



## Senate

Policy Name	<b>Research Ethics Policy for Research Involving Human Participants</b>
Policy Number	UREB-2012-01 (REB.POL.001)
Origin	University Research Ethics Board (UREB)
Authority	Senate
Date of Original Approval	2012-03-26
Supersedes	
Senate Approval Dates	2024-11-29; 2020-10-02; 2012-03-26
Effective from	2024-11-29
Review/Retirement Date	2029
Responsibility for Revision	UREB
Responsibility for Implementation	UREB

### 1. Purpose

The intent of this document is to develop and support the highest level of ethical standards possible and to protect both participants and members of the university community who conduct research. For the purposes of this policy, research is defined as an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation.

The University Research Ethics Board (UREB) is a standing committee of Senate established under the provisions of the Tri-Council Policy Statement. The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)* is a

comprehensive document that describes the policies of the three federal granting councils (CIHR, NSERC, and SSHRC) for research with human participants or their data. As part of its mandate, the UREB shall ensure that research that is carried out by MSVU researchers or research involving members of the MSVU community adheres to the TCPS as well as applicable institutional ethical procedures and guidelines.

## 2. Scope

This policy applies to any Mount faculty member, emeritus faculty, staff, part-time academic employees, administrators, students, visiting or adjunct scholars, post-doctoral fellows and chairs, paid and unpaid research associates and assistants, and any person in a like position, who conducts, engages with, or advances research in any capacity, or who accesses University students or staff as human research participants, and/ or; any other person who conducts, engages with or advances research as connected with the University, and/or; any person who conducts research using University resources (for instance, research space, materials, equipment, or human resources).

The UREB has developed this institutional human research ethics policy and has further developed procedures, guidelines and forms to guide both researchers and members of the UREB regarding the ethics of research involving humans that, as a minimum, meets the requirements set out in the TCPS.

The UREB provides a service to the MSVU research community by working with researchers to identify and resolve ethical issues in their research protocols, which results in the protection of participants, minimizing potential risks/harms and maximizing the benefits of the research.

## 3. Definitions

See the MSVU [REB Glossary of Terms](#) (REB.INFO.001)

#### 4. Policy

As a condition of eligibility to apply and receive Tri-Agency funding, MSVU has entered into the [Tri-Agency Agreement on the Administration of Agency Grants and Awards by Research Institutions](#) and agrees to follow the [Tri-Agency Guide on Financial Administration](#) with these Agencies. Part of this agreement requires that MSVU and MSVU researchers apply the ethical principles and the articles of the TCPS at MSVU. MSVU must therefore ensure that research conducted under their auspices complies with the TCPS. Researchers are expected, whether their study is funded or not, and regardless of where the research is conducted, to adhere to the TCPS. Failure to fulfill the requirements of the TCPS, by the researcher or the institution, may result in recourse by the Agencies, as set out in the [Tri-Agency Framework: Responsible Conduct of Research](#).

The [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans \(TCPS\)](#), will serve as the minimum standard for MSVU researchers. Additionally, the UREB will maintain institutional research ethics policies, procedures, forms, and guidelines, all of which are designed to support or enhance the TCPS and assist our research community.

In addition to the principles and guidelines in the TCPS and this Policy, researchers are responsible for ascertaining and complying with all applicable legal and regulatory requirements with respect to consent and the protection of privacy of participants (TCPS [Chapter 5](#)). These legal and regulatory requirements may vary depending on the jurisdiction in Canada in which the research is being conducted, and who is funding and/or conducting the research. They may comprise constitutional, statutory, regulatory, common law, and/or international or legal requirements of jurisdictions outside of Canada. Where the research is considered to be a governmental activity, for example, standards for protecting privacy flowing from the *Canadian Charter of Rights and Freedoms*, federal privacy legislation and regulatory requirements apply.

Research ethics focuses on the participants or subjects of the research rather than on the individuals doing the research. Fundamentally, research ethics review is geared

toward protecting participants by minimizing the harms or risk to which they are exposed. Mount Saint Vincent University is committed to manage, via the University Research Ethics Board, the approval and monitoring process of research involving humans or their data, under its authority and affiliates with highest ethical standards.

