

Ethical Review of Research with Human Participants

1.0 POLICY

All research that involves human participants requires review and approval by the Research Ethics Board (REB) in accordance with the Tri-Council Policy Statement (TCPS2): *Ethical Conduct for Research Involving Humans*, December 2010, before the research is started.

2.0 GUIDING PRINCIPLES

2.1 Core Ethical Principles

Respect for human dignity requires that research involving humans be conducted in a manner that is sensitive to the inherent worth of all human beings and the respect and consideration that they are due. Respect for human dignity is expressed through three core principles—Respect for Persons, Concern for Welfare, and Justice. These core principles transcend disciplinary boundaries and, therefore, are relevant to the full range of research covered by this policy.

2.1.1 Respect for Persons

Respect for Persons recognizes the intrinsic value of human beings and the respect and consideration that they are due. It encompasses the treatment of persons involved in research directly as participants and those who are participants because of their data or human biological materials, which for the purposes of this policy include materials related to human reproduction, are used in research. Respect for Persons incorporates the dual moral obligations to respect autonomy and to protect those with developing, impaired or diminished autonomy.

2.1.2 Concern for Welfare

The welfare of a person is the quality of that person's experience of life in all its aspects. Welfare consists of the impact on individuals of factors such as their physical, mental and spiritual health, as well as their physical, economic and social circumstances. Thus, determinants of welfare can include housing, employment, security, family life, community membership, and social participation, among other aspects of life. Other contributing factors to welfare are privacy and the control of information about the person, and the treatment of human biological materials according to the free, informed and ongoing consent of the person who was the source of the information or materials.

Ethical Review of Research with Human Participants

2.1.3 Justice

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

3.0 SCOPE AND DEFINITIONS

- 3.1 For the purposes of this policy, research is defined as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.
- 3.2 For the purpose of this policy, human participants are those individuals whose data, or response to interventions, stimuli or questions by the researcher, are relevant to answering the research questions.
- 3.3 All research that involves human participants and that is conducted within Grant MacEwan University, or by members of the University within the capacity of their employment or enrollment at the University, or that receives funding administered by the University, shall undergo MacEwan University REB review.
- 3.4 The following requires ethics review and approval by MacEwan University's REB before the research commences:
- a. Research involving living human participants.
 - b. Research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells.
This applies to materials derived from living and deceased individuals.
- 3.5 REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information.
- 3.6 Research that relies exclusively on publicly available information does not require REB review when:
- a. The information is legally accessible to the public and appropriately protected by law.
 - b. The information is publicly accessible and there is no reasonable

Ethical Review of Research with Human Participants

expectation of privacy.

- 3.7 Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purpose of this policy, and do not fall within the scope of REB review.
- 3.8 Creative practice activities, in and of themselves, do not require REB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review.
- 3.9 REB review is not required for research involving the observation of people in public places where:
 - a. It does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups.
 - b. Individuals or groups targeted for observation have no reasonable expectation of privacy.
 - c. Any dissemination of research results does not allow identification of specific individuals.
- 3.10 As part of research ethics review, the REB shall review the ethical implications of the methods and design of the research.
- 3.11 Following initial REB review and approval, research ethics review shall continue throughout the life of the project in accordance with Section 4.6
- 3.12 The opinion of the REB shall be sought whenever there is doubt about the applicability of this policy to a particular research project.

4.0 REGULATIONS

- 4.1 Roles and Responsibilities
 - 4.1.1 The Provost and Vice President Academic is responsible for this policy.
 - 4.1.2 The REB is responsible for functioning impartially, providing a fair hearing to the researchers involved, providing reasoned and appropriately documented opinions and decisions, and communicating all approvals and refusals to researchers in a timely manner in writing, or print or by electronic means.

