



Senate

Policy Name	Research Ethics Compliance
Policy Number	UREB 2012-02 (REB.POL.003)
Origin	University Research Ethics Board (UREB)
Authority	Senate
Date of Original Approval	2012-03-26
Supersedes	Section 13 in the MSVU Policies and Procedures for Ethical Review
Senate Approval Dates	2024-11-29; 2018-09-28, 2012-03-26
Effective from	2024-11-29
Review/Retirement Date	2027
Responsibility for Revision	UREB
Responsibility for Implementation	UREB

Purpose:

The Government of Canada’s Panel on Research Ethics (PRE) is a body of external experts established in November 2001 by three Canadian research agencies: the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC) and the Social Sciences and Humanities Research Council (SSHRC). To be eligible to receive and administer research funds from the different federal funding Agencies, institutions must agree to comply with a number of Agency policies and agreements set out such as the [Tri-Agency Agreement on the Administration of Agency Grants and Awards by Research Institutions](#), and the [Tri-Agency Guide on Financial Administration](#). PRE created the [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans \(TCPS\)](#) and requires that research proposals developed by members of the Mount community (students, full and part-time faculty, adjunct

professors, administrators, employees and other persons holding appointments by the Board of Governors) involving human participants, or their data, and falling under the TCPS be brought before the University Research Ethics Board (UREB) for review and approval. The TCPS is referenced in the MOU. Researchers are expected, as a condition of funding, to adhere to the TCPS. Institutions should support their efforts to do so.

In addition to the TCPS, institutions and their researchers must adhere to the other policies referenced in the Agreement, which include policies on responsible conduct of research (research integrity), peer review and conflicts of interest in research. In addition to the Tri-Agency requirements, there may also be additional federal, provincial, international or other regulatory requirements that are specific to the individual research protocol. MSVU and MSVU researchers must also maintain compliance with all applicable legal, professional, and regulatory requirements with respect to protection of privacy, and consent for the collection, use or disclosure of information about participants.

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.

Definitions:

Non-compliance refers to the failure to follow relevant research policies.

Research misconduct involves the deliberate violation of the relevant research policies, and/or principles of intellectual honesty and academic freedom.

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

Policy

Compliance with the TCPS includes obtaining ethics clearance by the UREB for any research conducted with human participants, or their data, following the protocol cleared by the UREB or obtaining a modification clearance, as well as allowing for continuing review of the project until it is completed, and a final report is submitted to the UREB. The UREB is obligated to report any cases of non-compliance or research misconduct regarding issues of research ethics to the Associate Vice-President Research in accordance with the Mount's *Policy for Integrity in Research and Scholarship*. Additionally, in compliance with the Tri-Agency policies and procedures, the UREB is required to inform the Associate Vice-President Research and Financial Services of a delay in a grant recipient(s) receiving ethics clearance for the research project if REB clearance is not obtained within six months of the award date.

Procedures:

Questions, concerns or complaints received by the Research Ethics Office will be evaluated regarding the nature of the issue and who should best handle the question/concern/complaint. Criteria involved in this assessment will include: the research area, level of risk of the study, sensitivity of the issue, and potential

repercussions. If an irregularity is detected in investigating the issue, or the issue is deemed serious or sensitive, the Chair of the UREB will be notified and the procedure for potential noncompliance will be followed.

Individuals, including those not part of the University community, may make allegations of noncompliance or research misconduct. Before doing so, complainants should attempt, if possible, to seek an explanation from the subject individual to ensure that there was not a misunderstanding.

Allegations

- Allegations of non-compliance submitted to the Research Ethics Office (REO) by the person(s) making the allegation and shall be recorded by the REO.
 - Allegations sent from anonymous sources or via a third party may be considered, but only if all relevant facts are publicly available or otherwise independently verifiable.
 - Parties making allegations over the telephone will be asked to provide follow-up contact information and informed that a written statement may be requested at a later date.
- The REO shall issue an acknowledgment of receipt to the source of the allegation and inform the UREB Chair and Vice-Chair within three working days of receiving the allegation. In instances where the Chair and/or Vice-Chair are unavailable or have a conflict of interest, a designate shall be appointed.
- The Chair and/or Vice-Chair shall conduct an investigation by reviewing existing files, contacting the source of the allegation to obtain any further details required, and contacting the researcher(s) for information.
 - If deemed necessary, UREB members or outside individuals with relevant expertise may be consulted concerning the allegation.

The level at which non-compliance issues are dealt with shall reflect the actual, potential or perceived harms involved. The Research Ethics and Compliance Officer, the UREB

Chair and/or Vice-Chair shall review the allegation and evidence, and decide on an appropriate course of action, which may include the following options:

- Dismissing and/or not pursuing the allegation any further;
- Undertaking to resolve the matter directly with the investigator(s), faculty supervisor and any third parties involved (e.g., REB members, research participants, and community members). The Chair, in consultation with the Vice-Chair or designate, may require that the research be suspended. See Category 1 below; and
- Determining the issue falls under the *Policy for Integrity in Research and Scholarship*, therefore referring the matter to the Associate Vice-President (Research) for investigation. The research must be suspended. See Category 2 below.
- **NOTE:** Any allegation of non-compliance made regarding research that is funded by the Tri-Council (SSHRC, NSERC, CIHR) will not be considered at the Category 1 level and shall automatically be delegated to Category 2.

