POLICY NAME	POLICY ON THE ETHICAL CONDUCT OF RESEARCH INVOLVING HUMAN PARTICIPANTS
Approving Body	Senate Board of Governors
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Executive Sponsor	Vice-President (Research and Innovation)

Related Documents	• Procedures for the Implementation of the Policy on the Ethical Conduct of Research Involving Human Participants • Regulation on the Conduct of Research

PURPOSE

A fundamental commitment of the University is to the advancement of learning through scholarly activities, including research involving human participants. The University recognizes that such activities flourish only in a climate of academic freedom, and therefore is committed to safeguarding, among others, the freedoms of inquiry and dissemination of research results. When these activities involve human participants, these freedoms must be integrated with the responsibility to conduct the research in a manner that respects the dignity, rights and welfare, and above all protects from possible harm, the persons who are the research participants.

The purpose of the Policy on the Ethical Conduct of Research Involving Human Participants ("Policy") is to promote and facilitate the conduct of research involving human participants in a manner consistent with the highest scholarly and ethical standards. To this end, the University is committed to adhering to the principles and articles stipulated in the most recent version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS). The three core principles are respect for persons, concern for welfare, and justice.

This Policy describes the administrative structures and responsibilities for the ethical review of research involving human participants at the University. All such research must be in compliance with the TCPS; this Policy; procedures and guidelines established by the McGill Advisory Council on Human Research Ethics and the individual Research Ethics Boards (REBs) as well as all relevant provincial, federal and international regulations and laws.

SCOPE

This Policy applies to all research involving human participants conducted at or under the auspices of the University and will be supported by Procedures for the Implementation of the Policy on the Ethical Conduct of Research Involving Human Participants ("Procedures").

Research involving human participants requires ethics review and approval by a McGill REB before the research may begin. Research falling under Article 21 of the Quebec Civil Code must be reviewed by a REB that is designated by the Ministère de la Santé et des Services sociaux (MSSS).

In some instances of multi-jurisdictional research, a review done by an external REB may be accepted by the McGill REB, in accordance with the requirements of the TCPS and the Procedures.

1. RESEARCH REQUIRING ETHICS REVIEW

1.1 The requirement for REB review applies to those activities described in the TCPS that meet the TCPS definition of 'research', defined as an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation, and 'human participants', defined as those individuals whose data, biological materials, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question(s).

As per the TCPS, the following requires ethics review and approval by a REB before the research commences. Research involving:

a. living human participants;
b. 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.

1.2 REB review is also required for all research conducted at or under the auspices of the University which includes:

a. All research projects involving human participants conducted by or under the supervision of any member of the University, whether the research is funded or non-funded, or conducted on University premises or elsewhere. For the purpose of this document, a "member of the University" means: academic and non-academic staff; sessional instructors; students; visiting or adjunct scholars; postdoctoral fellows, paid and unpaid research associates and assistants; and any person in a like position; all when acting in connection with their institutional role(s). This applies to arriving faculty in respect of ongoing research even though their current research may have received ethics approval at a previous institution;

b. All student research projects conducted as part of thesis or course requirements;

c. Pilot studies and feasibility studies;

d. All research involving human participants (including recruitment and/or data collection) conducted by organizations or individuals who are not members of the University while on University premises or using University facilities, equipment, or resources (including human resources);

e. Those aspects of collaborative research involving researchers, data or participants from other institutions in which a McGill member is active, whether as the Principal Investigator or otherwise; and

f. Research conducted by McGill members as part of consulting activities as defined by University regulations when those members use McGill facilities, equipment, or supplies, or rely on support from McGill staff or when the research data collected will be disseminated in association with the University and when the researcher purports to represent the University in any way.

1.3 Research involving human participants does not require REB review when:

a. It relies exclusively on information that is: i) made publicly available through a mechanism set out by legislation or regulation and that is protected by law; or ii) is in the public domain and the individuals to whom the information refers have no reasonable expectation of privacy.

b. It involves the observation of people in public places where: i) it does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups; ii) individuals or groups targeted for observation have no reasonable expectation of privacy; and iii) any dissemination of research results does not allow identification of specific individuals.

c. It 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. Anonymous means the data or materials has never had personal identifiers associated with it.

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 purposes of this Policy, and do not fall within the scope of REB review. If data are collected for the purposes of such activities are later proposed for research purposes, it would be considered secondary use of information not originally intended for research, and would require REB review in accordance with this Policy.

2. RESPONSIBILITIES

The ethical conduct of research involving human participants is a responsibility that is shared by the various constituents of the University. Notwithstanding this shared responsibility, there are specific responsibilities.

2.1 Responsibilities of the Board of Governors

a. The Board of Governors is responsible for approval of this Policy.

b. The Board of Governors, the highest body within the institution, is responsible for establishing the Research Ethics Boards (REBs), ensuring they are provided with necessary and sufficient ongoing financial and administrative resources to fulfill their duties, and ensuring that REBs are able to operate effectively and independently in their decision making.