The UREB shall be responsible for the ethical oversight of research involving human participants and their data. The Research Ethics Office provides centralized management and educational functions related to research ethics review. All human participant research conducted under the auspices and/or jurisdiction of MSVU must receive ethics clearance from the University Research Ethics Boards (UREB), or via a sanctioned Departmental Research Ethics Board (DREB) prior to the start of the project.

The UREB is authorized to clear, reject, propose modifications to, suspend, or terminate research protocols that involve human participants or their data and that fall under the jurisdiction of MSVU and the purview of the TCPS or relevant regulations and guidelines.

## 5. Core Principles

In designing and conducting research or reviewing the ethics of research, researchers and REBs must be mindful of the perspective of the participant. It may be necessary to consider the various contexts (e.g., social, economic, cultural) that shape the participant's life, to properly evaluate the implications of the research in terms of the TCPS Core Principles (TCPS Chapter 1, Article 1.1):

- **Respect for Persons** - A core principle of this Policy that recognizes the intrinsic value of human beings and the respect and consideration that they are due. It incorporates the dual moral obligations to respect autonomy and to protect those with developing, impaired, or diminished autonomy.
- **Concern for Welfare** - A core principle of this Policy that requires researchers and research ethics boards to aim to protect the welfare of participants, and, in some circumstances, to promote that welfare in view of any foreseeable risks associated with the research.

- **Justice** - A core principle of this Policy that refers to the obligation to treat people fairly and equitably. Fairness entails treating all people with equal respect and concern. Equity requires distributing the benefits and burdens of research participation in such a way that no segment of the population is unduly burdened by the harms of research or denied the benefits of the knowledge generated from it.

It is the policy of MSVU that all research involving human participants will be carried out by members of the University research community in a manner consistent with these fundamental principles. These principles can be expressed as:

- Protection of academic freedom and respect for the norms of academic responsibility;
- Respect for persons, who, having been adequately informed, should have the right to choose voluntarily what shall happen to them;
- The fair inclusion and equitable treatment of individuals, groups and/or communities in research;
- Risks of research should be reasonable in the light of the expected benefits, and every reasonable effort be made to minimize the potential risks of research;
- Researchers should be competent to both conduct the research and safeguard the welfare of the research participants.

The ethical components of all research protocols involving human participants or their data, prior to their commencement, must be reviewed, and cleared, by the UREB considering these principles.

## 6. Research Ethics Boards

All research with human participants by the Mount Community is required to undergo research ethics review. The University Research Ethics Board (UREB) shall be the primary research ethics board at MSVU.

The Tri-Council Policy Statement (TCPS) allows the UREB to delegate some of this responsibility to Departmental Research Ethics Boards (DREBs). DREBs are an extension of the UREB and therefore under its direction as per article 6.12 of the TCPS and procedures are outlined in the UREB standard Operating Procedure for DREBs - [REB.SOP.110](#). DREBs shall consult with the REB regarding policies and procedures, or any other issues that may arise while reviewing research ethics proposals. DREBs at MSVU will ensure that annual committee reports are submitted to the Research Ethics Office no later than June 30th each year

Research studies taking place at any of the regional affiliated hospitals (recruitment or data collection) must **first** be reviewed by the REB of that hospital. The hospital REB shall be the official board of record. Once cleared, researchers must submit the complete ethics package to the UREB for review.

## 7. **Proportionate Approach to UREB Review**

Because research seeks to understand something not yet revealed, research often entails risks to participants and others. For example, these risks can be trivial or profound, physical or psychological, and individual or social. Ethical principles and guidelines play an important role in advancing the pursuit of knowledge while protecting and respecting research participants to try to prevent such occurrences of risks. People have also had their lives enriched by their participation in research, either because they may have benefited directly or because their participation has contributed to the expansion of knowledge.

