Policy on Ethical Review of Research with Human Participants

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Advisory Body	Ad Hoc (to include Chair of Ethics Review Committee)	**Latest Approval Date**	March 22, 2013
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Contents

1. Introduction

Canadian Mennonite University (CMU) strives to engage in research and scholarship in accordance with the highest ethical standards. The purpose of this Policy is to

- ensure the adherence to common standards of ethical conduct by all investigators conducting research under the auspices of CMU;
- ensure the protection of the dignity and rights of all potential participants in research at CMU;
- outline clearly the responsibilities and obligations of the CMU Ethics Review Committee, and those of individual researchers; and
- summarize key elements of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* that pertain to research at CMU and describe how CMU will apply the *Tri-Council Policy*.

a. Relationship of This Policy to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans

CMU affirms the principles and guidelines outlined in the 2010 *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (hereinafter referred to as the *Tri-Council Policy*).[1] In addition to familiarizing themselves with this Policy, all individuals affiliated with CMU who conduct research with human participants should consult the *Tri-Council Policy* for further guidance if their investigations fall into any of the following areas:

- Research Involving the First Nations, Inuit and Métis Peoples of Canada (chap. 9)
- Qualitative Research (chap. 10)
- Clinical Trials (chap. 11)
- Human Biological Materials (chap. 12)
- Human Genetic Research (chap. 13)

All members of the Ethics Review Committee are **required** to participate in ethics training by completing the Tri-Council's online tutorial (CORE Tutorial).[2]

Researchers submitting a proposal for ethics review for the first time are also **strongly encouraged** to complete the online CORE Tutorial before submitting their proposal.

b. Guiding Principles

In keeping with Article 1.1 of the *Tri-Council Policy*, all research involving human participants shall be informed by the three core principles of Respect for Persons, Concern for Welfare, and Justice.

Furthermore:

- all investigators affiliated with CMU are responsible for the ethical conduct of endeavours in which they are involved;
- all research involving human participants requires adequate review;
- the level of ethical scrutiny shall be proportionate to the invasiveness and potential harm (i.e. to the level of risk) of the research or scholarship; and
- such research shall be subject to ongoing ethical review for the duration of the project.

[1] Available at www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf.
[2] Available at www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/.

2. Definitions

Research — As used in this document, "research" refers to any disciplined inquiry or systematic investigation designed to establish knowledge about human individuals. Included are procedures that have a low degree of invasiveness (e.g. surveys, interviews, observational research, examination of patient records) as well as more invasive procedures (e.g. blood sampling, administration of a substance).

Participants — "Human participants" or "participants" are those individuals whose data or whose responses to interventions, stimuli or questions by the researcher are relevant to answering the research question.

3. Applicability of Ethics Review

The criteria for ethics review outlined in this section apply to all research conducted at or under the auspices of CMU. This includes research undertaken by academic faculty, administrative or support staff, students, and persons with adjunct appointments, visiting professors or other research associates affiliated with CMU.

The criteria apply whether the research is carried out at CMU premises using University facilities, resources or equipment, or elsewhere under the auspices of the University.

a. Research Requiring Ethics Review

Except as provided for in Section 3b., the following research requires review and approval by a standing Ethics Review Committee (ERC) before the research commences:

- research involving living human participants;
- research using identifiable information about living individuals; that is, information that when used alone or combined with other information may identify an individual person;
- research data derived from human biological materials (organs, tissues, body fluids, remains, cadavers), as well as from human embryos, fetuses, fetal tissue, reproductive materials and stem cells.

In addition, prior ethics review is required for the following categories of research that may be overlooked or raise questions about the necessity for such a review:

- pilot studies and feasibility studies, even those involving only one human participant;
- research involving digital sites where there is an expectation of privacy because of identifiable information (e.g. Internet chat rooms, self-help groups with restricted membership);
- projects involving the secondary use of identifiable data; that is, identifiable data on human participants that was previously gathered for a different purpose;
- research where data linkage (merging two or more separate data sets) of publicly available information could lead to new forms of identifiable information that raise issues of privacy and confidentiality;
- research conducted by administrative and academic units that involves the collection of survey replies or the use of records as correlates of survey replies from human participants (e.g. student or staff records);
- research projects in which the researcher is a consultant, unless the research has a strict consulting relationship in which
    i. the researcher is hired on his or her own time; and

ii. the researcher holds no rights in the work; and
iii. neither the researcher nor CMU retains any data.

If any one of these three criteria is not met, prior ethics review and approval is required;

- all independent student research projects conducted in partial fulfillment of degree requirements. The course instructor or faculty supervisor is responsible to alert the student(s) to the need for an ethics review, and to guide him or her through the process of submitting a proposal for evaluation by the ERC;
- research projects conducted by students as part of formal course requirements may be subject to Course Project Review (see Section 9). It is incumbent on the instructor to check the applicability of this requirement with the Chair of the ERC.

b. Research and Activities not Subject to Ethics Review

Prior ethics review and approval is not normally required for research that relies exclusively on publicly available information that is

- legally accessible to the public and protected by law; or
- publicly accessible and carries no reasonable expectation of privacy.

Prior ethics review and approval is also not required for

- the observation of people in public places where
  i. there is no intervention by the researcher, or no direct interaction with the individuals or groups;
  ii. there is no reasonable expectation of privacy on the part of those targeted for observation; and
  iii. any dissemination of research results does not allow identification of specific individuals.
- Internet and cyber-material to which the public is given uncontrolled access and for which there is no expectation of privacy;
- research relying exclusively on the secondary use of anonymous information or anonymous human biological materials, as long as the process of data linkage or the recording or dissemination of results does not generate identifiable information;
- class projects involving class members as participants and are conducted by other members of the class as exercises in learning how to conduct research;
- class projects involving interviews with experts regarding their areas of expertise, provided the resulting data are not to be disseminated beyond the classroom;
- class projects involving students' interviews of their own family, provided the resulting data are not to be disseminated beyond the classroom.

