Part 5 - Academic

Ethics of Research Involving Human Participants Policy
POL 585-1

Policy Type:	**Academic with Management Implications**		
Policy Sponsor:	Provost and Vice-President Academic	**Effective:**	October 21, 2002
Office of Administrative Responsibility:	Associate Vice-President Research	**Last Reviewed:**	April 2010
Approver:	Board of Governors	**Approved:**	May 31, 2010

A. OVERVIEW

Research involving human participants is based on a fundamental moral commitment to advancing human welfare, knowledge and understanding. Such research also involves an imperative to respect human dignity and well-being. To this end, Mount Royal University (MRU) endorses the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS), and maintains a Human Research Ethics Board (HREB) to ensure that all research investigations involving human participants are carried out in compliance with the TCPS and Mount Royal policies.

The intention of the University is to ensure that, in research involving human participants:

- participants are treated with dignity;
- the selection of participants is fair;
- vulnerable persons are protected from abuse, exploitation and discrimination;
- standards for privacy and confidentiality are observed with respect to access, control and dissemination of personal information;
- the ethics review process is fair and effectively independent of the University's other academic and administrative decision-making processes;
- foreseeable harms will not outweigh the anticipated benefits;
- research participants will not be subjected to unnecessary risks of harm, and their participation in research must be essential to achieving scientific and societal aims that cannot be realized without the participation of human subjects; and
- actual and potential conflicts of interest of researchers and individuals in the review process are made known and dealt with appropriately.

B. PURPOSE

This policy is intended to create a research environment in which human research participants are protected, and to ensure responsibilities are discharged according to the relevant ethical standards, by promoting awareness of research ethics amongst faculty, staff and students, establishing an independent research ethics review process, and putting in place mechanisms for the protection of human participants in ongoing research.

C. SCOPE

This policy applies to all research that involves human participants in any of the following circumstances a) where such research is conducted by members or associated members of the University acting in their University capacity; b) where such research is conducted at the University, its affiliated sites, or through its systems of distributed learning; c) where such research is administered by the University; or d) where ethics clearance by the University is required for research pursuant to an affiliation agreement with other agencies.

It is the responsibility of the principal investigator on a project to ensure that all researchers involved in the project are aware of and comply with this policy, as well as all other relevant polices of the University.

D. POLICY STATEMENT

The University will regulate the conduct of all research involving human participants in accordance with the most current version of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* and, where applicable to specific research, other relevant national and international standards.

No research to which this policy applies may be undertaken, nor may University services or facilities be used, nor may funds for such purposes be released, nor financial accounts opened unless the research has received formal ethical clearance of the University's Human Research Ethics Board (HREB) before the proposed research begins and the research has received a Certificate of Clearance.

No material change may occur in research to which this policy applies, as proposed, without the clearance of the University's HREB.

The University shall ensure that those who conduct such research understand their responsibilities for the ethical conduct of their research, and receive appropriate training in the skills necessary for such conduct. This includes not only awareness of, but understanding of the relevant policies and professional standards.

E. DEFINITIONS

Minimal Risk research is defined as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by the participant in those aspects of his or her everyday life that relate to the research.

Research Involving Human Participants is defined as an undertaking intended to extend the collective knowledge of a field through a disciplinary inquiry or systematic investigation, which involves living individuals, human remains, cadavers, tissues, biological fluids, embryos or foetuses.

Notwithstanding the above, research involving human participants does not include:

- Research about a living individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interviews. Such research only requires an ethics review if the subject is approached directly for interviews or for access to private papers.

- Quality assurance studies, program evaluations, performance reviews or testing within normal educational requirements, or activities undertaken by the University for administrative or operational reasons with no intent to disseminate outside the participant pool.

- Use of secondary data where there is no identifying information involved and where the new use of the data will not harm the providers of the data.

- Minimal Risk student assignments that teach about the design, conduct and processes of research, but do not extend the collective knowledge of the field.

- Minimal Risk student activities for professional skills development including simulations, information gathering, observations, and interviews, such as those engaged in by journalism students and students of other fields.

