PROCEDURE TITLE	PROCEDURES FOR THE IMPLEMENTATION OF THE POLICY ON THE ETHICAL CONDUCT OF RESEARCH INVOLVING HUMAN PARTICIPANTS
Executive Sponsor	Vice-President (Research and Innovation)
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Date of Last Review	N/A

Related Documents	• Policy on the Ethical Conduct of Research Involving Human Participants

PURPOSE

This document describes the procedures to be followed to implement the requirements of the Policy on the Ethical Conduct of Research Involving Human Participants.

This document may be modified as needed by the Vice-President (Research and Innovation) after appropriate consultation with Senior Administration and the Advisory Council on Human Research Ethics.

1. ADVISORY COUNCIL ON HUMAN RESEARCH ETHICS

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.

1.1 Membership

a. The ACHRE shall, at a minimum, consist of:
   - the Chair, appointed by the Board of Governors, in consultation with the Vice-President (Research and Innovation) and with the other members of the ACHRE, who shall be a faculty member who is knowledgeable in research ethics.
   - the Associate Vice-President (Research and Innovation), ex-officio
   - the Chairs of the University Research Ethics Boards (REBs), ex-officio
   - the Associate Director, Research Ethics (OVPRI), who will serve as Secretary, ex-officio
   - the Associate Director, Research Ethics, Faculty of Medicine and Health Sciences, ex-officio
   - one person representing community interests and concerns, who has no formal affiliation with the institution, appointed by the Board of Governors, in consultation with the Vice-President (Research and Innovation) and with the other members of the ACHRE
   - one graduate student or postdoctoral fellow, to be named by the Post-Graduate Students' Society (PGSS).

b. Other members may be appointed as deemed necessary to carry out the mandate of the committee. The Board of Governors will appoint all such members in consultation with the Vice-President (Research and Innovation) and with other members of the ACHRE.

1.2 Meetings

a. Meetings are held annually and at the call of the Chair as needed.

b. Quorum will be 50% of the membership. The Chair has the final authority to decide if the quorum membership present is adequate for the proper conduct of the meeting.

c. Normally, decisions are arrived at by consensus. Only after reasonable efforts to reach a consensus have failed, decisions will be made on the basis of a simple majority vote of those members present.

d. Minutes will be taken of every meeting in sufficient detail to document attendance, decisions and dissents (when applicable including a record of voting), and a summary of the discussion of important issues.

e. Normally, regular ACHRE meetings are closed to the University community and the general public. Exceptions may be made when warranted.

2. RESEARCH ETHICS BOARDS

Research Ethics Boards (REBs) are mandated to review and maintain oversight on the ethical acceptability of research involving human participants conducted at or under the auspices of the University. The jurisdiction and number of REBs are established considering the range of research conducted at the University and consistent with appropriate workloads, as determined by the Vice-President (Research and Innovation), in consultation with the ACHRE.

2.1 Membership

a. The membership will be, at minimum, in compliance with the Tri-Council Policy Statement (TCPS), and as required by any other applicable membership requirements under which a REB must operate given the research it reviews.

b. The REB Chair must monitor the composition of the membership for appropriate representation. The number of members needed from each unit within an REB's jurisdiction is to be determined by the Chair of the REB and should be approximately in proportion to the number of submissions from that unit. For REBs that cover a large number of units, REB membership should be rotated to ensure that all units submitting projects have an opportunity to be represented.

c. The REB Chair must be an experienced REB member and is responsible for ensuring adherence to the applicable policies, regulations, procedures and guidelines. The REB Chair provides overall leadership to the REB and ensures consistency of review decisions. The REB Chair can delegate any of their

responsibilities, as appropriate, to a Vice-Chair or other qualified REB members. Any responsibilities that are delegated by the REB Chair must be documented.

d. At a minimum, the REB must have five members, of which two members have broad expertise in the methods or areas of research under review, one member who is knowledgeable about the relevant ethical issues, one member with no formal affiliation with the institution and, for biomedical research and all research under the auspices of Article 21 of the Quebec Civil Code, one member who is knowledgeable in the relevant law (that member must not be the University's legal counsel or risk manager). Members of the Board of Governors and institutional senior administrators shall not serve on the REB.

e. Except for community members, a member may fulfill more than one role however they may not fulfill more than one role during a full board meeting.

f. All members must sign a confidentiality and a conflict of interest agreement prior to the start of their duties.