2.2 Responsibilities of the Administration

a. The Vice-President (Research and Innovation) bears the responsibility for the implementation of this Policy. They must ensure that the University's adopted practices and procedures are being adhered to and are in compliance with all applicable ethical requirements.

b. Academic administrators such as Deans, Directors and Department Chairs, have a responsibility for the conduct of research carried out within their jurisdictions. They have a responsibility to be aware of ongoing research and a duty to create a climate for ethical practice in research by promoting widespread general awareness and knowledge of this policy and the need for ethics review.

2.3 Responsibilities of Researchers

a. Researchers have the primary responsibility to ensure that their research is carried out in an ethical manner. They are responsible for the protection of the rights and welfare of the research participants.

b. Researchers must be familiar with and comply with this policy and other ethical guidelines relevant to their research discipline. It is the responsibility of the researcher to obtain ethical approval as described in this policy for any project involving human participants before starting the research. If the McGill member is uncertain about whether the research needs ethical review and approval, the member ought to consult the appropriate REB for advice.

c. All members of a research team who conduct research under the supervision of others have a responsibility for the ethical conduct of research with human participants. The Principal Investigator has the responsibility to ensure that the members of the research team comply with the provisions of this policy. Principal Investigators must ensure that the members of the research team are aware of the contents of this policy and of other applicable ethical guidelines pertaining to human participants that derive from their discipline and that are relevant to their responsibilities. Principal Investigators must ensure that all individuals under their supervision have the training and competence needed to carry out their responsibilities in an ethical manner.

d. Researchers have a duty to inform the REB of any actual, potential or perceived conflicts of interest. A conflict of interest arises where the researcher has a material interest of any nature - personal, financial, career or otherwise – that may conflict with the researcher's duty of honesty and integrity.

e. Researchers are required to adhere with all conditions of approval of the REB.

f. Researchers are responsible for ensuring that all data is maintained in accordance with the confidentiality and security approved by the REB and in compliance with relevant University policies and any applicable legislation. Researchers are responsible for being aware of any specific data retention requirements applicable to their particular research.

2.4 Responsibilities of Faculty Members as Supervisors of Student Researchers

a. All student research must be supervised by a faculty member who accepts responsibility for reasonable oversight of the ethical conduct of the student's research project. The supervising faculty member has certain responsibilities even though the student may be the primary researcher. Supervisors must take reasonable measures to ensure that their students have the training and competence needed to carry out their responsibilities in an ethical manner. They must take reasonable efforts to ensure that the students are aware of and familiar with the contents of this Policy and of other applicable ethical guidelines that are relevant to their responsibilities. Once a student's research project is approved, the supervisor must take further reasonable measures to ensure that the research is conducted in accordance with the provisions of this Policy and other applicable ethical requirements.

b. In the case of all undergraduate research, the supervisor has full responsibility to ensure that a student's project receives the appropriate ethics approval. In the case of course research projects, the supervisor/instructor has full responsibility to ensure that a student's project receives the appropriate ethics approval.

c. In the case of graduate or postdoctoral research, it is the joint responsibility of the faculty supervisor and the student to ensure that the project receives the appropriate ethics approval.

2.5 Responsibilities of Student Researchers

a. Student research projects involving human participants must receive the appropriate ethics review and approval before the research may begin. Although a student's research must be supervised by a faculty member, this does not in any way relieve the obligation of the student to be familiar with and comply with the contents of this policy that are relevant to the student's responsibilities.

b. In the case of graduate or postdoctoral research, except for course research projects, it is the joint responsibility of the faculty supervisor and the student to ensure that the project receives the appropriate ethics approval.

3. STRUCTURE

The overall responsibility for overseeing the ethical conduct of research involving human participants is entrusted to the Vice-President (Research and Innovation). The following bodies have been established for developing and implementing University policies and procedures related to human participant research.

3.1 Advisory Council on Human Research Ethics

a. The Advisory Council on Human Research Ethics (ACHRE) is the University body responsible for coordinating University-wide understanding of, and compliance with, the applicable requirements for the ethical conduct of research involving human participants.

b. The ACHRE reports directly to the Board of Governors and to the Vice-President (Research and Innovation) and must submit an annual report of its activities.

c. The ACHRE is responsible for:

- Advising and making recommendations to the Vice-President (Research and Innovation) on policies and procedures to be established or modified, in order to ensure that all research involving human participants conducted at or under the auspices of the University is carried out in a manner consistent with the highest ethical standards. The ACHRE will actively monitor the consistency of these policies and procedures with other McGill policies, the TCPS, provincial, federal and international regulations, and all other applicable guidelines.

- Reviewing and advising the Vice-President (Research and Innovation) on the number, jurisdiction and responsibilities of the REBs at McGill.

- Developing and reviewing policies, guidelines and procedures, in conjunction with the REBs, to promote consistency of procedures and policy interpretation.