The following activities are not considered research under the terms of this Policy and therefore are not subject to ethics review:

- archival analysis of records by University departments normally engaged in the collection, maintenance and analysis of such records. Nevertheless, it is incumbent on such units to ensure that the anonymity of individuals and confidentiality of their records are maintained;
- quality assurance studies, program evaluation activities, performance reviews or testing within normal educational requirements, when used exclusively for assessment, management or improvement;

- creative practice activities (the process of making or interpreting a work of art). However, research employing creative practice as a means of eliciting responses that will be analysed as part of a research project is subject to ethics review.

c. Uncertainty About the Need for Ethics Review

For research or scholarly work where the researcher is uncertain about whether ethics review is required, the researcher should consult with the Chair of the ERC as to whether the research should be subjected to prior ethics review and approval. Researchers are also welcome to consult informally with the CMU Research Office on how requirements for ethics review may apply to their work.

4. Consent

a. General Principles

Research governed by this Policy may begin only after prospective participants or authorized third parties have given consent that is

i. **voluntary** – consent must be given freely, without manipulation, undue influence or coercion. Where incentives are offered to participants, they should not be so large as to encourage participants to overlook potential risks. Consent may be withdrawn at any time, and a participant who withdraws consent may request the withdrawal of his or her data or human biological materials;
ii. **informed** – at the beginning of the consent process, researchers shall provide to prospective participants or authorized third parties full and frank disclosure of all information relevant to free and informed consent. Prospective participants shall be given adequate time and opportunity to assimilate this information before giving their consent; and
iii. **ongoing** – consent shall be maintained throughout the research project. Researchers have a duty to provide participants with all information relevant to their ongoing agreement to participate in the research. This includes bringing to participants' attention any changes that may affect them, particularly changes to the potential risks or benefits of the research.

Under certain types of research these general requirements may be modified; see Sections 4f., 4g. and 6 (on the secondary use of non-identifiable information), below. See also the discussion of consent in qualitative research in Article 10.2 of the *Tri-Council Policy*.

Preliminary conversations that researchers may have with prospective participants as part of developing the design of their research do not in themselves constitute research, and therefore do not require consent.

Debriefing is a required part of the consent process in research that involves partial disclosure, deception or other modifications to the general requirements for consent. Debriefing is a full disclosure of the research purpose and other pertinent information to participants, with an opportunity for them to ask questions and offer feedback. Providing opportunities for questions and feedback is also encouraged in other types of research where this may be helpful to participants. Debriefing usually takes place after participation has ended, but may be done at any time during the study.

b. Documentation of Consent

Evidence of voluntary and informed consent by the participant or authorized third party should ordinarily be obtained in writing. Where written consent is culturally inappropriate or where there are good reasons for not

recording consent in writing, the procedures used to seek consent shall be documented. For consent to be informed, prospective participants shall be given adequate time and opportunity to assimilate the information provided, pose any questions and consider whether they will participate in the research.

c. Elements of Informed Consent

In seeking consent, researchers or their qualified representatives shall provide prospective participants with as many of following elements as are appropriate to the particular project:

- notice that the individual is being invited to participate in a research project;
- a statement of the research purpose in plain language, the identity of the researcher, the identity of the funder or sponsor, the expected duration and nature of the participation, a description of research procedures and an explanation of the responsibilities of the participant;
- a plain language description of reasonably foreseeable harms and benefits that may arise from participation, as well as the likely consequences of non-action, particularly in research related to treatment, or where invasive methodologies are involved, or where there is a potential for physical or psychological harm;
- an assurance that prospective participants are free not to participate, have the right to withdraw at any time without prejudice to pre-existing entitlements, will be given continuing and meaningful opportunities for deciding whether or not to continue to participate and if withdrawing from the study, have the right to also request withdrawal of their data or biological materials;
- information on the possibility of commercialization of research findings, and the presence of any apparent or actual or potential conflict of interest on the part of researchers, their institutions or the research sponsors;
- expected plans for the dissemination of research results and whether participants will be identified directly or indirectly;
- the identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research;
- the identity and contact information of individual(s) outside the research team whom participants may contact regarding possible ethical issues;
- an indication of what information will be collected about participants and for what purposes; an indication of who will have access to information collected about the identity of the participants; a description of the anticipated uses of data; and information indicating who may have a duty to disclose information collected and to whom such disclosures could be made;
- information about any payments or incentives for participants, reimbursements for participation-related expenses and compensation for injury;
- a statement to the effect that by consenting, participants have not waived any rights to legal recourse in the event of research-related harm.

d. Incidental Findings

Researchers are obligated to inform participants of any material incidental findings discovered in the course of their research (findings considered to have significant implications for the physical, psychological or social welfare of the participant). In some cases, incidental findings may trigger legal reporting obligations, and researchers should be aware of how these obligations may relate to safeguarding information and maintaining participant confidentiality.

e. Critical Inquiry

A researcher is not required to obtain permission from an organization in order to conduct research on that organization. However, where research engages the participation of members of an organization without the organization's permission, the researcher shall inform participants of this fact and of any foreseeable risks they may incur by their participation. In reviewing proposals of this nature, the ERC should concern itself with the welfare of participants and the security of research materials.