2.2 Meetings

a. The REB shall meet regularly, and as needed to review research proposals that are not assigned for delegated review.

b. As the number of members at a convened meeting increases beyond 6-8 members, there should be a proportionate number of community members present.

c. The Chair has the final authority to decide if the minimum quorum at a meeting is adequate to properly conduct reviews.

d. An REB should accommodate reasonable requests from researchers to participate in discussions of their proposals, but the researchers shall not be present when the REB makes its decisions.

e. Only regular members (or their alternates when replacing the regular member) have a vote. REB Office Personnel who are appointed as non-voting members of the REB may attend convened meetings and participate in discussions, but they shall not be counted in determining a quorum and they shall not participate in any votes.

f. Regular attendance by REB members at meetings is required.

g. Minutes will be taken of every meeting in sufficient detail to document attendance, decisions and dissents (when applicable including a record of voting), and a summary of the discussion of important issues. Normally, minutes of these meetings are only accessible to the committee members. In order to assist internal and external audits or research monitoring, and to facilitate reconsideration or appeals, the minutes will be made accessible to authorized representatives of the University, researchers and funding agencies.

h. Normally, regular REB and other REB sub-committee meetings are closed to the University community and the general public. The desirability of openness with respect to the business of the various committee meetings must be limited by considerations of privacy of human participants or of third parties, the confidentiality of proprietary data, the need to encourage free discussion at these meetings, and the desire to promote cooperation in carrying out the purposes of these committees. Exceptions may be made by each committee when warranted.

2.3 Resignations and Removals

a. A member may resign before the conclusion of their term upon provision of notice to the REB Chair.

b. A member automatically ceases to be a member if they no longer meet the criteria for the category under which they were appointed.

c. A member should resign immediately upon determination of research misconduct, mismanaged conflict of interest, or any other relevant behaviour that could be perceived as compromising their ethical judgement.

d. A member may be removed if they are not fulfilling their designated duties in a competent or ethical manner; upon determination of research misconduct, mismanaged conflict of interest, or any other relevant behavior that could be perceived as compromising their ethical judgment or considered incompatible with the role and function of the REB.

2.4 Documentation Management

a. The REB maintains comprehensive records of all documents related to the projects submitted for review, including, but not limited to, initial and continuing review requests(renewals, amendments, unanticipated issues report) and all associated attachments. The REB maintains comprehensive administrative records, including, but not limited to, meeting agendas, minutes, and REB membership rosters.

b. The REB retains all relevant REB records in accordance with the McGill University Records Retention Schedule and applicable legal and regulatory requirements.

2.5 Annual Reports

The Chair of each REB must submit an annual report to the Chair of the ACHRE, summarizing the nature and volume of the REB's activities. These reports are made publicly available. Confidential matters should not be included in such reports but should be conveyed separately. REBs designated by the MSSS are required to submit a MSSS specific annual report to the Board of Governors for acknowledgement. This report is then sent to the MSSS.

3. REVIEW OF RESEARCH

The review process is conducted in accordance with the standards and procedures of the TCPS as well as applicable provincial, federal and international requirements.

3.1 Levels of Review

a. Full REB Review

Ethics review by a full REB is conducted at a convened meeting of the REB at which a quorum is present. A full board review is the default review process. Research that is considered to be greater than minimal risk must be reviewed by the full REB as does any research conducted under the auspices of Article 21 of the Quebec Civil Code.

b. Delegated Review

While full REB review is the default process, the REB may delegate ethics review of minimal risk research to an individual or individuals from among the REB membership.

Minimal risk is commonly defined as follows: if potential participants can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the participant in those aspects of his or her everyday life that relate to the research then the research can be regarded as within the range of minimal risk.

The REB may also delegate review of modifications in response to full board review comments, to one or more individuals. REB Office Personnel that have been appointed to serve as non-voting REB members may perform delegated reviews as established by the REB.

c. Unit Level Review

The ethics review of course-based research projects with a primarily pedagogical purpose may, under prescribed circumstances as established by the REB, be delegated by the REB to non-REB members at the department/school/faculty level. To be delegated, the unit level representatives must have the necessary experience, expertise and training required to review and approve the course projects in accordance with the TCPS. All such members must, at a minimum, complete the TCPS tutorial. Training will be provided by the REB. The representative(s) must fulfill the function throughout the academic year (September-August). Reporting of the actions and decisions must be made on a regular basis, the timing and format as established by the REB. Accountability requires that, regardless of the review strategy, the REB continues to be responsible for the ethics of all research involving humans within its jurisdiction.