- Responding to any issues of concern raised by the REBs and facilitating the provision of ethical and legal expertise to the REBs as needed.

- Collaborating with the Office of the Vice-President (Research and Innovation) and the REBs to develop and implement educational resources and programs on the ethics of research involving human participants, for faculty, staff and students.

- Maintaining liaison with other organizations involved in the protection of human research participants.

- Creating subcommittees as required to carry out the business of the ACHRE.

d. Membership composition is outlined in the Procedures and is determined by the Vice-President (Research and Innovation) as deemed needed to fulfill the mandate of the committee. All non ex-officio members are appointed by the Board of Governors.

3.2 Research Ethics Boards

a. The REB remains accountable to the highest body of the institution that established it for the integrity of its processes. The University REBs report directly to the Board of Governors, and must submit an annual report of their activities.

b. The jurisdiction and number of REBs are established by the Vice-President (Research and Innovation), in consultation with the ACHRE, considering the range of research conducted at the University and consistent with appropriate workloads.

c. Each REB:

- Is mandated to determine the ethical acceptability of research involving human participants, with the primary objective of protecting the rights and welfare of the participants. The ethics review process is conducted in accordance with the standards and procedures of the TCPS as well as applicable provincial, federal, and international requirements.

- Is responsible for reviewing research projects involving human participants in a manner consistent with this policy. The REB conducts reviews in an independent manner, and the REB decisions are not subject to review by any other body or person except as allowed by the TCPS.

- Has the authority to approve, require modification of, or disapprove research projects.

- Has the authority to suspend or terminate approval of any ongoing research that has been associated with unexpected serious harm to participants or that it deems to pose an unacceptable risk of harm to participants. In this regard, the REB Chair is authorized to act on behalf of REB members in exigent circumstances.

- Is responsible for promptly reporting the suspension or termination of approval of a research project to the Principal Investigator, and the Vice-President (Research and Innovation) and other institutional officials as deemed appropriate by the REB, providing a statement of the reasons for the action taken.

- Has the authority to transfer the responsibility for ethics review to another McGill REB that is determined to have the relevant competencies to evaluate the submitted research, in consultation with the other REB.

- Is responsible for establishing and overseeing mechanisms for delegated review of course research projects in units within its jurisdiction.

- Is responsible for informing the ACHRE of issues arising that may affect the review process of the REBs, or any other issues of concern that may affect University policy relating to research involving human participants.

- Acts as a resource to the University community on matters pertaining to the ethical conduct of research involving human participants and can provide consultation to researchers at all stages of the application and review processes.

d. Membership composition is outlined in the Procedures. It will be, at a minimum, in compliance with the requirements of the TCPS, and, as applicable, with this Policy and any other provincial, federal or international requirements.

e. REB members must disclose to the REB real, potential or perceived possible conflicts of interest arising out of personal relationships, financial interests, multiple roles, or other factors. Members of an REB may not be present during the consideration of their own project or any other project in which the member has a conflicting interest.

f. The Board of Governors is responsible for the appointment, re-appointment and removal of REB members. The term of appointment for members will normally be 3 years, renewable, with staggered appointments. The Board of Governors shall notify the MSSS of any change in the membership of any MSSS designated REBs. The Chair will be appointed by the Board of Governors in consultation with the Vice-President (Research and Innovation). The other members will be appointed by the Board of Governors in consultation with the REB Chair.

g. REB Office Personnel may be appointed by the REB as non-voting members to serve in accordance with the requirements of the TCPS. REB Office Personnel serving as REB members shall have the knowledge, experience and training comparable to what is expected of all REB members. The REB shall ensure that REB Office Personnel can fulfill their responsibilities as REB members independently.

4. NONCOMPLIANCE

a. All researchers conducting human participant research are required to comply with this Policy and all applicable regulations and procedures. Instances of alleged noncompliance must be brought to the REB Chair for review and resolution.

b. When deemed appropriate, serious instances of noncompliance will be forwarded to the appropriate institutional officials for disposition.

c. If research misconduct is suspected, as defined under the University's Regulations Concerning Investigation of Research Misconduct, the Chair of the ACHRE shall immediately initiate the process described in said Regulations.

5. AUTHORITY TO APPROVE PROCEDURES

a. The Vice-President (Research and Innovation) has the authority to approve procedures and directives which are secondary to and comply with this Policy, to ensure the full implementation of this Policy. All such documents will be presented to the Board of Governors in the ACHRE Annual Report.

b. The REB is responsible for developing guidelines and standard operating procedures for implementing the requirements of this Policy consistent with the needs of the relevant research disciplines served by the REB. These may be more, but not less, stringent than those described in the present Policy and the Procedures. Such guidelines and standard operating procedures shall be formalized in writing and approved by the ACHRE.

6. REVIEW

After five years, this Policy shall be reviewed by a working group comprised of the Vice-President (Research and Innovation) or delegate; the Chair of the ACHRE; and one member from each University REB. The working group may make recommendations for modification to this Policy.

Legislative History:

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