- Research on organizations such as governments, agencies, corporations and the like, or research involving public policy issues, the writing of modern history, or literary or artistic criticism, so long as the research is based entirely on material to which the public has access.

Tri-Council Policy Statement or TCPS is short for the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.* This document is one of the tri-agency policies of the Natural Science and Engineering Research Council (NSERC), the Social Sciences and Humanities Research Council (SSHRC), and the Canadian Institutes of Health Research (CIHR). The latest official version is available on the web at http://pre.ethics.gc.ca.

Published Procedures to this Policy

- Procedures for Ethical Review of Research Involving Human Participants
- HREB Terms of Reference

Part 5 - Academic

Parent Policy: Ethics of Research Involving Human Participants
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Procedures for Ethical Review of Research Involving Human Participants

Policy Type:	**Academic with Management Implications**		
Policy Sponsor:	Provost and Vice-President, Academic	**Effective:**	October 21, 2002
Office of Administrative Responsibility:	Associate Vice-President, Research	**Last Reviewed:**	January 2010
Approver:	Provost and Vice-President, Academic	**Approved:**	April 14, 2010

1. RESPONSIBILITY OF RESEARCHERS

Each researcher is responsible to:

1.1 Read and be aware of the *Ethics of Research Involving Human Participants* policy and all related research policies and procedures.

1.2 Assess each planned research project, including student and classroom-based initiatives, for relevance to the *Ethics of Research Involving Human Participants* policy. If in doubt after reading this policy, associated procedures and definitions and the Tri-Council Policy Statement (TCPS), researchers should consult the Human Research Ethics Board (HREB) Office (local 6069, hreb@mtroyal.ca, Room A322) or the Chair of the HREB.

1.3 Submit an 'Application for Ethics Review' to the HREB Office using the form specified in the HREB operational procedures for each project relevant to this policy.

1.4 Promptly inform the HREB of any similar or equivalent proposal to research ethics boards or similar bodies at other institutions, and to funding agencies or regulatory bodies. The HREB shall determine if concurrent applications are acceptable.

1.5 Maintain any issued Certificate of Clearance in good standing during the research project.

1.7 Promptly notify the HREB when the study concludes.

1.8 Ensure that any amendments to the study personnel, funding, protocol, consent form or any recruitment procedures are cleared by the HREB prior to

implementation, except where necessary to eliminate apparent immediate hazards to participants.

1.9 Report all serious and unexpected study related events to the HREB in accordance with applicable regulations and guidelines.

1.10 Promptly notify the HREB of any unexpected incident, experience, outcome, or any new research knowledge that could impact the conduct of the study or alter the HREB's clearance to continue the study.

1.11 Ensure that informed consent, where required, is obtained from participants prior to their enrolment in the research project in a form and manner prescribed by the TCPS, the following section, and HREB procedures and directives.

2. INFORMED CONSENT

2.1 Research Involving Human Participants that is governed by MRU policies and for which free and informed consent is required may only include research participants if they, or their authorized third parties, have provided their free and informed consent and that consent has been maintained throughout their participation in the research. [TCPS v1 Article 2.1a]

2.2 Research participants must have freely agreed to take part in the research study on the basis of well-understood information about the objectives of the research and the nature of their participation. Research participants must be fully informed of any and all known or reasonably foreseeable risks of harm associated with the research, as well as possible benefits of their participation. They must have the opportunity to evaluate the relative weight of any risks and benefits.

2.3 Free and informed consent must be voluntarily given, without manipulation, undue influence, or coercion. There shall not be incentives offered that are so large as to become an undue influence and undermine the voluntary nature of their participation. Researchers must take care to avoid problems of informed consent based on a special relationship between researcher and research participant, so that such relationship does not unduly influence the research participant's free and informed consent. [TCPS v1 Article 2.2]

Withdrawal of Consent, Concern or Complaint

2.4 Research participants may withdraw their consent at any time during the research program, and such withdrawal shall not result in penalty or harm or loss of promised benefits that are not inherently dependent on completion of their participation.