f. Departures from General Principles of Consent

The ERC may approve a consent procedure that does not include or that alters some or all of the elements of informed consent set out above, or may waive the requirement to obtain voluntary, informed and ongoing consent, provided that the ERC finds and documents that all of the following apply:

i. The research involves no more than minimal risk to the participants; and
ii. The waiver or alteration is unlikely to adversely affect the rights and welfare of the participants; and
iii. The research could not practicably be carried out without the waiver or alteration; and
iv. After their participation or at a later time in the study, participants will be debriefed and provided with additional pertinent information where appropriate, following which they will be given the opportunity to refuse consent; and
v. The waived or altered consent does not involve a therapeutic intervention, or other clinical or diagnostic interventions.

g. Research Involving Partial Disclosure or Deception, or Randomization and Blinding

Some social sciences research can only be carried out if participants do not know the true purpose of the research goal. For example, participants may not know that they are part of a research project until it is over, be told about only one of several elements the researchers are observing, or be given false information about themselves, events and/or the purpose of the research. Subject to the requirements described under Section 4f. above, partial disclosure or deception is allowed if participants are

i. given a clear description of the tasks they will be asked to perform; and
ii. provided at the earliest opportunity with an opportunity for debriefing, where they are informed about the deception and then given the opportunity to consent or refuse their further participation in the project.

In studies including randomization and blinding in clinical trials, neither the research participants nor those responsible for their care know which treatment the participants are receiving before the project commences. Such research is not regarded as a waiver or alteration of the requirements for consent if participants are informed of the probability of being randomly assigned to one arm of the study or another.

h. Research and Consent in Emergency Health Situations

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 advance of such research by the ERC. The ERC may allow research that involves health emergencies to be carried out without the free and informed consent of the participant or of his or her authorized third party if all of the following apply:

i. A serious threat to the prospective participant requires immediate intervention; and

ii. Either no standard efficacious care exists, or the research offers a real possibility of direct benefit to the participant in comparison with standard care; and
iii. 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; and
iv. The prospective participant is unconscious or lacks capacity to understand risks, methods and purposes of the research; and
v. Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and
vi. No relevant prior directive by the participant is known to exist.

When a previously incapacitated participant regains capacity or when an authorized third party is found, free and informed consent shall be sought promptly for the participant's continuation in the project and for subsequent examinations or tests related to the study.

i. Capacity and Consent

Subject to applicable legal requirements, individuals who lack the capacity, either permanently or temporarily, to decide for themselves whether to participate shall only be asked to become research participants when the following conditions apply:

i. The research question can only be addressed using individuals within the identified group(s); and
ii. Free and informed consent will be sought and maintained from authorized third parties; and
iii. The research does not expose them to more than minimal risk without the potential for direct benefits for them; or
iv. Where the research entails only minimal risk, it should have the potential to provide benefits to the participants, or to a group that is the focus of the research and to which the participants belong.

For research involving individuals who lack the ability to consent on their own behalf, the ERC shall ensure that as a minimum, the following conditions are met:

i. The researcher involves the participant(s) to the greatest extent possible in the decision-making process;
ii. The researcher seeks and maintains consent from authorized third persons in accordance with the best interests of the persons concerned;
iii. The authorized third party is not the researcher or any other member of the research team;
iv. The researcher demonstrates that the research is being carried out for the participant's direct benefit, or for the benefit of other persons in the same category. If the research does not have the potential to directly benefit the participant but only other persons in the same category, the researcher shall demonstrate that the research will only expose the participant to minimal risk and burden, and demonstrate how the participant's welfare will be protected throughout his or her participation in the research; and
v. When a participant who was entered into a research project through third-party authorization acquires or regains capacity during the project, his or her informed consent shall be sought as a condition of continuing participation.

j. Consent by Third Parties

Where free and informed consent has been obtained from an authorized third party, and in those circumstances where the individual lacking capacity understands the nature and consequences of the research, the researcher shall seek to ascertain the wishes of the individual concerning participation. The potential participant's dissent will preclude her or his participation. Those who may be capable of assent or dissent include

- children whose capacity is in the process of development;
- those once capable of making an autonomous decision but whose capacity is diminishing or fluctuating;
- those whose capacity remains only partially developed, such as those living with permanent cognitive impairment.

k. Consent via Research Directives

A research directive expresses an individual's preferences for participation in future research in the event that she or he loses capacity. Where individuals have signed such a directive and are either lacking in capacity when the research is initiated or lose capacity during research, researchers and authorized third parties should be guided by the research directive. Use of research directives does not alter requirements for consent, in particular the requirement to seek the consent of an individual or authorized third party before the individual's participation in the research.

5. Fairness and Equity in Research Participation

Inclusiveness in research and fair distribution of benefits and burdens should be considered by researchers when planning their research, and by the ERC when reviewing research proposals. Particular individuals, groups or communities should neither bear an unfair burden through participating in research nor be unfairly excluded from potential benefits of research participation.

- Taking into account the scope and objectives of their research, researchers shall not exclude prospective participants on the basis of culture, language, religion, race, disability, sexual orientation, linguistic proficiency, gender or age, unless there is a valid reason for doing so.
- Researchers should consider ways to ensure the equitable distribution of any benefits of participation in research, and be sensitive to the expectations and opinions of participants regarding the potential benefits of research. Researchers should ensure that copies of publications, reports or other forms of research results are made available to the participating individuals or groups in culturally appropriate and meaningful formats (such as reports in plain language).

