where results may be published, or data complied to answer research questions), may need ethics review;
III. Observational research in public places where:
    a. It does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;
    b. Individuals or groups targeted for observation have no reasonable expectation of privacy; and
    c. Any dissemination of research results does not allow identification of specific individuals.

Whenever there is any doubt about the applicability of this Policy to a particular research project, the Principal investigator may contact the Chair of the Research Ethics Board.

4.0 The Ethics Review Process

4.1 Overview of the Ethics Review Process

All Research that is subject to ethics review must be approved by the appropriate ethics review body before the research may begin. Course-related (undergraduate), non-funded, minimal risk activities undertaken for pedagogical purposes may be ~~is~~ reviewed by a Faculty/Department/School Ethics Review Committee. All other research is reviewed by the University-wide Research Ethics Board (REB). 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[5].

Human participants research to be conducted with or in relation to Indigenous peoples in Canada must also be submitted to the ethics review process of the Trent Indigenous Education Council. The purpose of this ethics review is to ensure that Indigenous research at Trent observes recognized ethical standards of conducting Indigenous research, including the Tri-Council Policy Statement 2 with respect to Aboriginal peoples (Section 9), the Ethical Guidelines for Research outlined by the Royal Commission on Aboriginal Peoples to represent "best practices", and other emerging codes in Indigenous research.

All researchers must complete and submit the relevant Protocol Form[6] for ethics approval by the appropriate ethics review body. The review shall be conducted according to the principles and procedures set out in this document. If an ethics review body refuses to approve the research or if the body requires amendment to the research as a condition of approval and the Principal investigator disagree with the proposed amendments, the Principal Investigator may appeal the ethics review body's decision to the Trent Ethics Appeal Board[7] which shall conduct an ethics review of both the Application and the procedures followed by the body that conducted the first review. Research that is subject to ethics review and that is not approved may not be undertaken.

4.2 Governing Principles of the Ethics Review Process

I. Review procedures should ensure that there is accountability to Senate by way documented correspondence between the researcher and the Research Ethics Board (REB);
II. Reviews should be conducted, and structured feedback provided to the applicant, in an efficient and timely manner;
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 (2018)).

4.3 The Human Participants Research Ethics Board (REB)

The University-wide REB serves the Trent research community in three ways, it:

- Contributes to the education of research ethics;
- Conducts independent, multi-disciplinary review of research proposals; and
- Oversees the ethics review conducted by the Faculty, Department, or School review bodies.

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[5] The types of review are described in Section 4.6.
[6] Applications are submitted on the Romeo system found through the "MyTrent" portal.
[7] The Trent Ethics Appeal Board is described in Section 4.10.

Trent University, through Senate, establishes the Research Ethics Board to approve, propose minor or major modifications to, or terminate any proposed or ongoing research involving human participants that is conducted under the auspices of Trent University, using the considerations set forth in the Trent University Senate Policy for Research Involving Human Participants as a minimum standard.

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 President of Trent University on all matters of research involving human participants at Trent University. It is responsible for ensuring that researchers respect the safety, welfare, and dignity of human participants in their research and treat them equally and fairly and not as a means to an end.

Through both financial and in-kind support from the Office of Research and Innovation, and the Vice President, Research and Innovation, the REB shall have the requisite financial and administrative support to ensure that is has both the autonomy and resources to fulfill its responsibilities.

(a) Terms of Reference

The REB shall:

I. Conduct ethics reviews of proposals from members of the university, and others who conduct research involving human participants under the auspices of Trent University, to determine conformance with the whole of the Tri-Council Policy Statement 2 (2018): "Ethical Conduct for Research Involving Human Subject";
II. Delegate course-related, non-funded, minimal risk research activities for pedagogical purposes to the relevant Department, School, or Graduate Program ethics review body for review and approval and oversee that review process;
III. Suspend or terminate any research which deviates from its approved protocol, exposes research participants to unanticipated risks, has not been approved by the relevant review body, or continues research with human participants beyond the end date of its approval;
IV. Ensure that Departments, Schools, and Graduate Programs are familiar with, and adhere to this Senate Policy;
V. Act as an advisory body for the University, educating the community on ethics in research and providing guidance on the ethics review process;
VI. Report at least once a year to Senate on its activities, and provide Senate the number of protocols reviewed, approved, and rejected;
VII. Ensure that Departments, Schools and Graduate Programs advise students about the relevant aspects of ethics in research and the paramount need to treat participants ethically and respectfully.

(b) Composition

The composition of the REB shall reflect the University's commitment to gender equity. The term of service for members on the REB is a minimum three years, with approximately one-third of the membership appointed each year, thereby ensuring continuity and consistency of membership. Members of the REB shall be appointed by the Faculty Board Nominating Committee. [8]

[8] Representation on the REB will aim to reflect the disciplines of submitted proposals.