2.5 Where any research participants express significant concern about the nature of the informed consent or the use of the research, the researcher should report the concerns to the HREB Complaints Officer.

2.6 Free and informed consent should normally be provided in writing in a form specified under the authority of the Policy. If written consent is not culturally acceptable, or where there are good reasons for not recording consent in writing,

the procedures used to seek free and informed consent must be documented for review by the REB. [TCPS v1 Article 2.1b]

Altered or Waived Elements of Consent [TCPS v1 Article 2.1c]

2.7 The HREB may approve a consent procedure that does not include, or alters some or all of the elements of informed consent as noted above, or waives the normal requirements for informed consent, provided that the HREB decides and documents that:

2.7.1 the research involves no more than minimal risk to the research participants;
2.7.2 the waiver or alteration is unlikely to adversely affect the rights and welfare of the participants;
2.7.3 the research could not practicably be carried out without the waiver or alteration;
2.7.4 whenever possible and appropriate, the participants will be provided with additional pertinent information after participation; and
2.7.5 the waiver or altered consent does not involve a therapeutic intervention.

2.8 In studies that include randomized consent or blinding in clinical trials, neither the research participants nor those responsible for their care know which treatment the participants are receiving before the project begins. Such research is not regarded as a waiver or alteration of the requirements for consent if the participants are informed of the probability of being randomly assigned to one part of the study or another. [TCPS v1 Article 2.1d]

Naturalistic Observations

2.9 HREB review is normally required for research involving naturalistic observation, except for observation of research participants in public meetings, demonstrations, political rallies or like activities where research participants are expected to be seeking or are aware of public visibility. Naturalistic observation is used to study behaviour in a natural environment. If the naturalistic observation does not allow for the identification of the participants, and is not staged, then the research will normally be considered as of minimal risk. Research involving naturalistic observations will normally be reviewed by the HREB to ensure that concerns of privacy and the dignity of those being observed are handled appropriately. [TCPS v1 Article 2.3]

Information Disclosed

2.10 Researchers shall provide to prospective research participants, or to their authorized third parties, full and frank disclosure of all information relevant to their free and informed consent. Throughout this process, the researcher must ensure that prospective research participants, or to their authorized third parties, are given adequate opportunities to discuss and contemplate their participation. [TCPS v1 Article 2.4]

2.11 Researchers shall provide at a minimum the following information:

2.11.1 information that the person is being invited to participate in a research project;
2.11.2 a comprehensible statement of the research purpose, the identity of the researcher and their affiliation to MRU, the expected duration and nature of participation, and a description of the research procedures;
2.11.3 a comprehensible description of the known or reasonably foreseeable risks and benefits that may arise from participation in the research, as well as the likely consequences of non-action, particularly in research related to treatment, or where invasive methods are involved, or where there is a potential for physical or psychological harm;
2.11.4 assurance that the prospective research participants are free not to participate, and are able to withdraw at any time without prejudice to pre-existing entitlements, and will be given continuing and meaningful opportunities for deciding whether or not to continue to participate;
2.11.5 assurance that the research participants have ongoing opportunities to decide whether or not to continue to participate during the course of the research;
2.11.6 the potential of commercialization of research findings, and the presence of any apparent, actual, or potential conflict of interest on the part of the researchers, sponsors, or institutions; and
2.11.7 the name, and contact information for a person(s) who may be contacted for information on the nature of the research, or in the case of concerns, complaints, or consequences.

2.12 Researchers may be required by the HREB to provide additional information, depending on the nature of the research project, including:

2.12.1 assurance that new information will be provided to the research participants in a timely manner whenever such information is relevant to the research participant's decision to continue or withdraw from the research;
2.12.2 information on resources available outside the research team to contact regarding concerns with the research;
2.12.3 an indication as to who will have access to the information collected on the identity of research participants, descriptions of how confidentiality will be protected, and the anticipated uses of the data;
2.12.4 an explanation of the responsibilities of the research participant;
2.12.5 information on the circumstances under which the researcher may terminate the participant's participation in the research;
2.12.6 information on any costs, payments, reimbursement for expenses, or compensation for injury;
2.12.7 in the case of randomized trials, the probability of the research participant's assignment to each of the options;
2.12.8 the ways in which research results will be published, and how the research participants will be informed of the results of the research.

