Policy for Research Involving Human Participants

Category: Research Policy

Approval: Senate

Responsibility: Office of Research and Innovation

Date of Approval: January 2021; revised March 12, 2024

1.0 Context for an Ethical Framework

Trent University has formulated a policy for the conduct of research[1] involving human participants[2], human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals. This Policy applies to all Departments of the University. It is intended to protect the Researcher[3] and/or Principal Investigator (PI), the Participant, and protect various rights and responsibilities of the respective parties to the research endeavor. Information provided by the 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 2022 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].

[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 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 2022 and the Memorandum of Understanding are on file with the Coordinator, Research Conduct and Reporting.

2.0 Ethics in the Design of Research Projects Involving Human Participants

2.1 General Principles

A research investigation that involves human participants shall be designed in a way that shows respect for the persons who participate, concern for their welfare, and concern for justice. The autonomy of prospective human participants shall be respected by providing them with clear and full descriptions of the research purpose, the role that they will play in the research, the techniques and/or procedures they will experience, and any and all foreseeable risks and potential benefits, so that they can make the fully informed and voluntary decision to participate. Risks (if any) shall never be excessively harmful, and the risk-to-benefit ratio shall be taken into consideration in the design of the research. The level of privacy and confidentiality that the researcher can provide to participants shall be taken into consideration in the design of the research and clearly communicated to potential participants during the consent process. Every effort shall be made to protect participants' identity and the confidentiality of their data as fully as is permitted by the study design, unless this right is expressly waived or unless disclosure is authorized or required by law. Finally, all inclusion and exclusion criteria shall be justified and appropriate for the scope of the study. 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 shall be sensitive to ethical issues when the research involves not legally competent individuals and vulnerable populations (e.g., medical patients, prisoners, the homeless), as well as when it involves procedures that induce risks above and beyond those encountered in everyday life or deception, including withholding of information. Research design shall also be sensitive to values and perspectives unique to the cultural communities within 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 shall be addressed to the Chair, Research Ethics Board (REB).

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 have the right to full disclosure of all information necessary for making an informed decision to participate in a research project, presented in plain language (TCPS2 2022, Article 3.2), including the following:

- Information that their participation is voluntary and that they can decline to participate, refuse to answer questions, or withdraw at any time without consequence or loss of compensation for time spent;
- A statement of the research purpose;
- The expected duration and nature of participation;
- The research methods to be used (e.g., testing procedures, questionnaires, methods of observation, the topics to be broached during interviews, etc.);
- Any reasonably foreseeable risks or benefits associated with their participation in the research;

- The manner of collection, storage, encryption and final disposition of data;
- Their right to know in advance the level to which their identity will be protected and data confidentiality maintained (except where disclosures are required by law);
- How the data from the research are to be used now, who will have access to them, and the foreseeable ways they may be used and/or shared in the future;
- The type and level of identifying information, if any, that will be included in shared data files;
- Their right to ask questions;
- 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.

While the manner in which consent is obtained may vary, researchers must document that study information was provided to the person before consent was obtained, and that the person consented to participate, preferably in writing. The reviewing bodies shall be flexible in how consent is obtained where circumstances warrant (e.g., the status of the participants, culture-specific norms, etc.). The following methods of informed consent are common:

- Written Consent – The information and consent letter details the principles outlined above. The letter may be provided to the participant in person, by mail, by email, or online and requires the participant's or their representative'(s) signature(s), digital agreement, or digital signature. Proxies for signatures are acceptable, especially when this ensures anonymity.
- 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 PI inviting participation. This letter must incorporate the principles of informed consent outlined above. The participants' agreement to participate is taken as tacit consent.
- Verbal Consent – Researchers convey study information verbally, the script of which must be provided to the REB for review. The participant's verbal agreement should be documented by the researcher unless doing so would lead to substantial additional risk for the participant.

