



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	March 26, 2012
Supersedes	Section 13 in the MSVU Policies and Procedures for Ethical Review
Last Updated	
Effective from	March 26, 2012
Review/Retirement Date	2015
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 set out as schedules to a Memorandum of Understanding (MOU) between the Agencies and institutions¹. 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 (student, faculty, adjunct professors, administrators, employees and other persons holding appointments by the Board of Governors) involving human participants and falling under the TCPS be brought before the University Research Ethics Board (UREB) for review and approval. The TCPS is referenced in Schedule 2 of the MOU. Researchers are expected, as a condition of funding, to adhere to the TCPS. Institutions should support their efforts to do so.

¹ *Memorandum of Understanding (MOU) on the Roles and Responsibilities in the Management of Federal Grants and Awards.* www.nserc-crsng.gc.ca/NSERC-CRSNG/Policies-Politiques/MOURoles-ProtocolRoles/index_eng.asp

In addition to the TCPS, institutions and their researchers must adhere to the other policies referenced in the MOU, which include policies on research integrity, peer review and conflicts of interest². They 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.

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.

Policy

Compliance with the TCPS includes obtaining ethics clearance by the UREB for any research conducted with human participants, following the protocol approved by the UREB or obtaining a change to protocol, 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 misconduct regarding issues of research ethics to the Associate Vice-President (Academic & Research) in accordance with the Mount's *Policy for Integrity in Research and Scholarship*. Additionally, in compliance with the Schedule 2.1.g of the MOU, the UREB must inform the Associate Vice-President (Academic & Research) and Financial Services of a delay in a grant recipient(s) receiving ethics clearance for the research project if REB approval 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 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 of non-compliance shall be submitted to the Research Ethics Office (REO) by the person(s) making the allegation. All allegations shall be recorded by the REO.

² Schedules 4 (research integrity), 6 (peer review) and 14 (conflicts of interest).

- 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 REO, 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 (Academic & Research) for investigation. The research must be suspended. See Category 2 below.

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
- Any deviation from approved protocol, without 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 Level 1 non-compliance issues will be as follows:

- REO, REB 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.

- REO 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 (Academic & 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 Level 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 approved protocol, without 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 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 approved by the UREB or DREB);
- Intentional violation of the basic principles of the Tri-Council Policy Statement and/or Mount Saint Vincent University Research Ethics policies, procedures and guidelines.

Procedures for Level 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 (Academic & Research) who will then follow the procedure for investigating research misconduct outlined in Article 5 of the *Policy for Integrity in Research and Scholarship*
- A summary report will be given at the next full UREB meeting.