

TORONTO METROPOLITAN UNIVERSITY

POLICY OF SENATE

ETHICAL CONDUCT FOR RESEARCH INVOLVING HUMAN PARTICIPANTS

(formerly called: Ethical Conduct in Research Involving Human Subjects)

Policy Number:	51
Approval Date:	December 7, 2021
Previous Approval Dates:	December 6, 2016 October 4, 1999 (reformatted May 7, 2002)
Presented by:	Research Ethics Board (REB)
Responsible Office:	Vice-President, Research and Innovation
Implementation Date:	Fall 2021
Procedural Review:	Upon revision of the Tri-Council Policy Statement (TCPS)

The Research Ethics Board (REB), established by the Senate and operating independently of any administrative offices at the institution, is charged with the oversight of this policy within the institution. As per Article 6.2 of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Participants (TCPS2, 2018; hereafter TCPS), the institution shall ensure the REB has the necessary and sufficient ongoing financial and administrative resources to fulfill its duties.

1. MANDATE AND SCOPE

- 1.1 The University has both a legal and moral responsibility to take steps to ensure that any research¹ carried out by faculty, research staff, postdoctoral fellows and/or students meets appropriate standards of ethical acceptability as outlined by the TCPS. The Research Ethics Board (REB) will develop and implement procedures and guidelines to fulfill the objectives of this policy.
- 1.2 It is the responsibility of researchers (faculty, research staff, postdoctoral fellows and/or students) and the REB to ensure that the research is conducted in an ethical manner. As outlined in the latest version of the TCPS, research involving human participants must be guided by the following overriding core ethical principles:

¹The TCPS defines research as “an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation. The term ‘disciplined inquiry’ refers to an inquiry that is conducted with the expectation that the method, results, and conclusions will be able to withstand the scrutiny of the relevant research community” (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, & Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2018, pp 13-14).

- 1.2.1 **Respect for Persons** – Respect for persons recognizes the intrinsic value of human beings (including their data and biological materials) and incorporates the dual moral obligation to respect autonomy while protecting those with developing, impaired, or diminished autonomy. Respecting autonomy requires participants' free, informed, and ongoing consent and choice. Informed choice is based on as complete an understanding of the purpose of the research as is reasonably possible, including what it entails and its foreseeable risks and benefits. Respect for persons includes a commitment to accountability and transparency in the ethical conduct of research and ensuring privacy and confidentiality of the participant.
- 1.2.2 **Concern for Welfare** – Welfare of a person is the quality of that person's experience in life and is inclusive of physical, mental, and spiritual health, as well as their physical, economic, and social circumstances. Researchers should not only aim to protect the welfare of participants but promote that welfare in view of any foreseeable risks associated with the research. Such being the case, researchers and the REB must ensure that participants are not exposed to unnecessary risk. In addition, researchers and the REB must attempt to minimize risk and to achieve a balance of risks and potential benefits. Concern for welfare also includes welfare of groups. Groups may benefit from the knowledge gained from the research but might also suffer from stigmatization, discrimination, or damaged reputation. In such a perceived risk, engagement of such groups in the process of the design of the research is warranted so that group benefits and risks can be appropriately determined.
- 1.2.3 **Justice** – Justice refers to the obligation to treat people fairly and equitably. Treating people fairly and equitably does not always mean treating people in the same way. Differences in treatment or distribution are justified when failures to take differences into account may result in the creation or reinforcement of inequities. Historically some groups of people have been either excluded or inappropriately targeted in research. As such, the recruitment process should be based on inclusion and/or exclusion criteria that are justified by the research question. Inequity is created when particular groups fail to receive fair benefits of research or when excluded from research arbitrarily or for reasons unrelated to the research question.²

² Tri-Council Policy Statement 2, pp 5–9 (2018).