2.13 It is the responsibility of the researcher to collect and retain documentation of written consent for at least 5 years from the conclusion of the research study, or longer if specified by the HREB. If consent has been waived or the consent is not recorded in writing then the researcher must retain appropriate documentation evidencing this.

2.14 Researchers must ensure that they comply with all applicable federal and provincial legislative requirements and the legislative requirements of the jurisdiction in which participation takes place.

Competence

2.15 The competence of the potential research participants to provide free and informed consent is an important factor in the validity of the consent. Competence refers to the ability to understand the information presented about the research, to appreciate the potential consequences of a decision, and to provide free and informed consent to participate in a specific research project. Competence is not an all or nothing condition. The prospective research participants do not need to have the capacity to make every kind of decision, but they should be able to make an informed decision about participation in the specific research.

2.16 Individuals who are not legally competent to participate in the proposed research shall only be asked to become research participants when: [TCPS v1 Article 2.5]

- 2.16.1 the research question can only be addressed using the identified group(s); and
- 2.16.2 free and informed consent is sought from their authorized representatives, such as parents or legal guardians; and
- 2.16.3 the research does not expose them to more than minimal risk without the potential for direct benefits for them.

2.17 For research involving individuals who are not competent, the HREB shall ensure that, as a minimum, the following conditions are met: [TCPS v1 Article 2.6]

- 2.17.1 the researcher shall show how a) the free and informed consent will be sought from the authorized third party; and b) how the research participant's best interests will be protected;
- 2.17.2 the authorized third party is not the researcher or any other member of the research team;
- 2.17.3 the continued free and informed consent of the authorized third party is required in order for the continuation of the participation of the legally incompetent person in the research project, as long as the person remains incompetent; and
- 2.17.4 if the incompetent research participant becomes competent during the research project, his or her informed consent will be sought as a condition of continuing participation.

2.18 If the free and informed consent has been obtained from an authorized third party, and the legally incompetent research participant understands the nature and consequences of the research, the researcher must seek to determine the wishes of the research participant. Should the potential participant dissent then such dissent will preclude participation. [TCPS v1 Article 2.7]

Research in Emergency Health Situations [TCPS v1 Article 2.8]

2.19 Subject to all applicable legislative and regulatory requirements, research involving emergency health situations shall be conducted only if it addresses the emergency

needs of individuals involved, and then only in accordance with criteria established in advanced of such research by the HREB. The HREB may allow research that involves health emergencies to be carried out without the free and informed consent of the research participant or of his or her authorized third party if ALL of the following apply:

2.19.1 a serious threat to the prospective participant requires immediate intervention;
2.19.2 no standard efficacious care exists or the research offers a real possibility of direct benefit to the participant in comparison to the standard of care;
2.19.3 either the risk of harm is not greater than that involved in standard efficacious care, or it is clearly justified by the direct benefits to the participant;
2.19.4 the prospective participant is unconscious or, for any reason, lacks capacity to understand risks, methods and purposes of the research;
2.19.5 third party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and
2.19.6 no relevant prior directive by the participant is known to exist.

2.20 If a previously incapacitated participant of research, involving emergency health situations, regains capacity, or when an authorized third party is found, the free and informed consent of the participant or authorized third party shall be sought promptly for the participant's continuation in the project and for subsequent examinations or tests related to the study to be conducted.

3. THE HUMAN RESEARCH ETHICS BOARD (HREB) - AUTHORITY

3.1 The HREB is established by the Board of Governors of Mount Royal University and empowered to ensure that all research conducted under the auspices of the University is designed and conducted in such a manner that it protects the rights, welfare and privacy of research participants.

3.2 The HREB has the authority to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants that is conducted within, or by members of, the institution.

3.3 The HREB may terminate ongoing research:

3.3.1 where there is clear evidence that it is not being conducted in accordance with its requirements; or
3.3.2 that is associated with unexpected harm to participants.