6. Privacy and Confidentiality

Researchers are responsible to safeguard all information entrusted to them by participants, and not misuse or wrongfully disclose it. CMU is responsible to support researchers in maintaining promises of confidentiality by

providing adequate physical, administrative and technical measures to protect research data for the full life cycle of information.[3]

The ethical responsibility to ensure stringent protection of confidentiality is paramount when data involve information that may reasonably be expected to identify an individual, whether alone or in combination with other information (data linkage). Adequate protection of confidentiality is needed not only with directly identifying information, but also with information that may indirectly identify an individual (e.g. through date of birth or place of residence) or with information that has been coded, where re-identification may be possible. Ethical concerns regarding confidentiality decrease as it becomes more difficult or impossible to associate information with a particular individual, as in anonymized or anonymous information.

In certain research investigations where participants do not wish to keep their names or other identifying information confidential, the researcher shall ensure that their waiver to confidentiality is documented in the consent process. As part of informed consent, the researcher must explain to such participants any implications of their waiving confidentiality.

Researchers are not required to seek consent for the secondary use of **non-identifiable** information (secondary use refers to information originally collected for a purpose other than the current research investigation; for example, health survey datasets collected for statistical purposes but later used for other research). For further guidance on the secondary use of **identifiable** information, see Articles 5.5 and 5.6 of the *Tri-Council Policy Statement*.

7. Governance of Research Ethics Review

Because CMU is a small institution with the majority of its research occurring in the humanities and social sciences, the University operates with a single ERC. Where research projects in the sciences are brought to the ERC, the Chair will ensure that portions of the *Tri-Council Policy Statement* specific to science research are consulted, and that appropriate expertise is available on the committee to make an assessment.

a. Mandate, Authority and Accountability of the Ethics Review Committee

The ERC is mandated to evaluate, approve, reject, propose modifications to or terminate, in accordance with this policy, any proposed or ongoing research involving human participants that is conducted within CMU facilities or under the jurisdiction of CMU, as defined above in Section 3a., Research Requiring Ethics Review.

The ERC has the authority to deny permission to open research accounts or to access funding for projects that have failed to receive ERC approval.

The ERC shall be independent in its decision-making. The University may not override a decision of the ERC to reject a research proposal, and an appeal of an ERC decision can only take place as described in Section 8f. of this Policy.

The ERC shall report to the Senate Executive of CMU.

[3] According to CMU's *Policy and Procedures on Integrity in Research and Development*, Section 4.b.ii., "original data for a given study should be retained in the University for at least five years after the work is published or otherwise publicly presented (if the form of the data permit this, and if assurances have not been given that data will be destroyed to assure anonymity)."

b. CMU Support of the Ethics Review Committee

CMU shall ensure that the ERC has the appropriate financial and administrative independence to fulfill its mandate. CMU administration shall make available adequate resources to support the administrative processes involved in carrying out ethics reviews and to allow ERC members to participate in, from time to time, the educational activities provided by the Interagency Advisory Panel on Research Ethics, such as those outlined in Section 1a. of this Policy, so that CMU remains in compliance with the *Tri-Council Policy Statement*.

The Chair of the CMU Senate Executive shall ensure that faculty members are informed each year about the need to comply with this Policy and the *Tri-Council Policy Statement*. The Chair of Senate Executive will also ensure ongoing faculty education with regard to compliance with ethics review standards and the consequences of non-compliance.

c. Appointment of the Ethics Review Committee

Members of the ERC are appointed by the Nominating Committee of the Senate. Procedures for appointment, renewal and removal shall follow the usual processes of the Nominating Committee.

d. Membership of the Ethics Review Committee

The ERC shall consist of a minimum of five members, including both men and women and having multidisciplinary representation. The membership of the ERC shall specifically include

i. four CMU faculty members who will have broad expertise in the methodologies and content areas of research covered by the ERC, and in ethics of research;
ii. one member who has no affiliation with CMU, but is recruited from the community served by CMU (preferably a person with experience in making ethical evaluations of research at another institution). The primary role of this member is to reflect the perspective of the research participant, particularly when participants are vulnerable and/or subject to high risk;
iii. an alternate member who may be called upon by the ERC Chair to attend a meeting if a quorum would otherwise be impossible, if an ERC member's own research project is under review or if an ERC member is required to withdraw for other reasons of conflict of interest;
iv. at least one member who is knowledgeable in the area of ethics; and
v. if biomedical research is under review, at least one member (who is not the institution's legal counsel or risk manager) who is knowledgeable in the relevant law.

The ERC may also include an *ad hoc* advisor(s), who may be nominated by the ERC Chair for the duration of a particular review where a project under review requires specific community or research participant representation, or requires expertise not available from regular ERC members. *Ad hoc* advisors do not count towards a quorum on the ERC and do not participate in decisions taken by consensus or by vote.