- 1.3 The REB mandate is to approve, reject, propose modification to, or terminate any proposed or ongoing research involving human participants that is conducted within the University or by its faculty, staff, and/or students so as to protect research participants and ensure that research is conducted in an ethical manner. In addition, all research involving human biological materials, including human embryos, fetuses, fetal tissue, reproductive materials, and stem cells derived from both living and deceased individuals is subject to review by the REB before the research may be undertaken.
- 1.4 Review and approval are required for all research involving human participants and biological materials regardless of funding or where the research is conducted.³
- 1.5 This policy applies to all faculty, research staff, postdoctoral fellows, graduate and undergraduate students conducting research with human participants regardless of where the research is being conducted.
- 1.6 All course-based research activities involving human participants or biological materials are also subject to REB review. While the primary purpose is pedagogical, they may pose possible risks to those recruited to participate in such activities, and from their perspective, such activities may appear indistinguishable from those that meet the TCPS's definition of research.⁴
- 1.7 In cases where faculty, research staff, postdoctoral fellows and/or students are engaging in research outside of their roles at Toronto Metropolitan (e.g., faculty engaging in consulting or professional activities; students involved in professional activities at placements), such projects would not require REB review. However, if members of Toronto Metropolitan make reference to their affiliation with Toronto Metropolitan University and/or use any of Toronto Metropolitan's resources then REB review and approval may be required if it meets the definition of research in the TCPS.
- 1.8 The ethics review process itself must be fair both in standards and procedures, as well as impartial towards particular proposals and independent of institutional agendas or pressures. As per Article 2.7 of the TCPS, research ethics review includes scholarly review of the ethical implications of the methods and design of the research.
- 1.9 The REB **only** reviews research that falls within the scope of research as defined by the Tri-Council Policy Statement; however, the REB is responsible for reviewing research involving human participants to

³ Tri-Council Policy Statement 2, pp 13–20 (2018).

⁴ Tri-Council Policy Statement 2, pp 13–20 (2018).

determine if it is exempt from ethical review. Researchers are responsible for obtaining confirmation from the REB on whether or not their project is exempt from ethics review. In accordance with the TCPS, research not requiring REB review and approval include:

- 1.9.1 interaction with individuals who are not themselves the focus of the research (e.g., collecting information from authorized personnel about the ordinary course of their employment, organization, policies, procedures, professional practices, or statistical reports);
 - 1.9.2 legally and publicly accessible information or data where there is no reasonable expectation of privacy;
 - 1.9.3 observation of people in public spaces where there is no reasonable expectation of privacy, is not epidemiological in nature, involves no direct interaction or intervention by the researcher, and dissemination does not identify specific individuals;
 - 1.9.4 research that relies exclusively on secondary use of anonymous⁵ information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information. However, when there is a reasonable prospect that this data could generate information identifiable as originating from a specific Indigenous community or a segment of the Indigenous community at large, REB review is required;
 - 1.9.5 quality assurance and improvement studies, program evaluation and performance reviews, testing within normal educational requirements when used exclusively for assessment, management, or improvement purposes;
 - 1.9.6 creative practice whereby an artist makes or interprets a work or works of art or studies the process of how a work of art is generated. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review.
- 1.10 All research involving human participants must be submitted to the REB for review and approval before the research may proceed. Specifically,

⁵ The Tri-Council Policy Statement defines anonymous information as information that never had identifiers associated with it (e.g., anonymous surveys) and the risk of identification of individuals is low or very low (Article. 2.4).

REB approval must be obtained prior to recruitment and data collection.

2. COMPOSITION AND TERMS OF REFERENCE OF THE REB

- 2.1 The Senate shall approve appointments to the REB.
- 2.2 The REB is constituted by the Vice-President, Research and Innovation and approved by Senate. The REB membership shall have representation across Faculties at the University and be diverse in gender with appropriate representation from racialized and other distinct communities. The REB shall consist of:
 - 2.2.1 a Chair (1) with experience in research ethics;
 - 2.2.2 a Vice Chair (1) with experience in research ethics;
 - 2.2.3 at least twelve (12) faculty members, including representation from across Faculties as appropriate to ensure adequate expertise in relevant research disciplines, fields, and methodologies covered by the REB;
 - 2.2.4 at least three (3) members representing the School of Graduate Studies;
 - 2.2.5 at least one (1) member knowledgeable in ethics theory, knowledge, and practice;
 - 2.2.6 at least one (1) member knowledgeable in relevant law (cannot be legal counsel or risk management representative for the university);
 - 2.2.7 at least four (4) community members who have no current affiliation with the institution;
 - 2.2.8 at least two (2) undergraduate students;
 - 2.2.9 at least two (2) graduate students; and
 - 2.2.10 at least one (1) member who self identifies as First Nations, Inuit, or Métis and/or who is informed in the traditional knowledge and culture of First Nations, Inuit or Métis peoples.
- 2.3 The above noted composition is the minimum requirement. The REB shall establish the necessary composition above and beyond these minimal requirements to ensure adequate and appropriate review of ethics

protocols and to ensure protocols are reviewed in a timely manner. Given the demands on the REB, representation shall surpass the minimum requirement to ensure efficient and timely review of ethics protocols.