The REB is composed of the following:

- Voting Faculty Members:
- 1 REB Chair: Appointed by the Research Ethics Board Chair Selection Committee which is composed of the VP Research and Innovation, a former REB member, and a Dean.
- At least 6 faculty members appointed to ensure expertise in relevant research disciplines, fields, and methodologies covered by the REB; of whom at least 1 faculty member is knowledgeable in ethics;

  The committee also includes:

  - 1 graduate student (voting member);
  - 1 community representative who has no affiliation with the institution (voting member);
  - 1 ad hoc member who is knowledgeable in relevant law (voting member: mandatory for Biomedical Research; advisable but not mandatory for other areas of research);
  - 1 Ex-officio Non-Voting Member: The Certifications and Regulatory Compliance Officer (secretary).

Ethics Subcommittees:

- Indigenous Ethics Committee: members of this committee will review all undergraduate, graduate, and faculty research involving Indigenous participants (see IEC terms of reference for this committee), and
- Delegated Review Committee: All minimal risk applications will be reviewed by this committee (see 4.6a).

(c) Meetings

The REB shall meet regularly to review completed Protocol Forms. 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.

4.4 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 all course-related, non-funded, minimal risk research activities undertaken for pedagogical purposes that are subject to ethics review according to the policies and review criteria set out in this document; and

c) Report to the REB by May 30th of each year on the research proposals (name of both Principal Investigator and supervising faculty member if applicable, and topic or research title) reviewed and the decisions made for the 12-month period ending April 30th.

4.5 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 understood in relation to risks, which are defined in terms of magnitude of harm 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 is no greater than those encountered by participants in the aspects of their everyday life that relate to the research.

4.6 Types of REB Review

Proportionate review implies different levels of REB review for different research proposals. Trent ethics review shall be by way of a delegated or full review of the proposed research depending on the status of the research and the level of risk involved in the research.

(a) Delegated 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 during publicly declared emergencies.

Applications under delegated review shall be reviewed by a sub-committee of the REB. The Subcommittee will be made up of an assigned member of the REB who Chairs this sub-committee, the Certifications and Regulatory Compliance Officer, and additional member(s) of the REB as warranted.

(b) Faculty/Department/School
Course-related, non-funded, minimal risk research activities undertaken for pedagogical purposes shall 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.

(c) Full Review
All other research that is subject to review by the REB shall be reviewed by the full REB.

4.7 Scholarly Review as Part of the Ethics Review

a) In the case of research proposals that clearly present more than minimal risk, the design of the project must be peer reviewed to assure that it is capable of addressing 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:

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

4.8 Review Procedure

(a) General Considerations

The Principal Investigator must complete and file the Protocol Form with the relevant ethics review body. The REB will only consider applications for Principal Investigators who have proof of completion of the TCPS2 (2018) Course on Research Ethics (CORE) training within the previous four years.

(b) General Procedures

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 or the appropriate ethics review body should be directed to the Chair of the Research Ethics Board or to the person responsible for research in the Faculty (normally the Chair of the Department Research Ethics Committee). For research that is subject to ethics review, the Principal Investigator shall:

I. Complete and file the Protocol Form with the appropriate ethics review body;
II. Only proceed with the research once advised by the ethics review body that the research has been reviewed and approved;
III. Advise the ethics review body in writing of any change to a research procedure or the level of risk to human participants, 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 Compliance Officer, Office of Research), within a period of no more than 3 days subsequent to their occurrence;
V. For the duration of the research, which shall be for a maximum of four years before a resubmission to the REB is required, 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.

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.

4.9 Decisions

Following a review of the Protocol, the ethics review body 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 ethics review body 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.

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

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

4.11 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 his or her 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 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 continuation in the project and for subsequent examinations or tests related to the study.

5.0 Education and Dissemination

Trent University is committed to the provision of an education process and outreach service on ethics in research generally and this Senate policy specifically. 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 2018;
- 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
- Information about the HPRC, Animal Care Committee, and Biological Safety Committee;
- The Senate Policy for Research Involving Human Participants;
- Appropriate language for consent forms; and
- Ethics Forms submission deadlines

Questions about any of the above information can be addressed to the Chair, Research Ethics Board, c/o the Office of Research and Innovation.

6.0 Contact Officer

1. Chair, Research Ethics Board;
2. Certifications and Regulatory Compliance Officer, Office of Research and Innovation
3. Vice President, Research and Innovation

7.0 Date for Next Review

May 2023

8.0 Policies Superseded by this Policy

Trent University Senate Policy for Research Involving Human Participants, May 8, 2018, April 25, 2007