3.4 The HREB is authorized to specify a process for continuing review of approved projects in consultation with the researcher.

3.4.1 In accordance with the principle of proportionate review, research that poses at most Minimal Risk to participants will require only a minimal process, normally consisting of an annual report.
3.4.2 The HREB may require researchers conducting projects that are deemed greater than Minimal Risk to submit to additional review elements Such as random audit of the consent process, review of documents, or

establishment of a safety monitoring committee and report on a shorter time frame.

3.4.3 In cases where researchers depart from the approved research, the HREB shall specify appropriate review procedures or actions, to be carried out by the appropriate institutional authority and coordinated by the Office of Research Services (ORS). The HREB shall be promptly notified of the results of any such review process by the ORS.

4. REVIEW SCOPE AND STANDARDS

4.1 The HREB shall:

4.1.1 determine if it is the appropriate body to review the application and whether the application is within its jurisdiction or expertise;

4.1.2 consider scientific or technical aspects of the research as necessary to assess the risks and benefits;

4.1.3 determine whether proposals are acceptable on ethical grounds by considering two essential parts: a) the selection and achievement of ethically acceptable ends and b) the ethically acceptable means to those ends TCPSv1 Context, B on i.4;

4.1.4 determine the level and frequency of continuing review of the research appropriate to the degree of risk, provided it is not less than once per year;

4.1.5 determine that free and informed consent will be obtained and maintained TCPSv1 Article 2;

4.1.6 determine that the research is in compliance with the policy on *Ethics of Research Involving Human Participants*, the TCPS and other relevant standards.

4.2 The HREB shall refer any significant issues of research integrity, risk management, or other risk declarations specified on the ORS *Tracking and Signature Form*, and not covered under this policy, to the appropriate institutional authority for review, as discussed in policies on *Integrity in Research and Scholarship*, *Risk Management*, *Conflicts of Interest in Research*, and other relevant policies. If the issues are not relevant to the *Ethics of Research Involving Human Participants* policy the HREB shall not delay review on their account.

4.3 Where significant institutional conflicts of interest are identified (as part of an application or by the HREB during a review) the HREB shall forward such concerns to the Responsible Conduct of Research Committee (RCRC; the body tasked with assessing and managing COI) for assessment.

4.4 Conflicts of interest involving the researcher(s) related to the Research Involving Human Participants must be declared to and managed by the HREB as part of its review. These COI must also be declared as specified in the policy on *Conflicts of Interest in Research.*

5. INTENSITY AND NATURE OF REVIEW

5.1 The HREB shall scrutinize applications with an intensity proportionate to the magnitude and probability of potential harm to the human participants inherent in

the proposed research [TCPSv1 Sections 1.6, 1.13]. The concept of Minimal Risk, as defined herein, provides the foundation for proportionate review.

5.2 The HREB shall determine whether an application poses more than Minimal Risk, as defined herein and addressed in more detail in the TCPS. Where research poses more than Minimal Risk, the HREB shall satisfy itself that the design of the research project is capable of answering the questions asked in the research [TCPSv1 Section 1.5(a)]. In such cases it shall determine whether peer review is a requirement arising out of the *Ethics of Research Involving Human Participants* policy or out of traditions of the discipline and if so whether the requirement has been satisfied [TCPSv1 Section 1.5]. Normally, Minimal Risk research in the humanities and social sciences shall not require such peer review [TCPSv1 Section 1.5(c)].

5.3 The HREB shall only undertake review of the project design where the required expertise is available on the Board. Otherwise the applicant shall be responsible for providing a review that is satisfactory to the Board, subject to 4.2.

5.4 As a service to the applicant, Mount Royal may where possible, through its Office of Research Services, provide a peer review committee or specific peer reviewers [TCPSv1 Section 1.5].

6. MULTI-CENTRED AND EXTRA JURISDICTIONAL REVIEW

6.1 In cases where research involving human participants is located on or involves both MRU and other institution(s) the HREB may coordinate its review with the other institution(s') HREB or equivalent.