3.2 Scholarly Review as Part of Ethics Review

a. As stated in the TCPS, as part of research ethics review, the REB shall review the ethical implications of the methods and design of the research. When evaluating if the potential gains of the research warrant the costs and risks to be incurred by the participants and where risk of potential harm to participants exists, the REB must satisfy itself that the design of a

research project is capable of addressing the questions being asked in the research. REBs may therefore require that research be peer reviewed, particularly when the research involves greater than minimal risk to participants. The extent of the scholarly review that is required for biomedical research that does not involve more than minimal risk will vary according to the research being carried out. Research in the humanities and the social sciences that poses, at most, minimal risk shall not normally be required by the REB to be peer reviewed. REBs must respect the relevant guidelines that require REBs to evaluate the scientific aspects of the research as part of ethics review for specific types of research (e.g. clinical trials).

b. In cases where the research has already passed acceptable peer review, such as through a funding agency or through a peer review process established within the University, the REB will normally accept documentation of those reviews as evidence that appropriate scholarly standards have been met. However, in cases where the REB has a good and defined reason for doing so, the REB reserves the right to request further *ad hoc* independent peer review. REB members may also conduct the review of scholarly validity during the course of ethical review, which would require that the REB has members with the necessary expertise to carry out a proper peer review of the research in question. REBs shall base their judgment about scholarly value on a global assessment of the degree to which the research might further the understanding of a problem, issues or phenomenon; it shall not be based on methodological biases or a preference for particular procedures.

3.3 Decision Making and Outcome of the Review Process

a. A REB should accommodate reasonable requests from researchers to participate in discussions of their proposals, but the researchers shall not be present when the REB makes its decisions. Normally, decisions are arrived at by consensus. Only after reasonable efforts to reach a consensus have failed, decisions will be made on the basis of a simple majority vote of those members present. The REB shall provide the researcher with a written summary of its grounds for a decision.

b. A decision on a submission can be categorized as follows:
   - Approved
   - The REB endorses the submission with conditions that must be met before final approval is granted
   - The REB cannot make a decision based on the information provided and the decision is deferred pending receipt of additional information or major revisions. The REB will then re-review the submission
   - Not approved. A project can only be disapproved at a full board review.

c. A decision of the REB to allow or disallow research on ethical grounds is final unless reversed by the REB upon reconsideration. The University may however, refuse to allow certain types of research within its jurisdiction, even though it has been found to be ethically acceptable.

3.4 Reconsideration

Researchers have the right to request, and the REB has an obligation to provide, reconsideration of an REB decision. The researcher must provide a written rebuttal in response to the concerns

identified by the initial REB review. The researcher has the right to appear and be heard in a meeting with the REB to discuss the rebuttal. The researcher and the REB must have fully exhausted the formal reconsideration process and the REB must have issued its final decision before the Researcher may initiate an appeal.

3.5 Appeals of Decisions

a. If, after the REB has issued its final response after reconsideration, the researcher is still not satisfied with the outcome, such researcher may make a written request to the Chair of the Advisory Council on Human Research Ethics (ACHRE) to appeal such decision (the "Notice of Appeal"). The Notice of Appeal must be filed within twenty (20) working days of the final decision of the relevant REB and will clearly explain the grounds upon which the appeal is being sought. An appeal can be sought for procedural or substantive reasons. The onus is on the researcher to justify the grounds on which they are requesting an appeal and to indicate any breaches to the research ethics review process or any elements of the REB decision that are not supported by University policy or the TCPS.

b. The ACHRE Chair shall act as the Chair of the Appeal Committee. The Appeal Committee shall consist of the members of all the McGill REBs. Members for hearing an appeal will be drawn from the Appeal Committee by the Chair with the composition of the committee hearing the appeal satisfying the REB requirements set out in Section 2.1(d) of these Procedures. No member of the Appeal Committee who is hearing a particular appeal of a decision can be a member of the REB who made or reconsidered such decision. The Appeal Committee may appoint *ad hoc* experts as required.

c. Upon receipt by the Chair of the Appeal Committee of the Notice of Appeal, the Appeal Committee will normally have thirty (30) working days to review the file and a meeting will be convened on or before the final working day. The Appeal Committee shall function impartially, provide a fair hearing to those involved and provide reasoned and appropriately documented decisions.