The UREB will strike an appropriate balance between recognition of the potential benefits of research, and protection of participants from research-related risks and harms, including injustices and breaches of respect for persons. A crucial element of UREB review is to ensure that the level of scrutiny of a research protocol is determined by the level of risk it poses to participants given that research involving humans spans the full spectrum of risk, from minimal to significant. A reduced level of scrutiny applied to a research protocol assessed as minimal risk does not imply a lower level of adherence to the core principles. Rather, the intention is to ensure adequate

protection of participants while reducing unnecessary impediments to, and facilitating the progress of, ethical research. This approach is in keeping with the need to respect academic freedom and not to place unwarranted constraints upon it.

In the context of both initial and continuing research ethics review, the UREB assesses the ethical acceptability of a research protocol through consideration of the foreseeable risks, the potential benefits and the ethical implications of the protocol. These two steps constitute the proportionate approach to UREB review that is recommended throughout the TCPS.

Research ethics review is focused on protection of the participants and maximizing benefits while minimizing harms. The review process is determined by the level of risk the proposed research presents for the participants. The level of risk is dependent on the participants, their capacity to provide free and informed consent and the nature of the intervention or activity being studied. Minimal risk and above minimal risk research are conducted in all domains. Using a proportionate review process, the REBs ensure that individual research protocols involving human participants, identifiable data and/or human biological material meet the requirements of the current Tri-Council Policy Statement: *Ethical Conduct of Research Involving Humans* and University policy as well as provincial, federal and other legislation and regulations, as applicable.

## **8. Research Ethics Educational Requirement**

Understanding and adhering to the TCPS and University guidelines ensures that researchers carry out their research in an ethically balanced approach. With the changes to the TCPS as well as enhanced MSVU policies, procedures and guidelines, it is important that researchers are educated about, and are aware of, the principles, expectations and best practices associated with the ethical conduct of research involving humans.

On **July 1, 2014**, the UREB began phasing in the requirement that all researchers who are involved in research with human participants or their data complete the CORE Tutorial as a minimum education standard. This was fully implemented on **July 1**,

**2016 and** continues to be a mandatory requirement. This training requirement applies only to those who conduct or supervise research with human participants or their data, or who serve on the UREB or DREB (see Appendix A – CORE Tutorial Guidance for details).

The UREB is charged with the responsibility of ensuring that research carried out by the MSVU Community adheres to the TCPS as well as applicable ethical guidelines and principles. In keeping with this mandate, all researchers who are involved in research with human participants or their data must complete the Course on Research Ethics (CORE) Tutorial as a minimum educational standard. It is important that researchers are educated in, and aware of, the principles, expectations and best practices associated with the ethical conduct of research. The tutorial is a valuable tool in all research training and orientation and provides researchers with the background and awareness needed to ensure that their research meets TCPS and MSVU ethical standards.

Once completed, the UREB will not require researchers to complete this tutorial again, unless the Interagency Advisory Panel on Research Ethics (PRE) makes substantial modifications to the tutorial. PRE will continue to develop modules for specific areas of research. As they become available, they will be included in this policy initiative and this policy will be updated. The UREB will continue to develop and enhance learning initiatives in-house to complement the CORE Tutorial.

## **9. UREB Membership and Functions**

Membership of the UREB shall be consistent with the terms of reference as outlined in Senate By-law 14.13 and referred to in UREB documentation as the Terms of Reference (REB.POL.002), changes to which shall require Senate Approval.

## **10. Living Documents**

MSVU and PRE recognize that considerations around the ethical conduct of research involving humans are complex and continually evolving. We welcome comments and



discussion and commit to the continued evolution of this and other ethics-related documents.

The official versions of this MSVU Policy and the TCPS are the online versions, which are regularly updated by the bodies responsible for the policies. The **online** version of the TCPS will be considered the official version and serves as the minimum standard for MSVU researchers - [Policy: The Interagency Advisory Panel on Research Ethics \(PRE\)](#). The UREB shall also consider the online versions of their policies, procedures, forms, and guidelines to be the official, up-to-date versions.

Researchers are encouraged to utilize the online versions for consideration and use, as research ethics is constantly evolving and the UREB will strive to have the most recent information available.