Ethical Review of Research with Human Participants

- 4.1.3 The REB Chair is responsible for ensuring that the REB review process conforms to the requirements of this policy.
 - 4.1.4 Researchers are responsible for submitting their research proposals, including proposals for pilot studies, for REB review and approval of its ethical acceptability prior to the start of recruitment of participants, access to data, or collection of human biological materials. Researchers are also responsible for submitting requests for substantive changes to their originally approved research in a timely manner, and for submitting status reports or end of study reports when required.
 - 4.1.5 The Office of Research Services is responsible for providing REBs with necessary and sufficient ongoing financial and administrative resources to fulfill their duties.
 - 4.1.6 The MacEwan University REB needs independence in its decision-making process to carry out its role effectively, and to properly apply the core principles of the policy.
- 4.2 The Consent Process
- 4.2.1 The following consent principles apply:
 - a. Consent shall be given voluntarily.
 - b. Consent can be withdrawn at any time.
 - c. If a participant withdraws consent, the participant can also request the withdrawal of their data or human biological materials.
 - 4.2.2 Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research.
 - 4.2.3 Evidence of consent shall be contained either in a signed consent form or in documentation by the researcher of another appropriate means of consent.
 - 4.2.4 Researchers shall provide to prospective participants, or authorized third parties, full disclosure of all information necessary for making an informed decision to participate in a research project.
 - 4.2.5 At the commencement of the informed consent process, researchers or their qualified representatives shall provide prospective participants with information set out in the following list, as appropriate to the particular research project:

Ethical Review of Research with Human Participants

- a. Information that the individual is being invited to participate in a research project.
- b. A statement of the research purpose in plain language, and where appropriate the identity of the researcher, the identity of the funder or sponsor, the expected duration and nature of participation, a description of research procedures, and an explanation of the responsibilities of the participant.
- c. A plain language description of all reasonably foreseeable risks and potential benefits, both to the participants and in general, that may arise from research participation.
- d. An assurance that prospective participants:
 - Are under no obligation to participate; are free to withdraw at any time without prejudice to pre-existing entitlements.
 - Will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw from participation.
 - Will be given information on the participant's right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal.
- e. Information concerning the possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors.
- f. The identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants.
- g. The identity and contact information of the appropriate individual(s) outside the research team whom participants may contact regarding possible ethical issues in the research; generally the REB Chair would be the suitable contact.
- h. 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 participants, a description of how confidentiality will be protected, 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.
- i. Information about any payments, including incentives for participants, reimbursement for participation-related expenses and compensation for injury.
- j. In clinical trials, information on stopping rules and when researchers may remove participants from trial.

Ethical Review of Research with Human Participants

- 4.2.6 Consent shall be maintained throughout the research project. Researchers have an ongoing duty to provide participants with all information relevant to their ongoing consent to participate in the research.
- 4.2.7 Research shall begin only after the participants, or their authorized third parties, have provided their consent.
- 4.2.8 Permission is not required from an organization in order to conduct research on that organization. If a researcher engages the participation of members of an organization without the organization's permission, the researcher shall inform participants of any foreseeable risk that may be posed by their participation.
- 4.2.9 For research involving individuals who lack the capacity, either permanently or temporarily, to decide for themselves whether to participate, the REB shall ensure that, as a minimum, the following conditions are met:
- a. The researcher involves participants who lack the capacity to consent on their own behalf to the greatest extent possible in the decision-making process.
 - b. The researcher seeks and maintains consent from authorized third parties in accordance with the best interests of the persons concerned.
 - c. The authorized third party is not the researcher or any other member of the research team.
 - d. 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.
 - e. When authorization for participation was granted by an authorized third party, and a participant acquires or regains capacity during the course of the research, the researcher shall promptly seek the participant's consent as a condition of continuing participation.
- 4.2.10 The REB may approve research without requiring that the researcher obtain the participant's consent where the REB is satisfied, and documents, all of the following:
- a. The research involves no more than minimal risk to the participants.
 - b. The lack of the participant's consent is unlikely to adversely affect the welfare of the participant.

Ethical Review of Research with Human Participants

- c. It is impossible or impracticable to carry out the research and to answer the research question properly, given the research design, if the prior consent of the participant is required.
- d. Whenever possible and appropriate, after participation, or at a later time during the study, participants will be debriefed and provided with additional pertinent information in accordance with Sections 4.2.2, 4.2.4 and 4.2.5, at which point they will have the opportunity to refuse consent in accordance with Section 4.2.1.
- e. The research does not involve a therapeutic intervention, or other clinical or diagnostic interventions.

