

POLICY ON THE ETHICAL CONDUCT OF RESEARCH INVOLVING HUMAN PARTICIPANTS

TABLE OF CONTENTS

POLICY ON THE ETHICAL CONDUCT OF RESEARCH INVOLVING HUMAN PARTICIPANTS

Approved by Senate March 12, 2003 – Minute 9

Approved by Executive Committee – April 28, 2003 – Minute 6

Amended by Senate – May 23, 2007 – Minute 6

Amended by Board of Governors – June 5, 2007 – Minute 14

Amended by Senate - May 7, 2008 - Minute 5

Amended by Executive Committee - May 15, 2008 - Minute 1.3

Approved by Senate – December 5, 2012 – Minute 5

Approved by Board of Governors – December 13, 2012 – Minute 12.2

PREAMBLE

A fundament2 5.639 0eq99aT0.002 Tc2.0eq002 Tc 0(1)-1 62 Tw 0c 0 2(ut)-1(e1.32 TmTC /P <</M.002.157W10pUb

per Thesis Office guidelines, students will be required to include the ethics approval certificate when depositing their thesis.

2.0 STRUCTURE

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

2.1 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. The ACHRE reports directly to the Board of Governors and to the Office of the Vice-Principal (Research and International Relations) and must submit an annual report of its activities.

Policy 53(a)-82(1)-(16)) 289-307, 217-505 (I)-9()JT(R)--8(nand)(ar)-6(c)-8(h an)-6.0d Int-21a

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.

Receiving the annual reports of the REBs and forwarding them to the Board of Governors and the Office of the Vice-Principal (Research and International Relations).

Meetings

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

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.

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.

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.

2.2 Research Ethics Boards

The mandate of an REB is to determine the ethical acceptability of research involving human participants, with the primary objective of protecting the rights and welfare of the participants. Each REB reports to the Board of Governors and the Office of the Vice-Principal (Research and International Relations) through ACHRE, and must submit an annual report of its activities.

The jurisdiction and number of REBs are established considering the range of research cond22.ra20a-

nominated from each unit within the 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. Other regular members may be appointed as deemed necessary by the REB Chair to carry out the mandate of the REB.

Alternate members may be appointed for each of the regular members so as not to prohibit the functioning of the REB in case of illness or other unforeseen circumstances.

When membership of an REB extends beyond 5 members, the community representation should increase proportionately.

The REB Chair may appoint ad hoc members or seek outside advice when reviewing a project that requires specific expertise regarding methodology, community or research participant representation, or other matters.

No member of an REB may participate in the review of any project in which the member has a conflicting interest, such as their own or their student's project. Members must disclose to the REB possible conflicts of interest arising out of personal relationships, financial interests, multiple roles, or other factors. When the REB determines that a conflict exists, the member may be requested to provide information to the REB but may not be present during the consideration of the project.

Responsibilities

Each REB:

Is responsible for reviewing research projects involving human participants in a manner consistent with this policy.

Has the authority to approve, require modification of, or disapprove research projects according to the requirements of this policy.

Is responsible for conducting the continuing review of ongoing research projects.

Has the authority to suspend or terminate approval of any proposed or ongoing research that is not being conducted in accordance with the REB's requirements or other ethical requirements.

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. Actions taken by the REB Chair in relation to exceptional circumstances should be brought to the full REB for ratification as soon as is practicable and in all cases, no later than 30 days after the action was taken.

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

Is responsible for establishing and overseeing mechanisms for delegated review of course research projects (as described in Section 3.4) in units within its jurisdiction.

Is responsible for serving as the initial appeals committee for any appeal taken by an individual against a decision of a delegated review of course research projects.

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.

publicly available. Confidential matters should not be included in such reports, but should be conveyed separately.

Research Proposal – Each committee shall consider a research proposal and all accompanying information to be confidential documents.

3.0 RESEARCH REQUIRING ETHICS REVIEW

All research involving human participants conducted at or under the auspices of McGill University, must be reviewed and approved by the appropriate McGill approved REB. The requirement for REB review applies to those activities that meet the TCPS definition of ‘research’ and ‘human participants’. Researchers must consult the TCPS for discussion of what activities need ethics review and what exceptions may exist. Researchers are responsible for consulting with the REB for verification as to whether their research needs ethics review or not.

3.1 Scope of Review

The requirement for ethics review and approval by a McGill approved REB applies to

- all research conducted by or under the supervision of any member of McGill 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 is defined as including 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, when acting in connection with their institutional role. This applies to new faculty even though their current research may have received ethics approval at a previous institution.
- all student research projects conducted as part of thesis or course requirements
- pilot studies and feasibility studies
- all research or participant recruitment conducted by organizations or individuals who are not members of McGill University while on University premises or using University facilities, equipment, or resources (including human resources)
- research that involves the use of the University’s non-public information to identify or contact human research participants.

3.2 Research Projects in Which the Researcher is a Consultant

Research projects conducted by McGill members as part of consulting activities as defined by University regulations will need review and approval by the appropriate REB when

- a) McGill facilities, equipment, supplies, or support staff are used or
- b) the research data collected will be disseminated in association with the University or
- c) 53(he)-112(b)-18C /P <</M9
- c) llior

particular groups or communities. The investigator is responsible for ensuring that all the

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 ques

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 Advisory Council on Human Research Ethics. The Chair is responsible for investigating the allegation and must report such allegations to the Vice-Principal (Research and International Relations) for appropriate action.

7.0 NONCOMPLIANCE

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.

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.

Actions taken by an REB or the University administration, as appropriate, 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 an investigator in the future, or other actions as deemed appropriate by the REB or the University administration.

APPENDIX I

MCGILL APPROVED RESEARCH ETHICS BOARDS

1) McGill Research Ethics Boards - The University currently has 5 Research Ethics Boards formally approved to conduct the ethics review of research involving human participants in

APPENDIX II

Contact Information for Complaints, Concerns and Recommendations Related to Research Involving Human Participants

Research Ethics Officer, Office of the Vice-Principal (Research & International Relations)
– (514) 398-6831

Chair, University Advisory Council on Human Research Ethics – (514) 398-6831

Vice-Principal (Research and International Relations) – (514) 398-3991

www.mcgill.ca/research/researchers/compliance/human/ - lists all REB Chairs and contact information