



Policy Number:	AS-2100-2013
Policy Title:	Ethical Conduct for Research Involving Humans
Policy Owner:	Vice President, Academic
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1. Purpose

Mohawk College recognizes the value of ethical research integrity as it applies to research to be conducted under the auspices of Mohawk College.

This policy supports the establishment of an independent REB that has the authority and mandate to review the ethical acceptability of research on behalf of Mohawk College and is compliant with the [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, TCPS2 \(2014\)](#).

The TCPS2 (2014) is a joint policy of the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC), and the Social Sciences and Humanities Research Council (SSHRC). The TCPS2 (2014) describes the principles and procedures that govern research conducted with humans.

This policy supports the delegation of authority to the MCREB to review the ethical acceptability of research including approving, rejecting or proposing modifications to research applications on behalf of Mohawk College.

2. Application and Scope

This policy applies to all research involving humans conducted at, or under, the auspices of Mohawk College. This includes staff in the Academic and Support Staff bargaining units, sessional and part time staff, administrative staff, consultants, students conducting research as a requirement in their academic program and all other persons (researchers) conducting research at and/or under the auspices of Mohawk College.

The following requires ethics review and approval by MCREB before the research commences (TCPS2; Article 2.1):

- a) research involving living human participants; and/or
- 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.

The MCREB will review all research proposals following the TCPS2 (2014) and will be approved by the MCREB prior to conducting research.

3. Definitions

"Concern for welfare" is a core principle of the TCPS2 policy statement that requires researchers and research ethics boards to aim to protect the welfare of participants, and, in some circumstances, to promote that welfare in view of any foreseeable risks associated with the research.

"Confidentiality" is an ethical and/or legal responsibility of individuals or organizations to safeguard information entrusted to them, from unauthorized access, use, disclosure, modification, loss or theft.

"Consent" is an indication of agreement by an individual to become a participant in a research project. The term "consent" means "free (also referred to as voluntary), informed and ongoing consent".

"Delegated research ethics board (REB) review" is the level of REB review assigned to minimal risk research projects. Delegated reviewers are selected from among the REB membership, with the exception of the ethics review of student course-based research which can be reviewed by delegates from the student's department, faculty, or an equivalent level.

"Full research ethics board (REB) review" is the level of REB review assigned to above minimal risk research projects. Conducted by the full membership of the research ethics board, it is the default requirement for the ethics review of research involving humans.

"Harm" refers to anything that has a negative effect on participants' welfare, broadly construed. The nature of the harm may be social, behavioural, psychological, physical or economic.

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

"Observational research" is the study of behaviour in a natural environment in which people involved in their normal activities are observed whether with or without their knowledge. This term does not include observational methods used in epidemiological research.

"Participant" refers to an individual whose data, or responses to interventions, stimuli, or questions by a researcher are relevant to answering a research question; also referred to as "human participant", and in other policies/guidance as a "subject" or "research subject"/

"Principal investigator" is the leader of a research team who is responsible for the conduct of the research, and for the actions of any member of the research team.

"Privacy" is an individual's right to be free from intrusion or interference by others.

“Research ethics board (REB)” is a body of researchers, community members, and others with specific expertise established by an institution to review the ethical acceptability of all research involving humans conducted within the institution’s jurisdiction or under its auspices.

4. Principles

The MCREB will follow the three guiding principles:

a) **Respect for Persons**

“...recognizes the intrinsic value of human beings and the respect and consideration that they are due”. (TCPS2 (2014), p.6)

b) **Concern for Welfare**

Welfare includes physical, mental, spiritual, economic and social well-being. In addition, welfare includes privacy and control of personal information. REBs should aim to protect the welfare of participants by ensuring that participants have adequate information to make an informed decision about research participation. (TCPS2 (2014), p.7)

c) **Justice**

To ensure that all research participants are treated fairly and equitably. In recognizing differences in vulnerability levels, the REB will ensure that these differences are respected and mitigated in research studies with extra consideration given to the planning and conducting of research to ensure the principle of justice is demonstrated. (TCPS2 (2014), p.8.)

To ensure that all research conducted at Mohawk College by faculty, staff, students and the research community at large, meets the following research ethical principles:

- Requirement for free and informed consent;
- Respect for vulnerable persons;
- Respect for privacy and confidentiality;
- Respect for justice and inclusiveness;
- Balancing harms and benefits;
- Minimizing harm; and
- Maximizing benefit.

5. Accountability and Compliance

5.1 Accountability Framework

This policy has been approved by the Senior Leadership Team.