In order to ensure independence of ERC decision-making, senior administrators of the University (such as the Vice-President Academic) shall not serve on the ERC.

e. Specific Responsibilities of the Ethics Review Committee

All members of the ERC, including the Chair are required to complete the *Tri-Council Policy Statement*'s online tutorial (CORE Tutorial). In addition, the ERC is responsible to the CMU Senate for

- developing policies regarding ethics issues related to the use of human participants in research;

- reviewing periodically all policies regarding ethics in research, in order to ensure that the policies remain current, expeditious and effective;
- reviewing all submissions for ethics approval in research involving human participants, and evaluating the merit and scholarly standards of the research proposed in accordance with this Policy and the *Tri-Council Policy Statement*;
- maintaining up-to-date records of all ethics reviews carried out under its jurisdiction and preparing an annual report for submission to the CMU Senate at its May meeting.

f. Responsibilities of the Chair

The Chair shall be responsible for ensuring that the ERC carries out its duties in conformity with this Policy and with the *Tri-Council Policy Statement*. In addition, the Chair is responsible for

- reviewing all proposals received by the ERC, whether for Full, Delegated or Course Project Review;
- making provisional decisions regarding a proposal's eligibility for Delegated Review;
- conducting any aspects of Continuing Review delegated to the Chair of the ERC;
- determining whether proposals to change substantive elements of previously approved projects require Full Review, and if not, reviewing them on behalf of the committee;
- consulting as required with investigators concerning their proposals;
- signing proposal approvals, doing so only when satisfied that all relevant policies and procedures have been followed;
- ensuring that the committee meets at reasonable and scheduled times;
- appointing *ad hoc* committee advisors;
- consulting with the community member in the event that he or she cannot attend a meeting;
- participating in educational undertakings regarding research ethics at both the ERC and University level;
- ensuring that problems arising within this policy and its procedures are noted for the purpose of future revision, and that such revision occurs as required.

g. Meetings, Attendance and Quorum

The ERC shall meet as necessary to discharge its responsibilities. Given the expectation that the number of proposed projects will be relatively small, meetings may be scheduled as required. The committee shall also meet on an annual basis to review policies and protocols, and to prepare an annual report for submission to Senate.

The committee will normally meet face to face to review research proposals that have been assigned to a Full Review. Where ERC members are geographically dispersed or where exceptional circumstances (e.g. emergencies) prevent a member from being physically present, technologies such as videoconferencing or teleconferencing may be used.

A quorum of at least two-thirds of ERC members are required at all meetings requiring a Full Review. Any *ad hoc* advisors, research administration staff or others attending the meeting do not count towards quorum.

h. Record-Keeping

All research projects that receive ERC approval at any level shall require a proper file showing compliance with this Policy. Insufficient information in the file is grounds for refusing or delaying ERC approval.

The ERC Chair shall create an open file for an ethics review when a complete proposal has been received. All relevant information shall be kept in the file, including the original application, a copy of the research proposal, any correspondence between the ERC and the researcher, the participant consent form and any other research protocols, the ERC approval document, any revised materials, any comments received from participants along with any other information relevant to the project. When the project is completed and the researcher or principal investigator has submitted a final report to the ERC, the file shall be "closed" and kept as a record of compliance with this policy.

Minutes of ERC meetings shall be prepared and maintained by a secretary appointed by the committee for the purpose of assisting with internal and external audits or research monitoring, and to facilitate reconsiderations or appeals. The minutes shall clearly document the decisions of the committee, along with their rationale. The minutes shall also document any dissenting opinions and the reasons for them. Minutes will be made available to representatives of CMU, researchers and funding agencies upon request.

To ensure accurate and fair administration and integrity of the research process, the maintenance of satisfactory records and documentation is essential. Failure to do so may expose researchers and CMU to legal liability.

All files pertaining to the ERC shall be kept in the President's office. Ethics review files remain the property of CMU and may not be removed by researchers. The files shall be subject to audit by authorized representatives of CMU, members of any applicable appeal board and funding agencies.

8. Review Procedures

a. General Considerations

Principle of proportionate review – The ERC shall adopt an approach based on the principle of proportionate review: the greater the level of foreseeable risk to the participants, the greater the level of scrutiny is required. Whereas all research must be reviewed adequately, proportionate review is intended to reserve the most intensive scrutiny, and correspondingly more protection, for the most ethically challenging research.

A proportionate approach to ethics review begins with an assessment, primarily from the viewpoint of potential research participants, of the foreseeable risks, potential benefits and ethical implications of the research. The assessment of risk considers both the magnitude or seriousness of the harm, as well as its probability of occurrence.

This assessment is used to determine the level of the review as well as the approach to the review itself. The principle of proportionate review applies both to initial research ethics review and to continuing review.

Minimal risk – Minimal risk research is research in which the probability and magnitude of possible harms implied by participation in research is no greater than those encountered by participants in those aspects of their daily life that pertain to the research.

In keeping with a proportionate approach to ethics review, most minimal risk research will normally receive a Delegated Review, while research involving more than minimal risk shall receive a Full ERC Review.

In assessing the level of minimal risk, the ERC has a special ethical obligation towards research participants whose situation or circumstances make them vulnerable in the context of a specific research project, and to those who live with relatively high levels of risk on a daily basis. Their inclusion in research should not increase their vulnerability.

Scholarly review – As part of the review process, the ERC shall consider ethical implications of methods and design of research. However, the ERC should normally avoid duplicating previous professional peer-review assessments.

The ERC will satisfy itself that the design of a research project that poses more than minimal risk is capable of addressing the questions being asked in the research.

In evaluating the merit and the scholarly standards of a research proposal, the ERC shall assess the degree to which the research might further the understanding of a phenomenon, and not be driven by factors such as personal biases or preferences. The ERC shall not reject research proposals because they are controversial, challenge mainstream thought or offend powerful or vocal interest groups. The primary tests to be used by the ERC to assess research proposals shall be ethical probity and high scholarly standards.

Academic freedom – The ERC and all persons involved in the ethics review process shall act in such a manner as to ensure that there is no infringement of the academic freedom of researchers.

b. Levels of Review

All requests for ethics review must be prepared using the Submissions for Ethics Review: Guidelines and Forms.[4] The ERC Chair will examine proposals and projects received to ensure that the submitted documentation is complete. The Chair will determine whether a Full Review, Delegated Review or Course Project Review is appropriate and ensure that relevant materials are circulated to ERC members.

i. **Full Review** – This is the default requirement for all research involving human participants and is conducted by the full committee.