4.2.11 Where an authorized third party has consented on behalf of an individual who lacks legal capacity, but that person has some ability to understand the significance of the research, the researcher shall ascertain the wishes of that individual with respect to participation.

4.2.12 Evidence of consent shall be contained either in a signed consent form or in documentation by the researcher of another appropriate means of consent.

4.3 Privacy and Confidentiality

4.3.1 Researchers shall safeguard information entrusted to them and not misuse or wrongfully disclose it. Institutions shall support their researchers in maintaining promises of confidentiality.

4.3.2 Researchers shall describe measures for meeting confidentiality obligations and explain any reasonably foreseeable disclosure requirements:

- a. In application materials they submit to the REB.
- b. During the consent process with prospective participants.

4.3.3 Researchers shall provide details to the REB regarding their proposed measures for safeguarding information, for the full life cycle of information: its collection, use, dissemination, retention and/or disposal.

4.3.4 Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes if the REB is satisfied that:

- a. Identifiable information is essential to the research.

Ethical Review of Research with Human Participants

- b. The use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates.
- c. The researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information.
- d. The researchers will comply with any known preferences previously expressed by individuals about any use of their information.
- e. It is impossible or impracticable to seek consent from individuals to whom the information relates.
- f. The researchers have obtained any other necessary permission for secondary use of information for research purposes.

4.3.5 Researchers who wish to utilize information that falls under Alberta's Freedom of Information and Protection of Privacy (FOIP) Act (see especially Section 42 "Disclosure for research or statistical purposes") shall provide documentation to the REB of approval to access such information by the University's FOIP Coordinator. REB approval does not constitute FOIP approval.

4.3.6 A person who intends to conduct research using health information in the custody or under the control of a custodian or health information repository must submit a proposal to a designated research ethics board for review by that board (see Alberta's Health Information Act).

4.4 Inclusion in Research

4.4.1 It is important for researchers to take into account appropriate inclusion. Researchers shall not exclude individuals from the opportunity to participate in research on the basis of attributes such as culture, language, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age, unless there is a valid reason for exclusion.

4.5 The Research Ethics Board (REB)

4.5.1 Mandate and Membership

4.5.1.1 MacEwan University shall establish an REB to review the ethical acceptability of all research involving humans conducted within their jurisdiction or under their auspices, that is, by their faculty, staff or students, regardless of where the research is conducted, in

Ethical Review of Research with Human Participants

accordance with this policy.

4.5.1.2 One or more REBs are established by the Provost and Vice President Academic through General Faculties Council, and Terms of Reference are produced.

4.5.1.3 The REB shall consist of at least eight members, including both men and women, of whom:

- a. at least six members are full-time University faculty members or academic staff
- b. at least three members have expertise in relevant research disciplines, fields and methodologies covered by the REB
- c. at least one member is knowledgeable in ethics
- d. at least one member is knowledgeable in the relevant law
- e. for research involving students as participants, one member is a full-time student at the University
- f. at least one community member who has no affiliation with MacEwan University.

4.5.1.4 The REB shall submit an annual report of its activities to the Vice President Academic and Research.

4.5.1.5 The REB shall, as it deems appropriate, review the policy and procedures concerning research ethics, and shall refer its recommendations for revisions to the General Faculties Council Standing Committee, Academic Policies Committee.

4.5.2 Decision-Making of REB

4.5.2.1 Determining the Level of Research Ethics Review
The REB shall adopt a proportionate approach to research ethics review such that, as a preliminary step, the level of review is determined by the level of risk presented by the research: the lower the level of risk, the lower the level of scrutiny (delegated review); the higher the level of risk, the higher the level of scrutiny (full board review). A proportionate approach to assessing the ethical acceptability of the research, at either level of review, involves consideration of the foreseeable risks, the potential benefits and the ethical implications of the research.

Ethical Review of Research with Human Participants

4.5.2.2 Two levels of research ethics review may apply:

- 1) Full REB review
Research ethics review by the full REB should be the default requirement for research involving humans.
- 2) Delegated REB review of minimal risk research
The REB delegates research ethics review to one or more REB members.