Category 1: The non-compliance issue is considered to be minor resulting in actual, potential or perceived harms that are considered to carry no more than minimal risk. Examples include, but are not limited to, the following:

- Failure to submit appropriate supplemental documentation when requested;
- Failure to submit a request for renewal/annual report or the final report as required. The Research Ethics Office will provide 2 courtesy notices of upcoming REB Protocol expiries and one notice of REB suspension. Failure to provide the appropriate report will result in the termination of the UREB clearance and a notice will be sent to the Associate Vice-President Research and to Financial Services if the protocol is funded.
- Any deviation from approved protocol, without prior UREB clearance of revision or modification, where the resulting actual, potential or perceived harms are considered to carry no more than minimal risk.

Procedures for Category 1 non-compliance issues will be as follows:

- Research Ethics and Compliance Officer, UREB Chair and/or Vice-Chair will establish a realistic schedule for resolving the situation, including meeting with the investigator(s) and faculty supervisor (if relevant).
- Whenever possible, an educative approach will be taken. Actions will be determined to rectify any harm that may have been perceived or experienced by participants or community members.
- The Research Ethics Office will produce a report of proceedings, which will be sent to the UREB Chair, Vice Chair, Investigators and Faculty Supervisor (if relevant).
- The Associate Vice-President Research will be notified and receive copies of all correspondence but generally will not be involved in the case.
- A summary report will be given at the next full UREB meeting.

Non-compliance issues not resolved at Category 1 to the satisfaction of the UREB Chair, and/or Researcher and faculty supervisor (if relevant) will consequently advance to Category 2.

Category 2: The non-compliance issue is considered to be serious in nature resulting in actual, potential or perceived harms that are considered to carry more than minimal risk, or the issue involves not only non-compliance but also research misconduct. Examples include, but are not limited to:

- Issues that cannot be resolved to the satisfaction of the UREB Chair, and/or Researcher(s) and Faculty Supervisor (if relevant) at Category 1;
- Failure to obtain ethics clearance prior to starting research involving human participants;
- Any deviation from the cleared protocol, without prior UREB clearance of revision or modification, where the resulting actual, potential or perceived harms are considered to carry greater than minimal risk;
- Failure to disclose, or incomplete disclosure of the potential risk of research to the UREB and/or research participants;

- Intentionally providing incorrect or misleading information to the UREB and/or research participants (please note that this does **not** include research using deception that has been cleared by the UREB or DREB); Intentional violation of the basic principles of the Tri-Council Policy Statement and/or Mount Saint Vincent University’s Research Ethics policies, procedures and guidelines.

Procedures for Category 2 non-compliance issues will be as follows:

- The research must be immediately suspended.
- The Chair or Vice Chair will refer the matter to the Associate Vice-President Research who will then follow the procedure for investigating research misconduct outlined in the MSVU [Policy on Responsible Conduct of Research](#) .A summary report will be given at the next full UREB meeting.

Related Documents and Resources

- [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans \(TCPS\)](#)
- [Tri-Agency Framework: Responsible Conduct of Research](#)
- [Tri-Agency Guide on Financial Administration](#)
- [MSVU Policy on Responsible Conduct of Research](#)
- [MSVU Research Ethics Website](#)
- [MSVU Research Ethics Policies, Procedures and Guidelines](#)
- MSVU REB.FORM.013 – Breach Allegation – Responsible Conduct of Research - Please contact ethics@msvu.ca

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	https://science.gc.ca/site/science/en/interagency-research-funding/policies-and-guidelines/institutional-agreement
Tri-Agency Guide on Financial Administration	https://www.nserc-crsng.gc.ca/InterAgency-Interorganismes/TAFA-AFTO/guide-guide_eng.asp
Tri-Agency Framework: Responsible Conduct of Research.	https://rcr.ethics.gc.ca/eng/framework-cadre.html
Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)	https://ethics.gc.ca/eng/policy.html
MSVU Policy on Responsible Conduct of Research	https://www2.msvu.ca/DocumentCentral/Documents/Responsible%20Conduct%20of%20Research%20(Policy%20on).pdf
MSVU Research Ethics Website	www.msvu.ca/ethics
MSVU Research Ethics and Related Policies	https://www.msvu.ca/research-at-the-mount/research-ethics/human-research-ethics/research-ethics-documentation/
MSVU REB.FORM.013 – Breach Allegation – Responsible Conduct of Research	Contact ethics@msvu.ca

Policy Revision History

SOP Number & Version	Key Changes	Effective Date
UREB 2012-02 (REB.POL.003)	Administrative review; Formatted for accessibility; Addition of Scope; Addition of definitions/glossary; Minor housekeeping for clarity and to reflect	2024 -11-29

SOP Number & Version	Key Changes	Effective Date
	current practice; Updates to URLs and Federal policy requirements; Addition of Related documents and resources; Addition of accessible URLs listing; Addition of Revision History	
UREB 2012-02 (REB.POL.003)	Minor changes to reflect human research also includes their data; Minor corrections for typos; punctuation; clarity; Addition of “Note” in the Allegation section to be in compliance with the Federal requirements of the Secretariat on responsible Conduct of Research.	2018-11-23
UREB 2012-02 (REB.POL.003)	Revisions to the reflect Federal requirements of the Secretariat on responsible Conduct of Research;	2012-09-24
UREB 2012-02 (REB.POL.003)	Original - Section 13 in the MSVU Policies and Procedures for Ethical Review now a stand-alone Policy Document	2012-03-26