   The ERC will meet face to face to review proposals assigned to a Full Review. The review shall be based upon a fully detailed research proposal or, where applicable, an interim report (see Sections 8d. and 8e., below). Committee decisions following a Full Review will normally be made within **four weeks**.

   No project under Full Review shall receive ERC approval, acceptance with conditions, suspension (pending clarification or further information) or refusal unless a quorum exists. In the event that there is less than full attendance, decisions requiring Full Review will be adopted only if the members attending the meeting possess the relevant expertise, competence and knowledge needed for an adequate review of the proposal(s) under consideration.

ii. **Delegated Review** – Research determined by the ERC Chair to carry minimal risk may be reviewed by the Chair and one other member of the ERC. Decisions following a Delegated Review will normally be made within **two weeks**. Delegated Review may also be used for renewals of minimal-risk research (Section 8d.); minimal-risk changes to approved research (Section 8e.); or renewals of more-than-minimal-risk research where the research no longer involves new interventions to current participants, new participants will not be recruited, and the remaining research activities are limited to data analysis. Any concerns about the appropriateness of renewing an approval shall be forwarded to the ethics committee for a Full Review.

iii. **Course Project Review** – see Section 9, below.

[4] Available through the CMU Research Office and on the Research Office web page.

c. Decision-Making Process

The ERC shall function impartially, provide a fair hearing to those involved and provide reasoned and appropriately documented opinions and decisions in a timely manner.

Formal ERC decisions on whether to allow a research proposal to proceed will often be preceded by extensive discussion of (a) ethics concerns, and (b) possible means of improving such aspects as the research design or the information to be provided as part of a free and informed consent process. As participation by the researcher(s) in such discussion is often very helpful to both the ERC and researcher(s), an applicant or the ERC may request that the applicant attend and be heard at a committee meeting. The applicant shall not be present during deliberations or voting.

The ERC shall make every effort to reach its decisions by consensus, whereby each member clearly indicates his or her acceptance of the decision. If consensus is not possible, the decision will be made by voting. A majority vote in favour of the decision will be required. Absent a conflict of interest, all voting members present, including the ERC Chair, may vote on all proposals.

Submissions shall be judged by the ERC to be one of the following:

- ethically acceptable;
- acceptable with conditions;
- suspended (in need of clarification or further information);
- in need of Full Review (where initially assigned to Delegated Review); or
- unacceptable and requiring revision and resubmission.

The applicant shall receive a written summary of the results of the meeting, including dissenting opinions. In the event that the ERC is considering judging the submission unacceptable, the researcher shall be informed of the reasons and given an opportunity to respond before the ERC makes a final decision.

Interim approval – The ERC Chair may grant interim approval when a researcher requires agency consent for carrying out a research investigation. In the event that interim approval is granted, it must be understood that the project cannot commence without a letter of formal approval. Researchers who require ethics review of their projects in order to obtain research funding from granting agencies may request interim approval.

d. Review of Ongoing Research

Following an initial review and approval by the ERC, ethics review shall continue throughout the life of the project. As part of each proposal submitted to the ERC for initial ethics review, the researcher will propose a continuing review process deemed appropriate for that project. The ERC will make the final determination as to the nature and frequency of continuing ethics review, in accordance with the proportionate approach to ethics assessment. Normally, continuing review shall consist of

i. an annual status report for multi-year projects; and
ii. an end-of-study report for all projects.

However, the ERC may request more frequent and/or more substantive reports if deemed necessary (for example, in the case of research that poses a greater than minimal risk to participants.)

e. Requests for Changes to Approved Research, and Reports of Unanticipated Issues

Researchers shall submit requests for substantive changes (that is, changes having significant ethical implications and/or changes in potential risk to participants) to originally approved research in a timely manner to the ERC for fresh approval.

Researchers shall immediately report to the ERC any unanticipated issue or event that may increase the level of risk to participants, or that has other ethical implications that may affect participants' welfare in the course of the research.

In reviewing requests for changes and reports of unanticipated issues, the ERC shall base its response on a proportionate approach to research ethics review.

f. Reconsiderations and Appeals

Researchers are entitled to request, and the ERC has an obligation to provide, reconsideration of a decision affecting a research project.

In cases where researchers and the ERC cannot reach agreement through discussion and reconsideration, CMU shall permit review of the ERC decision by an appeal board. No *ad hoc* appeal boards are permitted. Researchers must apply to the Vice-President Academic for an appeal within one month from the date of the ERC's decision. A copy of the appeal letter must also be sent to the Chair of the ERC.

CMU has a formal bi-lateral agreement with the University of Winnipeg whereby that institution agrees that its research ethics board will serve as the Appeal Board for CMU.

In appealing an ERC decision, the onus is on researchers to justify the grounds on which they request an appeal and to indicate any breaches to the research ethics review process or any elements of the ERC decision that are not supported by the *Tri-Council Policy*. Equally, non-compliance with the *Tri-Council Policy* may be grounds for refusing to grant an appeal. Appeals may be granted only on procedural grounds or where there is a significant disagreement over an interpretation of some aspect of the *Tri-Council Policy*. The decision of the appeal board shall be binding.