d. The researcher and the REB member designated by the REB whose decision is being appealed will be informed of the meeting date at least one week in advance. Each of the parties has the right to be assisted by an advisor who shall be a member of the McGill community and will not receive any remuneration for acting as an advisor. Both the appealing researcher and a member of the REB whose decision is being appealed shall have the opportunity to address the Appeal Committee, but neither (nor their advisors, if any) shall be present when the Appeal Committee deliberates and makes a decision.

e. At the meeting, the researcher presents evidence to support the grounds for the appeal. The designated REB member of the REB whose decision is being appealed responds. The Appeal Committee can pose questions to both parties. Each party is given a single opportunity for brief summation, with the researcher speaking last. The Appeal Committee may elect to hear witnesses if, in its opinion, it is relevant to reaching a decision on the grounds of appeal.

f. The decision made by the Appeal Committee on behalf of the University shall be final and shall be communicated in writing to the researcher and to the REB whose decision was appealed within ten (10) working days of the meeting at which the decision was reached. An Appeal Committee decision may be categorised as follows:
   - Approved as submitted and the decision of the REB is overturned.
   - Declined as submitted and the decision of the REB is upheld.
   - Modifications are proposed and the final decision is pending. In this case the appealing researcher has 10 working days to make the requested modification and resubmit the application to the Appeals Committee for re-review. If the researcher does not respond to the request for modifications within the 10 working days, the appeal will be declined and the decision of the REB upheld.

g. The original REB assumes the sole responsibility for administering and monitoring a project that was approved by the Appeal Committee. The number of appeals made and the final decision of each will be reported in the ACHRE Annual Report.

3.6 Continuing Review

a. Ongoing research shall be subject to continuing ethics review based on the associated risks to the participants. Continuing review may be conducted by delegated review, as determined by the REB, and in accordance with applicable regulations. Approvals are granted for a maximum of one year and researchers must provide, at a minimum, an annual report on the status of all ongoing research projects. The greater the risk to the participant, the greater the scrutiny of the continuing review process. The design of this process will depend upon the particular circumstances of the project and might include but is not limited to:
   - requiring the researcher to submit status reports at various intervals
   - requiring the researcher to propose an appropriate monitoring mechanism
   - requiring reports from an independent data and safety monitoring board.

b. The REB may require further monitoring activities or schedule audits of ongoing research projects, although it is not expected that the REB will be responsible for conducting these activities.

c. Researchers must notify the REB when the project has terminated and provide a final report.

3.7 Modification of an Approved Project

Researchers proposing changes to the research project must obtain the approval of the REB before proceeding with these changes, except when necessary to eliminate an immediate hazard to a participant. The REB must then be immediately notified and the modification submitted for consideration immediately thereafter. Modifications may include, but are not limited to, changes in research design, participant population, consent procedures, change of Principal Investigator, new funding, or new co-researchers. Modifications involving minimal risk may be conducted by delegated review.

3.8 Unanticipated Issues

Researchers are obligated to immediately notify the REB of any unanticipated issues that may affect the risk level to participants or that may have other ethical implications. There may also be additional reporting requirements that researchers must adhere to for specific types of research (e.g. clinical trials). Researchers must consult the REB guidelines for specific reporting responsibilities. It is also the responsibility of a researcher to share any new knowledge with the REB that may affect a participant's welfare or have other ethical implications.

3.9 Conflicts of Interest

Conflicts may arise when the researcher serves dual roles (e.g. treating physician, teacher or employer, as well as researcher) and as such may unduly influence the participant to participate in the research. The REB has the responsibility to seek clarification of situations where conflicts of interest may exist. REBs should be provided with the relevant details regarding the research projects, budgets, commercial interests, consultative relationships and any other information needed to allow them to properly identify and address possible conflicts of interest. When a significant real, potential or perceived conflict of interest is brought to the attention of the REB, the researcher may be required to disclose the conflict to potential participants, to abandon one of the interests in conflict, or to take some other action to address the conflict, as specified by the REB. This section does not attempt to address all matters relating to conflicts of interest therefore, as appropriate, reference should also be made to existing University guidelines and regulations on conflicts of interest.

4. Multi-jurisdictional Research

As described in the Policy, research involving human participants conducted at or under the auspices of the University requires ethics review and approval by a McGill REB before the research may begin. However, 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 Policy and the requirements of the TCPS.

