

# Toronto Metropolitan University Policy of Senate: Ethical Conduct for Research Involving Human Participants

(Formerly: Ethical Conduct in Research Involving Human Subjects)

**Policy Number:** 51

**Approval Date:** TBD

**Previous Approval Dates:** December 7, 2021; 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:** TBD

**Procedural Review:** Upon revision or replacement of the Tri-Council Policy Statement (TCPS)

## 1. Preamble

Accountability for Research carried out within the jurisdiction or under the auspices of Toronto Metropolitan University (TMU) lies with the institution, as per the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Participants (TCPS). TMU is responsible for developing and implementing relevant university policies that adhere to TCPS, establishing Research Ethics Board structures, including defining an appropriate reporting relationship with the REBs, and ensuring that its REBs have the necessary and sufficient ongoing financial and administrative resources to fulfill their duties.

TMU's Research Ethics Boards (REBs) are approved by, and accountable to, Senate. The REBs operate independently in determining the ethical acceptability of all Research involving Human Participants conducted within TMU's jurisdiction or under its auspices.

Researchers are responsible for conducting their Research in accordance with the TCPS, relevant TMU policies and procedures, and applicable legal and regulatory requirements.

## 2. Definitions

Within this policy, definitions are provided in logical, not alphabetical, order:

**"SRC Activity"** means funded or unfunded creative, scholarly, and/or knowledge-generating activities, whether fundamental or applied, whose primary objective is discovery, problem-solving or to achieve some desired result that can be specified to a significant extent but that cannot be produced with existing knowledge. SRC activity is undertaken in the course of an individual's role at the University and is made, discovered or developed using the University

facilities, support personnel, support services, equipment, materials or funds, or otherwise under the auspices of the University.

**“Research”** as defined by the TCPS is “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”.<sup>1</sup>

**“Researcher”** means all individuals undertaking SRC activity under the auspices of the University, no matter where the research is undertaken.

**“Human Participant”** is defined by the TCPS as “an individual whose data, biological materials, or responses to interventions, stimuli, or questions by a researcher are relevant to answering the research question(s)”.

**“The University”** means Toronto Metropolitan University.

### 3. Mandate and Scope

- 3.1 The University has both the legal and moral responsibility to take steps to ensure that any research<sup>2</sup> involving Human Participants<sup>3</sup> carried out by its Researchers meet appropriate standards of ethical acceptability as outlined by the TCPS. The REBs are responsible for developing and implementing procedures and guidelines to fulfill the objectives of this policy. Guidance is provided to Researchers on an ongoing basis through support resources, standard operating procedures and other communications.
- 3.2 This policy applies to all Researchers conducting Research involving Human Participants, regardless of where the Research is being conducted.
- 3.3 It is the responsibility of both Researchers and the REBs to ensure that all Research is conducted in an ethical manner. Research involving human participants must be guided by the TCPS core ethical principles: Respect for Persons, Concern for Welfare and Justice.<sup>4</sup>
- 3.4 All Research involving Human Participants, whether it includes primary data collection or the secondary use of existing data or biological materials, must be submitted to the REB

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<sup>1</sup> Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022, p. 4.

<sup>2</sup> Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022, p. 4.

<sup>3</sup> Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022, p. 14.

<sup>4</sup> Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022, pp. 6-10.

for review and approval before the Research may proceed. Specifically, REB approval must be obtained prior to participant recruitment and data collection.

- 3.5** An REB's mandate is to approve, reject, propose modifications to, or terminate any proposed or ongoing Research involving Human Participants that is conducted within the jurisdiction or under the auspices of the University 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. Review and approval are required for all Research involving Human Participants and biological materials, regardless of funding or where the Research is conducted.<sup>5</sup>
- 3.6** 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.<sup>6</sup>
- 3.7** In cases where TMU Researchers are engaging in Research that meets the TCPS definition of Research outside of their roles at TMU (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 Researchers make reference to their affiliation with TMU and/or use any of TMU's resources, then REB review and approval may be required.
- 3.8** The REBs only review Research that falls within the scope of Research as defined by the TCPS. REBs are also responsible for assessing Research involving Human Participants to determine if it is exempt from ethical review. Researchers are responsible for obtaining confirmation from the REB on whether or not their project may be exempt from ethics review.
- 3.9** 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.
- 3.10** The REBs may establish arrangements or agreements with other REBs, review networks, agencies, universities and institutions for the purpose of streamlining the ethics review of Research studies involving multiple institutions, or more generally, to facilitate the ethics review process of Research as permitted under the TCPS.

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<sup>5</sup> Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022, p. 13.

<sup>6</sup> Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022, p. 14.

## **4. Authority of the Research Ethics Board(s)**

- 4.1** The REBs are independent in their decision-making. They are accountable to Senate for their research ethics review processes. Reporting of REBs to Senate shall be in the form of an annual report that includes general statistics related to REB review and any challenges experienced by the REBs in executing their mandate.
- 4.2** In conducting research ethics reviews, the REBs must operate in an impartial manner, without interference, and the decisions of the REBs with respect to any given Research project are not subject to review by the Vice-President, Research and Innovation or any other person. An REB decision may be appealed according to the procedures associated with Policy 51.