## 11. Related Documents and Resources

- [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans \(TCPS\)](#)
- [MSVU Research Ethics Website](#)
- [MSVU Research Ethics FAQs](#)
- [MSVU Research Ethics Policies, Procedures and Guidelines](#)
- [MSVU Research Ethics Forms](#)
- [CORE Tutorial Main Page](#)

## 12. Accessible URLs

What follows is a list of URLs that are included in this document:

REB Glossary of Terms      <https://www2.msvu.ca/sites/ResearchDocumentCentre/Research%20Ethics%20%20Human/REB.INFO.001%20REB%20Glossary%20of%20Terms.pdf>

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Tri-Agency Agreement on the Administration of Agency Grants and Awards by Research Institutions	<a href="https://science.gc.ca/site/science/en/interagency-research-funding/policies-and-guidelines/institutional-agreement">https://science.gc.ca/site/science/en/interagency-research-funding/policies-and-guidelines/institutional-agreement</a>
Tri-Agency Guide on Financial Administration	<a href="https://www.nserc-crsng.gc.ca/InterAgency-Interorganismes/TAFA-AFTO/guide-guide_eng.asp">https://www.nserc-crsng.gc.ca/InterAgency-Interorganismes/TAFA-AFTO/guide-guide_eng.asp</a>
Tri-Agency Framework: Responsible Conduct of Research.	<a href="https://rcr.ethics.gc.ca/eng/framework-cadre.html">https://rcr.ethics.gc.ca/eng/framework-cadre.html</a>
Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)	<a href="https://ethics.gc.ca/eng/policy.html">https://ethics.gc.ca/eng/policy.html</a>
Departmental Ethics Boards (REB.SOP.110)	<a href="https://www2.msvu.ca/sites/ResearchDocumentCentre/Research%20Ethics%20%20Human/REB.SOP.110%20DREBs.pdf">https://www2.msvu.ca/sites/ResearchDocumentCentre/Research%20Ethics%20%20Human/REB.SOP.110%20DREBs.pdf</a>
MSVU Research Ethics Website	<a href="http://www.msvu.ca/ethics">www.msvu.ca/ethics</a>
MSVU Research Ethics FAQs	<a href="https://www.msvu.ca/research-at-the-mount/research-ethics/ethics-frequently-asked-questions/">https://www.msvu.ca/research-at-the-mount/research-ethics/ethics-frequently-asked-questions/</a>
MSVU Research Ethics Policies, Procedures and Guidelines	<a href="https://www.msvu.ca/research-at-the-mount/research-ethics/human-research-ethics/research-ethics-documentation/">https://www.msvu.ca/research-at-the-mount/research-ethics/human-research-ethics/research-ethics-documentation/</a>
MSVU Research Ethics Forms	<a href="https://www.msvu.ca/research-at-the-mount/research-ethics/human-research-ethics/research-ethics-documentation/forms-and-applications/">https://www.msvu.ca/research-at-the-mount/research-ethics/human-research-ethics/research-ethics-documentation/forms-and-applications/</a>
Core Tutorial Main Page	<a href="https://tcps2core.ca/welcome">https://tcps2core.ca/welcome</a>

### 13. Acknowledgements

The development of this document has benefited directly from similar documents made public by the Tri-Council, as well as several Canadian universities. In some instances, specific formulations drawn from these sources have been incorporated into this document. Similar documents developed and made public by additional agencies, such as those of the Interagency Advisory Panel on Research Ethics (PRE), have also been consulted extensively through the course of developing the policy governing research with human participants.

### 14. Policy Revision History

SOP Number & Version	Key Changes	Effective Date
UREB 2012-01 (REB.POL.001)	Administrative review; Minor housekeeping for clarity and to reflect current practice; updates to URLs in additional Resources (#11) and Federal policy requirements; addition of definitions/glossary (#3); clarification on Research Ethics Boards (#6); Addition of accessible URLs listing (#12); and Addition of Revision History (#14)	2024-11-29
UREB 2012-01 (REB.POL.001)	Revisions made to ensure accurate reflection of standards and procedures in the updated TCPS (released 2019); Revisions to enhance clarity; Inclusion of mandatory completion of the CORE tutorial and subsequent retirement of Senate Policy UREB 2013-001 (REB.POL.004) as a stand-alone training requirement	2020-10-02
UREB 2012-01 (REB.POL.001)	Original	2012-03-26