4.5.3 Meetings and Record Keeping

4.5.3.1 REBs shall have regular meetings to discharge their responsibilities, and shall normally meet face to face to review proposed research that is not assigned to delegated review.

4.5.3.2 MacEwan University's REB shall prepare and maintain comprehensive records, including all documentation related to the projects submitted to the REB for review, attendance at all REB meetings, and accurate minutes reflecting REB decisions. Where the REB denies ethics approval for a research proposal, the minutes shall include the reasons for this decision.

4.5.3.3 The REB shall accommodate reasonable requests from researchers to participate in discussions about their applications, but the latter shall not be present when the REB makes decisions.

4.5.3.4 When reviewing research proposals, REB members shall disclose real, potential or perceived conflicts of interest to the REB. When necessary, the REB may decide that some of its members must withdraw from REB deliberations and decisions.

4.5.3.5 The REB may consult ad hoc advisors in the event that it lacks the specific expertise or knowledge to review the ethical acceptability of a research proposal competently. Ad hoc advisors should not be counted in the quorum for an REB, nor be allowed to vote on REB decisions.

4.6 Continuing Research Ethics Review

Ethical Review of Research with Human Participants

- 4.6.1 Research is subject to continuing research ethics review from the date of official REB approval throughout the life of the project.
 - 4.6.2 Researchers shall report to the REB any unanticipated issue or event that may increase the level of risk to participants, or has other ethical implications that may affect participants' welfare.
 - 4.6.3 At minimum, continuing research ethics review shall consist of an annual status report (for multi-year research projects), and an end-of- study report (for projects lasting less than one year).
- 4.7 Multi-Jurisdictional Research
- 4.7.1 MacEwan University currently adopts the model of independent ethics review for multi-jurisdictional research.
 - 4.7.2 MacEwan University remains responsible for the ethical acceptability and ethical conduct of research undertaken within its jurisdiction or under its auspices irrespective of where the research is conducted.
 - 4.7.3 When conducting research outside the jurisdiction of their home institution, whether at a site abroad, or in Canada, researchers shall provide their home REBs with:
 - a. The relevant information about the rules governing research involving humans and the ethics review requirements at the research site, where any exist.
 - b. The names and contact information for the relevant REBs or comparable ethics bodies, if known, that will review the proposal at the research site.
 - c. Relevant information about the target populations and circumstances that might have a bearing on the research ethics review by the researchers' home REB.
- 4.8 Research Involving First Nation, Inuit and Métis Peoples of Canada
- 4.8.1 Where the research is likely to affect the welfare of an Aboriginal community, or communities, to which prospective participants belong, researchers shall seek engagement with the relevant community.
 - 4.8.2 The nature and extent of community engagement in a project shall be determined jointly by the researcher and the relevant community, and shall be appropriate to community characteristics

Ethical Review of Research with Human Participants

and the nature of the research.

4.8.3 In engaging territorial or organizational communities, researchers should ensure, to the extent possible, that they take into consideration the views of all relevant sectors – including individuals and subgroups who may not have a voice in the formal leadership.

4.9 Qualitative Research

4.9.1 Researchers shall submit their research proposals, including proposals for pilot studies, for REB review and approval of its ethical acceptability prior to the start of recruitment of participants, or access to data.

4.9.2 Researchers shall explain in their research design the proposed procedures for seeking consent and the strategies they plan to use for documenting consent.

4.9.3 In research involving observation in natural environments or virtual settings where people have a reasonable or limited expectation of privacy, the researcher shall explain the need for an exception to the general requirement for consent.

4.9.4 In some research contexts, the researcher may plan to disclose the identity of participants. In such projects, researchers shall discuss with prospective participants or participants whether they wish to have their identity disclosed in publications or other means of dissemination. Where participants consent to have their identity disclosed researchers shall record each participant's consent.

4.9.5 In studies using emergent design in data collection, researchers shall provide the REB with all the available information to assist in the review and approval of the general procedure for data collection.