6.2 If such research is to be conducted at another institution the researcher must undergo ethics review by both the HREB (who may coordinate its review) and the research ethics board, if one exists, that has the legal responsibility and equivalent ethical and procedural safeguards in the jurisdiction where the research is being done. [TCPSv1 Section 1.14]

6.3 In no case may a Certificate of Clearance be issued by the HREB for research under this section unless the research is compliant with the *Ethics of Research Involving Human Participants* policy and conditional upon compliance with the legal and ethical safeguards of the institution where the research is being done.

7. DELEGATED REVIEW

7.1 Delegated review of both initial applications and subsequent revisions are permissible only when research activities, in the opinion of the Chair, constitute no more than Minimal Risk to participants or minor changes in approved research. Should the delegated reviewer(s) determine that this is not the case, the delegated review shall cease and a full-Board review shall ensue.

7.2 A review by a subgroup or individual of the HREB may be specified at the discretion of the Chair, and in keeping with the HREB operational procedures. In such a case of delegated review, the HREB Chair or designate(s) will constitute the HREB and

will review the application as specified herein. Such reviews will be reported to the full HREB.

7.3 Delegated reviews are subject to the same standards of recording and reporting as full-Board reviews.

7.4 Requests for reconsideration of a delegated review will be heard by the full HREB.

8. REVIEW OF UNDERGRADUATE RESEARCH

8.1 Mount Royal encourages undergraduate student involvement in Research Involving Human Participants. These activities are subject to the same review requirements as faculty research, with the following exceptions.

8.2 As noted in the definitions (Section 16), research activities undertaken specifically for training or professional skills development purposes that a) do not involve extending the collective knowledge of the field and b) are Minimal Risk are exempt from review.

8.3 Research Involving Human Participants undertaken by undergraduate students outside of the formal requirements of a course must be supervised by a faculty member TCPSv1 Section 1.4, who submits an application on the student's behalf. The level of risk will determine the nature of the review, as described in Sections 4 through 7. The faculty member is fully responsible for the project and for obtaining clearance from the HREB.

8.4 Research Involving Human Participants, posing no more than Minimal Risk, and undertaken within the formal requirements of a course is subject to course-level review by the HREB, using an abbreviated process and forms. Recruitment and data gathering activities cannot commence prior to issuance of clearance by the HREB or a delegated committee as described in Section 9.

8.4.1 Course-level clearance is issued to a single course instructor, who is responsible for implementing the proposed activity in compliance with the *Ethics of Research Involving Human Participants* policy and any additional conditions imposed by the HREB.

8.4.2 Course-related activities that are, in the opinion of the HREB, greater than Minimal Risk to participants shall be subject to full board review.

9. DELEGATED ETHICS COMMITTEES

9.1 The HREB may choose to delegate review of Minimal Risk, course-related undergraduate Research Involving Human Participants to a departmental or institutional student research committee.

9.2 Those conducting the delegated review are accountable to the HREB and must comply with any directions from them regarding their procedures or decisions.

9.3 The appeal board for delegated reviews is the HREB.

10. RECORDS, REPORTS AND COMMUNICATIONS

10.1 The HREB shall make its membership list and all operational procedures available publicly.

10.2 The HREB shall, for every decision, communicate in writing to the applicant the decision made and the reasons for the decision.

10.3 The HREB shall retain records of the following for the duration of the research and an additional five years, or as directed by the Alberta Freedom of Information and Personal Privacy Act:

10.3.1 the application made and any modifications, including all attachments;
10.3.2 minutes of its meetings, clearly documenting decisions, any dissents, and the reasons for them and;
10.3.3 all other documentation relevant to the decisions.

10.4 HREB records as specified above shall be made available to authorized representatives of the University, the researchers, funding agencies, and other relevant authorities involved in the research.

10.5 The HREB shall report to the Board of Governors of Mount Royal University on an annual basis. The report shall, at a minimum, consist of decisions issued, reasons for those decisions, continuing review requirements and results of continuing review, training of MRU Members, the adequacy of resources provided, and any confirmed violations of protocols and sanctions imposed by the HREB.