## **5. Related Documents**

[Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 \(2022\)](#)

[Senate Policy 118: Scholarly, Research and Creative Activity \(SRC\) Integrity Policy](#)

[Senate Policy 154: Signing of Research Applications and Agreements in Support of Research](#)

# **Policy 51: REB Terms of Reference, Processes, and Procedures**

## **1. Composition and Terms of Reference of the REB(s)**

- 1.1** The Senate shall approve appointments to the REBs.
- 1.2** The REBs are 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 sex and gender, with appropriate representation from racialized and other distinct communities. In accordance with the TCPS, the REBs shall consist of the following:
  - 1.2.1** A chair (1) with experience in research ethics.
  - 1.2.2** A vice chair (1) with experience in research ethics.
  - 1.2.3** At least twelve (12) faculty members, including representation from across TMU faculties, as appropriate, to ensure adequate expertise in relevant research disciplines, fields and methodologies covered by the REB. Of these faculty members, at least three (3) will be members of the Yeates School of Graduate and Postdoctoral Studies.
  - 1.2.4** At least one (1) member knowledgeable in ethics theory, knowledge and practice.
  - 1.2.5** At least one (1) member knowledgeable in relevant law (cannot be legal counsel or risk management representative for the University).
  - 1.2.6** At least one (1) community member who has no current affiliation with the institution.
  - 1.2.7** At least two (2) students and/or learners.
  - 1.2.8** At least one (1) member who self-identifies as First Nations, Inuit, Métis and/or who is informed in the traditional knowledge and culture of First Nations, Inuit or Métis peoples.
- 1.3** The above-noted composition is the minimum requirement. The REBs 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.
- 1.4** The REBs 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.
- 1.5** The REB chairs, appointed by the Vice-President, Research and Innovation and approved by Senate, are responsible for ensuring that the REB review process conforms

to the requirements of the TCPS and university policies and procedures. The REB chairs provide overall leadership for the REBs, oversee decisions of the REB for consistency and ensure that the REBs' decisions are recorded accurately and communicated clearly to researchers in writing as soon as possible by the chair(s) or their designates.

- 1.6** The REBs shall have regular meetings to discharge their duties and meet face-to-face to review proposed research that is more than minimal risk (i.e., not assigned to delegated review).
- 1.7** Quorum for decisions of the REBs must satisfy the following minimum requirements:
  - 1.7.1** At least two members with expertise in relevant research disciplines, fields and methodologies covered by the REB.
  - 1.7.2** At least one member knowledgeable in ethics theory, knowledge and practice.
  - 1.7.3** For biomedical research, at least one member knowledgeable in the relevant law (cannot be legal counsel or risk management representative for the University).
  - 1.7.4** At least one community member who has no current affiliation with the institution.
- 1.8** The REBs shall present an annual report to Senate that includes general statistics related to REB reviews and any challenges experienced by the REBs in executing their mandate.

## **2. REB Review Process and Procedures**

The REBs only review research that falls within the scope defined by the TCPS. REBs are also responsible for reviewing research involving human participants to determine if it is exempt from ethical review. Researchers are responsible for obtaining confirmation from the REB on whether or not their project may be exempt from ethics review.

In accordance with the TCPS, research not requiring REB review and approval include:

- 2.1** Collecting organizational information from 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).
- 2.2** Publicly available through a mechanism set out by legislation or regulation and that is protected by law; or in the public domain, and the individuals to whom the information refers have no reasonable expectation of privacy.
- 2.3** 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.
- 2.4** Research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage, 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.

- 2.5** Quality assurance and improvement studies, program evaluation and performance reviews, testing within normal educational requirements when used exclusively for internal assessment, management or improvement purposes.
- 2.6** 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.

### **3. Reconsideration of REB Decisions**

A Researcher may request reconsideration of a decision made by an 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 REBs shall review the reconsideration request and respond to the Researcher within 30 days of receiving the request. Final decision rests with the respective REB.<sup>7</sup>

### **4. Appeal of REB Decisions**

- 4.1** If, after the completion of the REB's reconsideration, a Researcher believes that the REB's decision is inconsistent with the TCPS or that it is in breach of the established review process, the Researcher may make a written request to the Vice-President, Research and Innovation to appeal within 30 days of receiving the REB's final decision.
- 4.2** The Vice-President, Research and Innovation shall appoint individuals to an Ad Hoc Research Ethics Appeal Committee, which shall hear such appeals.
- 4.3** 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:
  - 4.3.1** At least two members with expertise in relevant Research disciplines, fields and methodologies covered by the REB.
  - 4.3.2** At least one member knowledgeable in ethics theory, knowledge and practice.
  - 4.3.3** For biomedical Research, at least one member knowledgeable in the relevant law (cannot be legal counsel or risk management representative for the University).

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<sup>7</sup> Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022, p. 84.

- 4.3.4** At least one community member who has no current affiliation with the institution.
- 4.3.5** Diversity in sex and gender and appropriate representation from racialized and other distinct communities.
- 4.4** No person can serve as a member of the Ad Hoc Research Ethics Appeal Committee with respect to review of a decision made by the REB if such a person was a participant in the original review, decision or reconsideration of the original decision.
- 4.5** 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.
- 4.6** 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.
- 4.7** 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 projects.
- 4.8** 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.