4.10 Clinical Trials

4.10.1 In the design and review of a clinical trial, researchers and REBs shall consider the type of trial (e.g., pharmaceutical, natural health product, medical device, psychotherapy etc.), its phase (if appropriate) and the corresponding particular ethical issues associated with it, in light of the core principles of this policy.

4.10.2 All clinical trials shall be registered before recruitment of the first

Ethical Review of Research with Human Participants

trial participant in a recognized and easily web-accessible public registry.

4.10.3 Researchers and REBs should ensure that the foreseeable risk to participants in clinical trials is:

- a. justified by the potential benefits to be gained
- b. appropriately minimized

4.11 Reconsideration and Appeals

4.11.1 Researchers have the right to request, and REBs have an obligation to provide, prompt reconsideration of decisions affecting a research project.

4.11.2 An REB appeal committee with documented processes shall handle appeals from researchers when, after reconsideration, the REB has refused ethics approval of the research. Normally Research Ethics Appeal Boards (REAB) shall convene within two weeks of receiving a reconsideration request.

4.11.3 The ad hoc appeal committee has the authority to review negative decisions made by the REB. In doing so it may approve, reject or request modifications to the research proposal. Its decision on behalf of the institution shall be final. Procedures for the ad hoc REAB are established in Standard Operating Procedures.

4.11.4 REAB Members

The REAB shall consist of six members, including males and females:

- a. who are selected from faculty and professional staff
- b. at least one of whom is a student, in cases where project has student participants
- c. at least two of whom have broad expertise in research methods
- d. at least one of whom has extensive knowledge in ethics or previous experience in evaluating the ethical treatment of human research participants

Ethical Review of Research with Human Participants

FACT SHEET

DATES:

Approval 2011.10.24
Review 2016.10

SOURCE:

98.05.14 New policy approved 98.05.14 by Board motion 7-5-14-97/98. Recommended by Academic Council 98.04.28.03.

2000.11.21 Updated terminology (Grant MacEwan University). Reformatted to new format. Revisions approved by Academic Council motion 00.11.21.03.

2003.12.18 Policy updated to include Tri-Council policy statement on “Ethical Conduct for Research Involving Humans” approved by Board motion 01-12-18-2003/04 as recommended by Academic Council motion 03-11-18-03 and was endorsed by Executive Committee.

2004.02.24 Implementation date of July 1, 2004 approved by Board motion 01-2-24-2003/04.

2004.11.18 Revisions and title change approved by Board motion 01-11-18-2004/05 as recommended by Academic Council motion 04-09-14-05 and was endorsed by Executive Committee.

2006.04.12 Policy Statement was reworded for clarity and it renames the committee to a “research ethics Board”. To be effective immediately. Amended as recommended by Academic Council 06.02.14, and approved 06.04.12 by Board motion 01-04-12-2005/06.

2006.10.17 Additional regulation 3.6.1 (V) was added to align with the Tri-Council Policy Statement. Approved by Executive Committee, October 17, 2006.

2009.10.08 Terminology updated to reflect name change to Grant MacEwan University. Approved by Board motion 01-10-8-2009/10.

2011.10.24 Revised as recommended by Academic Policies Committee, and approved by Academic Governance Council motion AGC-07-10-24-2011.

2014.10.28 Terminology updated to reflect housekeeping and textual changes, and approved by Academic Governance Council motion AGC-04-10-28-2014.

2014.12.22 Updated to reflect current policy names and numbers, references to retired policies, and Related Policy listings.

**Grant MacEwan University
Policy Manual**

Ethical Review of Research with Human Participants

- 2015.03.17 Terminology updated to reflect housekeeping and textual changes, and approved by Academic Governance Council motion AGC-02-03-17-2015.
- 2018.12.12 Minor change to replace Academic Governance Council with General Faculties Council effective February 1, 2019. Approved by Policy Sponsor on December 12, 2018.

RELATED POLICIES:

Academic Integrity
Visiting Scholars
Titled Chairs
Research, Scholarship and Creative Activity
Responsible Conduct of Research and Scholarly Activity
Animal Research Ethics
Research Partnerships and Affiliations

REFERENCE NOTES:

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2010.*

IMPLEMENTATION DATE: November 1, 2011