5.2 Compliance

As an entity that draws its authority and resources from Mohawk College, the MCREB remains accountable to the highest body of the institution that established it for the integrity of its processes. The MCREB is responsible for and oversees the ethical review and practice of research involving humans at the College by ensuring and monitoring compliance with TCPS2 (2014). The MCREB submits an annual report to the Board of Governors via the Vice President, Academic (VPA).

MCREB is independent in its decision-making and is accountable to the highest body that established the REB for the process of research ethics review, the Board of Governors. Institutional policies and procedures shall also support and promote the independence of MCREB in decision making so that MCREB may be free of inappropriate influence, including situations of real, potential or perceived conflicts of interest. (TCPS2 Article 6.2)

The MCREB will:

- meet regularly to fulfill the terms of reference, maintain minutes and documentation;
- The MCREB Chair/s and Research Ethics Co-ordinator are responsible for the administration of the day to day operations of the MCREB; and
- The VPA will be kept informed of substantive issues related to policy, process and compliance; and submit an annual report to the Board of Governors.

With the establishment of an independent REB, this policy will ensure compliance with ethical research principles to ensure eligibility for research funding.

5.3 Record Keeping of MCREB Documents (TCPS2; Article 6.17)

REBs 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.

6. Mohawk College Research Ethics Board (MCREB)

6.1 MCREB Membership

The membership of the REB is designed to ensure competent independent research ethics review. Provisions respecting its size, composition, terms of appointment and quorum are set out below.

Article 6.4 The REB shall consist of at least five members, including both men and women, of whom:

- a) at least two members have expertise in relevant research disciplines, fields and methodologies covered by the REB;
- b) at least one member is knowledgeable in ethics;
- c) at least one member is knowledgeable in ethics involving Indigenous peoples;
- d) at least one member is knowledgeable in the relevant law (but that member should not be the institution's legal counsel or risk manager). This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research; and
- e) at least one community member who has no affiliation with the institution. It is advisable that each member be appointed to formally fulfil the requirements of only one of the above categories. To ensure the independence of REB decision making, institutional senior administrators shall not serve on the REB.

6.2 Terms of Appointment/Meetings and Attendance

The term of office for the MCREB Chair and MCREB members will be three years. The MCREB Chair term will run for three years, with the opportunity for renewal. The MCREB Chair and members may be re-elected for second term, however, membership will be reviewed annually to ensure representation from all areas of the college generating research. Rotation of MCREB membership will reflect the diversity of opinion and provide the opportunity to advance knowledge and expertise gained from MCREB membership. MCREB members will receive an orientation upon appointment. All MCREB members will be required to complete the TCPS2 (2014) Core Training online tutorial within three (3) months of appointment.

MCREB members will meet annually for professional development. The MCREB Chair and/or at least one member will attend the annual CAREB conference and regional professional development opportunities.

The MCREB will meet whenever necessary during the Academic year at the discretion of the REB Chair/s. Virtual delegated review may be used for minimal risk research applications. More than minimal risk applications will undergo full board review. A quorum for full board review meetings is 50% plus one additional member present.

6.3 MCREB Chair/s

The MCREB Chair(s) are responsible for ensuring that the REB process complies with the TCPS2 (2014) Policy Statement. The MCREB Chair(s) will provide overall leadership for the MCREB and facilitate the REB review processed based on institutional policies and procedures and the TCPS2 (2014). The MCREB Chair(s) will monitor the MCREB's decisions for consistency and to ensure that all decisions are documented and communicated clearly to researchers in a timely manner.

6.4 Concepts of Risks and Potential Benefits (TCPS2; Article 2.9)

MCREB 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.

7. Mohawk College Research Ethics Boards Research Review Process

7.1 Initial Research Ethics Review (TCPS2; Article 6.11)

Researchers shall submit their research proposals, including pilot studies, for MCREB review and approval of its ethical acceptability prior to the start of recruitment of participants, access to data, or collection of human biological materials. MCREB review is not required for the initial exploratory phase, which may involve contact with individuals or communities intended to establish research partnerships or to inform the design of a research proposal.

7.2 Determining the Level of Research Ethics Review (TCPS2; Article 6.12)

In keeping with a proportionate approach to research ethics review, the selection of the level of MCREB review shall be determined by the level of foreseeable risks to participants: 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).

Levels of research ethics review that may apply, includes:

a) Full REB review

Research ethics review by the full MCREB should be the default requirement for research involving humans that is more than minimal risk.

b) Delegated REB Review

The MCREB delegates research ethics review to an individual or individuals where the review is for minimal risk research, amendment requests, and annual reviews. Delegates shall be selected from among the MCREB membership.

c) Student course-based research

Course-based research varies in scope but includes activities such as students conducting interviews, administering standardized tests, or distributing questions. It also includes conducting projects that pose research questions, gather data from human participants and analyze that data for presentation.