9. Student Research and Course Project Review

Note that **all student research and course projects undertaken for courses taught at Menno Simons College shall be subject to the University of Winnipeg's ethics review process**. All other student research and course projects taught under the auspices of CMU shall be subject to CMU's requirements and review procedures, as outlined in this Policy.

a. Course Project Review

Student research undertaken as course projects or labs may be subject to ethics review. Class work involving human participants that is exempt from review is defined in Section 3b. above. Course Project Review will be conducted by the Chair of the ERC in conjunction with the course instructor or a departmental committee.

i. **Labs, exercises and demonstrations designed by the instructor and conducted with class members as participants** – The instructor submits two copies of a completed *Submissions for Ethics Review: Guidelines and Forms* to the Chair of the ERC prior to the first use of the project. The instructor is responsible to notify the Chair of the ERC of any subsequent use of the same classroom procedure. The

Chair may or may not require further review. Course instructors shall indicate in the course syllabus that students are encouraged but not required to serve as research participants in class projects.

ii. **Course projects designed by the instructor in which students collect data from participants who are not class members** – The instructor submits to the Chair of the ERC two copies of a single *Submission for Ethics Review* containing generic descriptions for each different project (if more than one project is planned). Following approval, it is the instructor's responsibility to notify the Chair of the ERC of any subsequent use of the same project(s). The Chair may or may not require further review.

In addition to the instructor's submission of a proposal for ERC approval, students individually complete and submit proposals to their instructor. These must include the following sections of the *Submission for Ethics Review: Guidelines and Forms*:

1. **Project Identification Form**
2. **Basic Questions about the Project**
3. **Research Protocol, item no. 2, Research Instruments**: copies of all materials (e.g. interview or survey questions) must be given to participants.

The instructor may also require students to complete other items under **Research Protocol** but the level of description is left to the instructor's discretion.

The instructor only (not the ERC) reviews student proposals (requiring modifications if necessary), approves them and retains them on file for one academic year.

iii. **Course projects in which both student and instructor contribute to project design and where data are collected from participants who are not class members** – In addition to the materials described in the previous case, each student completes a proposal description that elaborates on any additions she or he has made to the instructor's design. The instructor screens these for completeness and ethical acceptability, and then submits to the ERC a generic proposal description for the project, relevant attachments and all student submissions. By definition, such projects will vary on re-use depending on student contributions, so that they must be re-reviewed by the ERC each time they are used.

iv. **Fully student-designed projects in courses in which the project is only one course component** – Students individually provide complete *Submissions for Ethics Review*. The instructor screens these for completeness and ethics and then submits them to the ERC. Any alterations made to a project after approval must be approved by the instructor (if they are minor) or by the ERC (if they are substantive). It is the responsibility of the instructor to inform student that no project may proceed until appropriate approvals have been granted.

b. Other Student Research

The following categories of student research involving human participants **do not** qualify for Course Project Review but must undergo the usual ERC processes for Full or Delegated Review described in Section 8:

- independent student research projects (e.g. fourth-year projects or independent studies courses) conducted in partial fulfillment of degree requirements, in which the student takes substantial responsibility for the design and conduct of a project;
- student research that is part of an instructor's own research program.

c. Responsibilities of Instructors as Research Supervisors

Instructors who are supervisors of course projects and student research (including when a student is the primary researcher collecting the data) have the following responsibilities for the protection of human participants:

- During the design of a project, instructors should advise students on the ethical conduct of research and help them prepare proposal submissions for ethics approval. As assurance that the instructor acknowledges their responsibility to see that University policy will be followed, she or he is required to sign the student's proposal submission to the ERC.
- After ERC approval, instructors should take an active role to ensure that projects are conducted in accordance with the ERC's requirements. Meeting periodically with students to review their progress is one way to meet this responsibility.

10. Conflicts of Interest

In managing conflicts of interest, the ERC should adopt a proportionate approach. Where conflict is so pervasive that it cannot be managed by disclosure to the relevant parties, the ERC may require the researcher to abandon one of the interests in conflict. In other cases, the ERC may conclude that the identified conflict of interest does not require specific actions. The ERC should use the ongoing review process (see Section 8d., above) to monitor conflicts of interest that have been identified.

a. Institutional Conflict of Interest

The *Tri-Council Policy* defines institutional conflict of interest as involving "a conflict between at least two substantial institutional obligations that cannot be adequately fulfilled without compromising one or both obligations" (chap. 7, p. 90). An institutional conflict of interest may occur when the institution

- sponsors a research project;
- stands to benefit from intellectual property resulting from research;
- holds equity in companies and/or receives major donations; or
- assigns conflicting roles to one institutional official (for example, an individual responsible for the promotion of research activity and funding, and also for the oversight of research).

In order to mitigate against situations where CMU might have a strong interest in seeing a project approved before all ethical questions are resolved, the ERC shall maintain an arms-length relationship with CMU as an institution, and avoid and manage any real or apparent institutional conflicts of interest involving research with human participants.

b. Ethics Review Committee Member Conflicts of Interest

When reviewing research proposals, ERC members shall disclose any real, potential or perceived conflicts of interest to the committee. The ERC may decide that a member with a conflict of interest should withdraw from the committee's deliberations and decisions.

If the ERC is reviewing research in which a member of the ERC has a personal interest in the research under review (e.g. as a researcher, an instructor or advisor of student research, or an interest of a financial nature),

conflict of interest principles require that the member not be present when the ERC is discussing or making its decision.

c. Researchers and Conflicts of Interest

Researchers shall disclose in the materials they submit to the ERC any real, potential or perceived individual conflicts of interest, as well as any institutional conflicts of interest of which they are aware that may have an impact upon their research. The ERC, in discussion with the researcher, shall determine appropriate steps to manage the conflict.