10.6 The HREB and its Chair shall maintain open lines of communication with the HREB Coordinator and the Associate Vice-President Research, who shall do the same.

11. CERTIFICATES AND TERMS OF CLEARANCE

11.1 If the HREB determines that the research proposed in an application is acceptable, it shall direct the issuance of a Certificate of Clearance that is compliant with the applicable granting agency standards, as appropriate.

11.2 A Certificate of Clearance may impose conditions and require scheduled or event-driven reporting to the HREB. The rigour of the conditions and the reporting required shall be, at least, proportionate to the risk level and the assessment required TCPSv1 Section 1.6 and 1.13. Further details of continuing review are detailed in section 2.4.

11.3 The HREB retains a continuing interest in the project throughout its span, and may withdraw or modify a Certificate of Clearance at any time with written notification to the researcher. Normally, if the HREB is considering such withdrawal or modification, the researcher will be given opportunity to make a submission.

11.4 Provided the components specified in 1.7 do not change, the Certificate of Clearance shall be valid for one year from the date of issuance. Prior to that date an application for renewal must be submitted if the research procedures involving humans is to continue.

11.5 If at any time the researcher wishes to modify the study, an application for amendment must be submitted to the HREB. Such modifications may not be implemented prior to approval of the amendment, which will not alter the expiry date of the Certificate of Clearance.

12. RECONSIDERATIONS AND APPEALS

12.1 Researchers have the right to request, and the HREB has the obligation to provide, reconsideration of decisions. In cases where the HREB and the researcher cannot reach an agreement through face-to-face discussion, the researcher has the right to file an appeal.

12.2 Researchers wishing to file an appeal shall make a written request to the Associate Vice-President Research, who shall convey it to the Chair of the Appeal Board.

12.3 As established by a formal agreement between Mount Royal University and the University of Calgary, the HREB Appeal Board is the Research Ethics Appeal Board of the University of Calgary. The University of Calgary's policy governing the Research Ethics Appeal Board may be consulted on their Research Office website. The Associate Vice President Research (AVPR) is responsible for updating and maintaining this agreement.

12.4 Decisions of the Research Ethics Appeal Board are final and binding in all respects.

13. COMPLAINTS FROM PARTICIPANTS

13.1 The HREB shall appoint a Complaints Officer from its membership who shall be listed as the contact point for research participants or potential participants who wish to complain or comment about a research project.

13.2 All complaints and responses will be recorded in the protocol file.

13.3 The Complaints Officer will determine if a complaint warrants re-examination by the HREB of a previously approved project.

13.4 In all cases complaints will receive a written response from the Complaints Officer detailing the HREB actions in response to the complaint.

14. VIOLATIONS OF POLICY

14.1 Violations of this any and other University research policy are subject to procedures detailed in the *Integrity in Research and Scholarship* policy. A representative of the HREB sits on the advisory committee detailed in that process and will represent the HREB's expertise and interests there.

14.2 Otherwise, the HREB's role in violations of policy is detailed in section 2.

15. EDUCATION

15.1 The HREB Chair shall jointly coordinate with the Associate Vice-President Research the holding of general meetings and education retreats or workshops during which HREB members may take advantage of educational opportunities that may benefit the operation of the HREB, discuss general issues arising out of HREB activities and recommend revisions to policies and procedures.

15.2 The Associate Vice-President Research shall work with the Responsible Conduct of Research Committee and the Human Research Ethics Board to develop appropriate ethics training curricula for faculty and students of Mount Royal.

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Quality assurance studies, program evaluations, performance reviews or testing within normal educational requirements, or activities undertaken by the University for administrative or operational reasons with no intent to disseminate outside the participant pool.

Use of secondary data where there is no identifying information involved and where the new use of the data will not harm the providers of the data.

Minimal Risk student assignments that teach about the design, conduct and processes of research, but do not extend the collective knowledge of the field.

Minimal Risk student activities for professional skills development including simulations, information gathering, observations, and interviews, such as those engaged in by journalism students and students of other fields.

Research on organizations such as governments, agencies, corporations and the like, or research involving public policy issues, the writing of modern history, or literary or artistic criticism, so long as the research is based entirely on material to which the public has access.