Student course-based research activities are different from Professional Skill Development activities, which are exempt from ethical review requirements. In the case of course-based research, the instructor holds primary responsibility for the ethics review application and for student adherence to ethical treatment of human participants. The student(s) hold secondary responsibility.

7.3 Institutional Survey and Administrative Approval Process

All researchers, whether internal to Mohawk College or external, requesting research, surveys, interviews, focus groups or pre-existing data/information of College stakeholders (e.g., students, employees, graduates, staff etc.) must obtain approval through Mohawk College's Institutional Research (IR) Department in accordance with the "Survey and Administrative Approval Policy" in conjunction with receiving Mohawk College Research Ethics Board approval.

Institutional Research approval does not constitute Research Ethics Board approval and vice versa.

7.4 Conflicts of Interest (TCPS2; Chapter 7)

Conflicts of interest must be assessed when conducting research as they may jeopardize the integrity of the research and the protection offered to participants. Conflicts that create divided loyalties may distract researchers, research ethics boards (REBs), and institutions from concern for the welfare of participants and are contrary to the core principles on which this Policy is based. Failure to disclose and manage conflicts may impede the informed and autonomous choices of individuals to participate in research. Prospective participants need to know about real, potential or perceived conflicts of interest in order to make an informed decision about whether or not to participate.

Conflicts of interest may also undermine the respect for participants that is fundamental to the principle of Justice.

a) REB Member Conflict of Interest (TCPS2; Article 7.3)

MCREB members shall disclose real, perceived conflicts of interest to the MCREB. When necessary, the MCREB may decide that some of its members must withdraw from MCREB deliberations and decisions.

b) Researcher Conflict of Interest (TCPS2; Article 7.4)

Researchers shall disclose in research proposals they submit to the MCREB 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 on their research. Upon discussion with the researcher, the MCREB shall determine the appropriate steps to manage the conflict of interest.

7.5 Consent

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.

a) Free and Informed (TCPS2; Article 3.1, 3.2)

- Consent shall be given voluntarily.
- Consent can be withdrawn at any time.
- If a participant withdraws consent, the participant can also request the withdrawal of their data or human biological materials.

b) Ongoing Consent (TCPS2; Article 3.3)

- 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.
- Consent Shall Precede Collection of, or Access to, Research Data (TCPS2; Article 3.5).
- Research shall begin only after the participants, or their authorized third parties, have provided their consent.

c) Documented Consent (TCPS2; Article 3.12)

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

8. Research Involving the First Nations, Inuit and Métis peoples of Canada

The TCPS2 includes the ethical conduct and interpretation of ethics policies in relation to First Nations, Inuit and Métis Peoples. Researchers conducting studies in collaboration

with these communities are required to show they are aware of, and sensitive to, the issues of conducting research with these communities and follow the guidelines outlined in TCPS2(2014); Chapter 9.

8.1 Requirement of Community Engagement in Aboriginal Research (TCPS2(2014); Article 9.1)

Where the research is likely to affect the welfare of an Aboriginal community(ies), to which prospective participants belong, researchers shall seek engagement with the relevant community.

The conditions under which engagement is required, include, but are not limited to:

- a) research conducted on First Nations, Inuit or Métis lands;
- b) recruitment criteria that include Aboriginal identity as a factor for the entire study or for a subgroup in the study;
- c) research that seeks input from participants regarding a community's cultural heritage, artefacts, traditional knowledge or unique characteristics;
- d) research in which Aboriginal identity or membership in an Aboriginal community is used as a variable for the purpose of analysis of the research data; and
- e) interpretation of research results that will refer to Aboriginal communities, peoples, language, history or culture.

9. Multi-jurisdictional Research

a) Common College Multi-site Research

The MCREB, working in collaboration with other college REBs in Ontario accepts the multi-site application form for researchers who are planning to conduct a study at more than one college in Ontario. The researcher completes the Common College application form rather than a separate form for each college which the researcher then submits for Expert Panel Review. Once Expert Panel approval has been obtained, it is the researcher's responsibility to contact all college sites to determine where and how to submit the form for REB approval at each college site.

b) Researchers not affiliated with Mohawk College

Principal investigators, who are not affiliated with Mohawk College, should submit the research ethics application of their home institution, along with all supporting documents once the application has been approved by the home institution's REB. Researchers will be expected to obtain Institutional Survey and Administrative Approval in addition to submitting a research ethics application to MCREB.

c) McMaster / Mohawk / Conestoga (MMC) Coordinated Review Ethics Process

Ethics review for multi-center research presents many challenges to researchers and REBs. In order to minimize the duplication of effort and the time delays associated with concurrent or serial ethics review, McMaster University, Conestoga College and Mohawk College shall co-ordinate a coordinated ethics review process.