11. Multicentred Research and Research in Other Jurisdictions

Research conducted in the form of collaborative partnerships may involve multiple institutions and jurisdictions, with multiple Research Ethics Boards (REBs). Principles of institutional accountability require that the ERC be responsible for the ethical acceptability of all research undertaken under the auspices of CMU.

a. Research Involving Multiple Institutions and/or Multiple REBs

When a minimal risk ethics proposal has been reviewed and approved by another institution working under the *Tri-Council Policy Statement*, the proposal and approval may be submitted to the Chair of the ERC, who is given the discretion to decide whether the proposal may be approved or requires further consideration by the ERC. If the Chair believes that all CMU ethics requirements have been met, she or he may accept the approval from the other institution without further review. Where further expertise is needed to determine whether the proposal meets CMU requirements, the Chair may consult experts and/or decide that a normal ERC procedure is required.

Proposals for multicentred research that carry a higher than minimal risk require a full review by the ERC, and shall be reviewed independently by the ERC and REBs at each participating institution. The ERC and other REBs will each conduct an independent review and provide their separate decisions, either concurrently or sequentially.

To facilitate the coordination of ethics review when submitting a proposal for multicentred research, the principle investigator should work with the ERC and other REBs to devise a strategy for addressing procedural inconsistencies or substantive disagreements that may arise among participating REBs. For example**,** the researcher may wish to distinguish between core elements of the research that cannot be altered without invalidating the pooling of data from the participating institutions, and those elements that can be altered to comply with local requirements without invalidating the research project.

b. Review of Research in Other Jurisdictions or Countries

Research to be performed outside the jurisdiction of CMU or outside Canada shall undergo prior ethics review by both (a) the ERC of CMU; and (b) the REB or other responsible review body or bodies, where such exist, with the legal responsibility and equivalent ethical and procedural safeguards in the country or jurisdiction where the research is to be done.

Where an established ethics review mechanism does not exist at the research site, researchers should inform the ERC and report their efforts to identify any other suitable review mechanisms in the country. Additionally, both researchers and the ERC should consult Articles 8.3 and 8.4 of the *Tri-Council Policy* for further guidance. Note that the *Tri-Council Policy* advises the ERC not to prevent research from proceeding on the grounds that

there is no formal ethics review process in another country or jurisdiction. Instead, researchers should develop an awareness of and respect for relevant norms and cultural practices at the research site, so as to maintain the *Tri-Council Policy*'s three core principles of Respect for Persons, Concern for Welfare, and Justice.

The ERC shall not veto research about authoritarian or dictatorial countries on the grounds that the regime or its agents have not given approval for the research project, or have expressed a dislike of the researchers. It will, however, legitimately concern itself about the safety of the research subjects and the researchers, and the security of the research materials.

University research should be open. It is thus unethical for researchers to engage in covert activities for intelligence, police or military purposes under the guise of university research. The ERC will disallow any such research.

Researchers should normally provide copies of publications or other research reports to an institution in the host country, normally the host institution for the research project, that is best suited to act as a repository and disseminator of the research results. This may not be necessary in countries where the results are readily available in print or electronically. However, such reporting is particularly important in countries where Western publications are unavailable or prohibitively expensive. If feasible, and so long as the human rights of the research subjects and the ethical rights set out in this Policy are not compromised, a copy of the field material will be provided as well, with due regard to commitments concerning anonymity and confidentiality of research subjects. These latter safeguards are especially important in countries with authoritarian regimes.

Furthermore, researchers should ensure that the benefits of their research are available in the host country. Benefits may, for example, take the form of information-sharing, training for local personnel both in the host country and in Canada, or the provision of health care or similar services. However, researchers are not aid agencies and the ERC shall not try to force them to undertake aid work**.**

12. Indemnity Clause

CMU agrees to indemnify members of the ERC to the maximum amount permitted by law against all costs, charges and expenses (including, without limitation, an amount paid to settle an action or satisfy a claim and any liability for income or other tax by reason of a payment made to a member) that a member may reasonably incur in respect of any civil, criminal, administrative, investigative or other proceeding in which he or she is involved by reason of being or having been a member of the ERC, if

i. the member acted honestly and in good faith with a view to the best interests of CMU; and
ii. in the case of a criminal or administrative proceeding, the member had reasonable grounds for believing that his or her conduct was lawful.

CMU agrees to advance money to members in respect of all costs, charges and expenses (including, without limitation, an amount to settle an action or satisfy a claim) in respect of a proceeding referred to above, it being CMU's intention that no member of the ERC should be out of pocket for such costs, charges and expenses, provided that the member repay the money to CMU forthwith upon his or her admission, a negotiated settlement or a judicial determination that he or she has not fulfilled the conditions for indemnification set forth in points i. and ii., above.

This indemnity shall survive after an individual ceases to be a member of the ERC and shall ensure to the benefit of his or her heirs, executors, administrators and other legal personal representatives and shall be binding upon CMU and its successors.

13. Policy Review

Three years after the date fixed for implementation of this policy, the Vice-President Academic shall appoint a committee (which shall include the Chair of the ERC) to review the policy and its implementation, and if appropriate, to recommend revisions to this policy.

Approved by the CMU Senate on 22 March 2013.

14. Acknowledgments

In preparing this policy, CMU has relied substantially on the 2010 *Tri-Council Policy: Ethical Conduct for Research Involving Humans*, and consulted the research ethics policies of the University of Manitoba, the University of Winnipeg and Redeemer University College (Ancaster, Ontario).

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