Multi-jurisdictional research may involve multiple institutions, multiple researchers and multiple REBs Examples include, but are not limited to:

a. a research project conducted by a team of researchers affiliated with different institutions;
b. several research projects independently conducted by researchers affiliated with different institutions, with data combined at some point to form one overall research project;
c. a research project conducted by a researcher affiliated with one institution, but that involves collecting data or recruiting participants at different institutions or different provinces or countries;

In instances where an official agreement is not required, the implementation of the processes to follow to accept an external ethics review is delegated to the REB. Researchers must contact the REB for the applicable conditions and processes for acceptance of an external ethics review.

Where official agreements are required, the Board of Governors delegates responsibility to the Vice-President (Research and Innovation) to enter into agreements to accept reviews undertaken by an external REB for research conducted under the auspices of McGill.

The following agreements are in place authorizing an external Research Ethics Board to conduct, on behalf of McGill University, the ethics review of research involving human participants conducted under the auspices of McGill University:

- Research Ethics Boards Authorization Agreement Between McGill University and Centre intégré universitaire de santé et de services sociaux de l'Ouest-de-l'Île-de-Montréal (CIUSS-ODIM)
- Research Ethics Boards Authorization Agreement Between McGill University and Centre intégré universitaire de santé et de services sociaux du Centre-Ouest-de- l'Île-de-Montréal (CIUSS-CODIM)
- Research Ethics Board Authorization Agreement Between McGill University and McGill University Health Centre (MUHC)
- Entente-cadre régissant l'évaluation éthique des projets de recherche à risque minimal faisant intervenir plusieurs établissements universitaires québécois.

5. COMPLAINTS AND CONCERNS

a. Participants who have specific complaints or concerns about any aspect of their participation in a research study are provided with the name of a contact person in their consent form, who is removed from the study and study team.

b. Other individuals who have concerns about the research study, research team or other specific concerns, should contact the Associate Director, Research Ethics in the Office of the Vice-President (Research and Innovation).

c. The REB Chair and the ACHRE Chair will be immediately notified of the complaint for review. Once all the information is received, the Chair of the ACHRE, in consultation with the REB Chair, will determine if any further action is necessary.

d. All complaints and actions taken, with confidentiality maintained, shall be reported in the ACHRE annual report. All founded complaints including the researcher's nominative information, must be reported to the relevant authorities as required by the applicable regulations, policies, code or collective agreement to which the researcher is subject. This may include the Dean/Chair of the Faculty, School or Department, the Vice-President (Research and Innovation), the REB that approved the research, and where relevant, the study sponsor, the Board of Governors and the Ministry of Health and Social Services, and to other persons who have a legitimate need to know. All REB records, including nominative information, shall be made available to authorized individuals for the purposes of auditing, monitoring and investigation of complaints or research misconduct.

e. Complaints regarding an REB should be made to the Chair of the ACHRE. The Chair is responsible for investigating the complaint and reporting such complaints to the Vice-President (Research and Innovation). All complaints, with confidentiality maintained, must be reported in the ACHRE Annual Report.

f. Any REB member or other individual involved in the review of research involving human participants who believes they are or have been the target of undue pressure by a researcher or any other individual should report the incident to the Chair of the ACHRE. The Chair is responsible for investigating the incident and must report such incidents to the Vice-President (Research and Innovation) for appropriate action.

6. NONCOMPLIANCE

a. Instances of noncompliance with policies or procedures for research involving human participants should be brought to the attention of the Chair of the appropriate REB for review and resolution. When deemed appropriate, serious instances of noncompliance will be forwarded to the appropriate institutional officials for disposition.

b. Noncompliance can include, but is not limited to, failure to obtain prior REB approval before starting a research project, inadequate supervision of the research, failure to report unanticipated issues or protocol changes to the REB, failure to provide ongoing progress reports, or significant deviation from the approved protocol.

c. Actions taken by an REB or the University administration, as appropriate, will be in accordance with the regulations, policies, codes or collective agreement to which the researcher is subject and in proportion to the nature, impact and severity of the noncompliance. These actions may include, but are not limited to, education measures, compliance audits, terminating or suspending REB approval of active studies, restrictions on the ability to serve as a Principal Investigator on research projects involving human participants, freezing of research funds. Any action taken by the REB or the University administration will be reported promptly, in writing, to the researcher.

d. 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 reporting process described in said Regulations.