10. Non-compliance with MCREB Requirements

Non-compliance shall include failure to obtain MCREB approval for research involving humans, failure to comply with any conditions of an approval issued by the MCREB, as well as failure to obtain MCREB approval for substantive changes to approved research project.

1. Reports of non-compliance or suspected non-compliance will be forwarded to the MCREB Coordinator.
2. The MCREB Coordinator will work with the REB Chair to investigate all reports of non-compliance to determine their credibility. The REB may request that research is suspended during an investigation.
3. The MCREB Coordinator will inform the Vice-President Academic and Chief Operating Officer, and the appropriate dean/director, that the REB has initiated an investigation and indicate if they are requesting that senior administration suspend research during the investigation.
4. The MCREB will determine whether there is non-compliance and the severity of non-compliance.
5. The VPA and the supervisor (at the Dean or higher level) of the investigator(s) shall be informed of:
 - a. requests to suspend research;
 - b. specific actions/modifications requested; and
 - c. if the MCREB finds an investigator in non-compliance.
6. In cases of non-compliance the MCREB shall contact the investigator(s) involved and request specific action be taken to bring the research into compliance. Findings will also be reported to the appropriate Dean/Director, Vice President, Academic and Chief Operating Officer.
7. When the MCREB has requested that research be modified and/or suspended, or in the case of non-compliance, halted, the Vice President, Academic will take reasonable steps to monitor compliance with the MCREB's recommendations and stop the research if necessary.
8. The MCREB Chair and/or MCREB Coordinator may act on behalf of the MCREB pending a meeting of the Board.

11. Appeal Process

Where researchers do not receive ethics approval, or receive approval conditional on revisions that they find compromise the feasibility or integrity of the proposed research, they are entitled to reconsideration by the REB. If that is not successful, they may appeal using the established appeal mechanism in accordance with the institution's procedures. Information on the Appeal process is available at [TCPS2 \(2014\) Chapter 6, Section C, Article 6.19.](#)

12. Policy Revision Date

12.1 Revision Date

May 2021

12.2 Responsibility

The Vice President, Academic, in conjunction with the Mohawk College Research Ethics Board will review this policy every three years or earlier when required.

13. Attachments

Appendix A – Ethical Conduct of Research involving Humans Procedure

14. Specific Links

AS-2102-2007 Academic Freedom in Research

AS-2103-2007 Administration of Research Grants and Contracts

AS-2104-2007 Ethical Conduct of Research Involving Animals

AS-2105-2007 Integrity in Research and Scholarship

AS-2106-2007 Research Involving Biohazardous and Radioactive Materials

GC-4100-2013 Intellectual Property Policy

GC-4010-2013 Copyright Policy

[Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans 2 \(2014\)](#)

[Mohawk College Research Ethics Board Online Submission Site](#)

[Guidelines and Procedures for Course-Based Student Research Activities Involving Human Participants](#)



Ethical Conduct of Research Involving Humans Procedure

- Researchers will register and submit applications electronically through the [Mohawk College Research Ethics Board Online Submission Site](#).
- Minimal risk studies will be reviewed by the MCREB Chair and at least one other member. Greater than minimal risk studies will undergo full MCREB review.
- Amendment, extension, and completion documents will be emailed to the MCREB Coordinator to undergo delegated review by the Chair. All approvals, amendments and completion reports will be documented and presented to the MCREB at the following meeting.
- The MCREB will meet at least twice in an academic year to review approvals, amendments and completion reports. Other items on the agenda may include the review of forms, the review of policies, or other matters relevant to the interests of ethical research practice.
- Members of the REB will act individually to give an impartial opinion on the ethics of each research project.
- Where there is a conflict of interest, the member of the MCREB with the conflict will absent themselves from the room during discussion of the particular application. Each member will make a decision based only on the ethical acceptability of the research. Ideally, members of the MCREB will reach a consensus on each application.
- In cases where one or more members have concerns, the MCREB will work together to identify needed revisions that will make a project ethically acceptable. In cases where consensus cannot be reached, the MCREB will consult first with the Vice President, Academic. If a disagreement persists, the majority position will stand, and the minority position will be communicated to the researcher in writing by the MCREB Coordinator.
- Following each meeting, the MCREB Coordinator will communicate rejections, approvals and requests for revision within five working days of the meeting.