(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 acknowledging and accepting the incapacitated person's 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 consent 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 relates to any of the researchers must be described to participants during the information and consent process, 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 biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals., 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, etc.;

III. Any work of research that initially did not involve human participants, but due to necessity has changed to involve human participants;

IV. Multi-jurisdictional research: Research that involves multiple institutions and/or multiple Research Ethics Boards (TCPS2, Chapter 8); and/or a research project that a Trent University researcher conducts alone or with collaborators in another province, territory or country;

V. Any program evaluation, quality assessment, or quality assurance research involving human participants where the results will be shared publicly through dissemination in research journals, chapters, books, websites, traditional and social media, etc.;

VI. Minimal-risk course-based research activities for pedagogical reasons. These are research activities presented as formal, graded course assignments or lab activities that ask students to collect and retain 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. REB review is needed for

these activities because, in terms of both risk and experience, the participants' experience is indistinguishable from participating in research (TCPS 2 (2022), Article 2.1). These protocols will be submitted for department-specific delegated ethics review (TCPS 2 (2022), Article 6.12);

VII. While working with publicly available data does not require REB review, where data linkage of different sources of information is involved, it could give rise to new forms of identifying information that would raise issues of privacy and confidentiality when used in research, and would therefore require REB review. In this situation, the REB's review will focus on determining that the linkage is essential to the research and that the researcher will apply sound data management principles to the linked data (TCPS2, Article 5.7).

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 (see 3.1.VII): This research requires ethics review only if the individual is approached to provide information directly to the researcher by participating in an interview, answering written questions or questionnaires either in person or online, or for access to private papers;

II. In the course of a research project, a researcher may obtain information from individuals who are not themselves the focus of the research. For example, one may collect information from persons who are authorized to release information or data in the ordinary course of their employment about organizations, policies, procedures, professional practices or statistical reports. These individuals are not considered research participants for the purposes of this Policy. This is distinct from situations where individuals are considered participants because they are themselves the focus of the research. For example, people who are asked for their personal opinions about organizations or who are observed in their work setting for the purposes of research are considered participants (TCPS 2 (2022), Article 2.1);

III. Quality assurance studies, performance reviews or testing within normal educational requirements are not subject to ethics review. This means that activities 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., scholarship of teaching and learning; where results may be published, or data complied to answer research questions, see 3.1.V), will need ethics review;

IV. 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 PI may contact the Chair of the REB or the Coordinator, Research Conduct and Reporting.

4.0 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.

Trent University, through Senate, establishes the Research Ethics Board (REB) 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 REB is a standing committee of Senate, reporting and accountable to Senate. The REB 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 it 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 (2022): “Ethical Conduct for Research Involving Humans”;

II. Delegate minimal-risk course-based research activities for pedagogical reasons 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. Act as a resource to ensure that faculty and students in Trent University Departments, Schools, and Graduate Programs are familiar with, and adhere to this Senate Policy and to the ethical guidelines presented in the TCPS2;

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 with the number of protocols reviewed, approved, and rejected;

(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 (3) 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.[5]
The REB is composed of the following:

- Voting Faculty Members:

- One (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 six (6) faculty members, appointed to ensure expertise in relevant research disciplines, fields, and methodologies covered by the REB; of whom at least one (1) faculty member is knowledgeable in ethics;

- Two (2) faculty 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. This 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 committee also includes:

  - One (1) graduate student (voting member);
  - One (1) community representative who has no affiliation with the institution (voting member);
  - One (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);
  - One (1) Ex-officio non-voting member: The Coordinator, Research Conduct and Reporting (secretary).

Ethics Subcommittees:

- All minimal-risk faculty and graduate student research applications involving and/or impacting Indigenous Peoples or communities are delegated to the REB members from the Chanie Wenjack School for Indigenous Studies.

- Delegated Review Committees: All minimal risk faculty and graduate student applications will be reviewed by these committees, composed of subsets of the REB.

- Department-specific Delegated Review Committees: All applications for minimal-risk course-based research activities for pedagogical reasons will be reviewed by these committees.

5.0 Other relevant documents

- Trent University Research Ethics Procedures (2023)

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

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

Contact Officer:

- Chair, Research Ethics Board
- Coordinator, Research Conduct and Reporting, Office of Research and Innovation
- Vice President, Research and Innovation

Date for Next Review:

March 2029

Policies Superseded by this Policy:

a) Trent University Senate Policy for Research Involving Human Participants - January 19, 2021; May 8, 2018; April 25, 2007