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POL 585-1

Human Research Ethics Board Terms of Reference

Policy Type:	**Academic with Management Implications**		
Policy Sponsor:	Provost and Vice-President, Academic	**Effective:**	October 21, 2002
Office of Administrative Responsibility:	Associate Vice-President, Research	**Last Reviewed:**	January 2010
Approver:	Provost and Vice-President, Academic	**Approved:**	April 14,2010

1. HREB MEMBERSHIP

1.1. The Board of Governors of Mount Royal University delegates to the Provost and Vice-President Academic (VPA) responsibility for HREB membership and implementation of this policy and procedures.

1.2. The Chair of the HREB is a faculty member appointed by the VPA, normally for a period of up to two years, with the possibility of one renewal.

1.3. Members of the HREB will be appointed by the VPA in consultation with the HREB Chair. Normally appointments will be for a three year term, with the possibility of renewal for a further three year term. Terms of individual appointments should be staggered in order to ensure continuity of expertise.

1.4. The VPA, in consultation with the Chair of the HREB, will appoint a Vice-chair, for a period of up to two years. The Vice-chair will chair the meetings and make decisions in the absence of the Chair.

1.5. The HREB will consist of at least 7 core members, in addition to the Chair, composed of both men and women, as follows:

1.5.1. At least one from each of the following research areas: health and community studies, physical sciences (including information and communication technologies), social sciences and humanities, and teaching and learning -- having broad expertise in the methods or in the areas of research common to their discipline.

1.5.2. At least one member knowledgeable in research ethics (who may be one of the above).

1.5.3. At least one member with no affiliation with Mount Royal recruited from the community served by the University.

1.5.4. A student member, recruited through the Students Association of Mount Royal University, and appointed for a period of one year, with the possibility of one renewal of one year.

1.6. The majority of the above members should have both the training and the expertise to make sound judgements on the ethics of research proposals involving human participants

1.7. Additional members may be appointed by the VPA, including but not limited to:

1.7.1. a member knowledgeable in the relevant law that is not the legal counsel of the University (as the HREB does not review biomedical applications this member is not mandatory),

1.7.2. additional community members in keeping with the overall size of the Board,

1.7.3. ad hoc members appointed for special purpose reviews, who will not be part of the decision, and

1.7.4. substitute members to serve as replacements for regular members when they are unable to attend meetings.

2. HREB MEETINGS

2.1. Meetings will normally be held monthly during the academic year. Other meetings may be called by the Chair as necessary.

2.2. Normally, HREB meetings shall be face-to-face, though where circumstances require a communications medium for some members may be utilized.

2.3. Quorum for protocol decisions (i.e., clearance, sanctions and related matters) will consist of at least 5 members, including both men and women, of whom:

2.3.1. at least two members have broad expertise in the methods or areas of research under review;

2.3.2. at least one member is knowledgeable in ethics; and

2.3.3. at least one member has no affiliation with the institution and is recruited from the community served by the University.

2.4. It is preferred that HREB decisions are made by consensus. Where consensus is not achieved the decision shall be made by majority vote.

2.5. Members of the HREB must act with integrity and adhere to the highest ethical standard at all times. If the HREB is reviewing research in which a member of the HREB has a personal interest (e.g., as a researcher or as an entrepreneur), conflict of interest principles require that the member not be present when the HREB is discussing or making its decision.

2.6. In order to preserve the independent decision making capacity of the Board, the Associate Vice-President Research and other University officials above the level of Dean/Director shall not be members of the HREB, nor attend meetings other than as an invited guest or applicant.

3. HREB SUPPORT

3.1. The University shall provide sufficient financial support to the HREB to enable them to effectively carry out their responsibilities.

3.2. The Office of Research Services shall host the HREB Office, and shall provide the administrative support required to process applications, take minutes, and maintain appropriate records.

4. HREB OPERATIONAL PROCEDURES

4.1. The HREB shall formalize all operational procedures and make them publicly available.

4.2. HREB operational procedures must comply with all University policies and procedures.