- 2.4 The REB shall make use of ad hoc advisors in the event that it lacks specific expertise and/or to assist with excessive workload. Ad hoc reviewers shall not be counted in quorum for the REB, nor be allowed to vote.
- 2.5 The REB Chair, appointed by the Vice-President, Research and Innovation and approved by Senate, is responsible for ensuring that the REB review process conforms to the requirements of the TCPS and University policies and procedures. The REB Chair provides overall leadership for the REB, oversees decisions of the REB for consistency, and ensures that REB decisions are recorded accurately and communicated clearly to researchers in writing as soon as possible by the Chair or their designate.
- 2.6 The REB shall have regular meetings to discharge its duties and meet face-to-face to review proposed research that is more than minimal risk (i.e., not assigned to delegated review).
- 2.7 Quorum for decisions of the REB must satisfy the minimum requirements:
 - 2.7.1 at least two members with expertise in relevant research disciplines, fields, and methodologies covered by the REB;
 - 2.7.2 at least one member knowledgeable in ethics theory, knowledge, and practice;
 - 2.7.3 for biomedical research, at least one member knowledgeable in the relevant law (cannot be legal counsel or risk management representative for the university);
 - 2.7.4 at least one community member who has no current affiliation with the institution; and
 - 2.7.5 diversity in gender and appropriate representation from racialized and other distinct communities.
- 2.8 The REB shall present an annual report to Senate that includes general statistics related to REB review and any challenges experienced by the REB in executing their mandate.

3. AUTHORITY OF THE RESEARCH ETHICS BOARD

The REB is accountable to the Senate for its research ethics review processes. However, in conducting research ethics reviews, the REB must operate in an impartial manner, without interference, and the decisions of the REB with respect to any given research project are not subject to review by the Vice-President, Research and Innovation or any other person except to the extent that such decisions may be appealed pursuant to the procedures to this policy.

4. RECONSIDERATION OF REB DECISION

A researcher may request reconsideration of a decision made by the REB within 30 days of receiving notice of the REB's decision. The onus is on researchers to justify the grounds on which they request reconsideration and to indicate any alleged breaches to the established research ethics review process, or any elements of the REB decision that are not supported by the TCPS. The REB shall review the reconsideration request and respond to the researcher within 30 days of receiving the request. Final decision rests with the REB.⁶

5. APPEAL OF REB DECISION

- 5.1 If, after the completion of the REB's reconsideration, a researcher believes that the REB's decision is in breach of the established review process or that it is inconsistent with the TCPS, the researcher may make a written request to the Vice-President, Research and Innovation to appeal such decision within 30 days of receiving the REB's final decision.
- 5.2 The Vice-President, Research and Innovation shall appoint individuals to an Ad Hoc Research Ethics Appeal Committee, which shall hear such appeal.
- 5.3 The composition of the Ad Hoc Research Ethics Appeal Committee, as well as its terms of membership and quorum requirements, must satisfy the minimum REB requirements of the TCPS including:
 - 5.3.1 at least two members with expertise in relevant research disciplines, fields, and methodologies covered by the REB;
 - 5.3.2 at least one member knowledgeable in ethics theory, knowledge, and practice;
 - 5.3.3 for biomedical research, at least one member knowledgeable in the relevant law (cannot be legal counsel or risk management representative for the university);

⁶ Tri-Council Policy Statement 2, p 84 (2018).

- 5.3.4 at least one community member who has no current affiliation with the institution; and
- 5.3.5 diversity in gender and appropriate representation from racialized and other distinct communities.
- 5.4 No person can serve as a member of the Ad Hoc Research Ethics Appeal Committee with respect to a review of a decision made by the REB if such person was a participant in the original review, decision, or reconsideration of the original decision.
- 5.5 The Research Ethics Appeal Committee shall function impartially, provide a fair hearing to those involved, and provide reasoned and appropriately documented decisions and reasons for such decisions.
- 5.6 Both the appealing researcher and a representative of the REB whose decision is being appealed shall be granted the opportunity to address the Ad Hoc Research Ethics Appeal Committee, but neither shall be present when the Ad Hoc Research Ethics Appeal Committee deliberates and makes a decision.
- 5.7 When reviewing decisions made by the REB with respect to a research project, the Ad Hoc Research Ethics Appeal Committee may approve, reject, or request modifications to such research project.
- 5.8 The decision made by the Ad Hoc Research Ethics Appeal Committee on behalf of the University shall be final and shall be communicated in writing to the relevant researcher and to the REB whose decision was appealed.

6. RELATED DOCUMENTS

[Tri-Council Policy Statement \(2018\)](#)

Senate Policy 118: Scholarly, Research and Creative Activity (SRC) Integrity Policy