McGILL UNIVERSITY **SENATE**

Memorandum

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TO:	Senate
FROM:	Dr. Rima Rozen, Associate Vice-Principal (Research and International Relations)
SUBJECT:	Revision of McGill's Policy on the Ethical Conduct of Research Involving Human Subjects
DATE:	December 5, 2012
DOCUMENT #:	D12-30
ACTION REQUIRED:	☐ INFORMATION ☒ APPROVAL/DECISION

ISSUE:

Approval is needed for revisions to the current version of McGill's Policy on the Ethical Conduct of Research Involving Human Subjects.

BACKGROUND & RATIONALE:

Canadian research institutions are required to have a written policy on human research ethics that is compliant with Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS).

The current version of McGill's Policy (Amended by Senate-May 7, 2008- Minute 5; Amended by Executive Committee – May 15, 2008- Minute 1.3) is based on the first edition of the TCPS. Recent changes to the TCPS have prompted the McGill Policy to be revised accordingly.

Summary of key changes:

- Revisions are primarily to terminology to be in accordance with the revised TCPS vocabulary. For example, the word 'subjects'; has changed to 'participants'; 'expedited review' has changed to 'delegated review'.
- There are also topics expanded upon in the revised TCPS which are reflected in the revised McGill Policy such as multi-jurisdictional research and unanticipated issues. Other minor changes were made to enhance overall clarity and readability.
- Another change to the TCPS is that appeals can now be made on procedural or substantive grounds, whereas before they were only allowed on procedural grounds. This change is reflected in the revised McGill Policy. The actual appeal procedures to follow are not dictated by the TCPS. These procedures are managed at the university level by the Advisory Council on Human Research Ethics and may change over time. For that reason, the McGill Policy no longer covers this (appendices 3 and 4 have been removed).
- The purpose of the McGill Policy is not to reproduce the TCPS document. Therefore there is no need to include an appendix of all TCPS articles (appendix 1 has been removed).

MOTION OR RESOLUTION FOR APPROVAL:	Be it resolved that Senate approve, and recommend to the Board of Governors for approval, the proposed revisions to the *McGill Policy on the Ethical Conduct of Research Involving Human Subjects*.
PRIOR CONSULTATION:	The Advisory Council on Human Research Ethics (ACHRE), which includes the 5 Research Ethics Board Chairs, carefully reviewed the revised TCPS and prepared the necessary corresponding revisions to the McGill Policy. The revisions were then approved by the Research Advisory Council and The Academic Policy Committee approved the revisions and recommended them for Senate's approval (as indicated in the 442nd Report).
NEXT STEPS:	Approval by the Board of Governors
APPENDICES:	Appendix A: Revised Policy on the Ethical Conduct of Research Involving Human Subjects

POLICY ON THE ETHICAL CONDUCT OF RESEARCH INVOLVING HUMAN ~~SUBJECTS~~PARTICIPANTS

TABLE OF CONTENTS

POLICY ON THE ETHICAL CONDUCT OF RESEARCH INVOLVING HUMAN ~~SUBJECTS~~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

PREAMBLE

A fundamental commitment of the University is to the advancement of learning through scholarly activities, including research involving human ~~subjects~~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 ~~the subjects of~~ these activities involve human participants ~~are human beings~~ 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 ~~subjects of the~~ research participants.

The purpose of this policy is to promote and facilitate the conduct of ~~human subject~~ research involving human participants in a manner consistent with the highest scholarly and ethical standards. To this end, McGill 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 ~~guiding ethical~~three core principles are respect for ~~human dignity~~persons, ~~respect for free and informed consent, respect for vulnerable persons, respect for privacy and confidentiality, respect for justice and inclusiveness, minimizing harm and maximizing benefict,~~concern for welfare, and justice. ~~The articles are presented in full in Appendix I of this policy.~~ Researchers are responsible for knowing about and adhering to the standards articulated therein.

This policy describes the administrative structures and procedures for the ethical review of ~~human subject~~ research involving human participants at McGill University. All such research ~~involving human subjects~~ must be in compliance with the TCPS~~Tri-Council Policy Statement *Ethical Conduct For Research Involving Humans*~~; this policy; the policies, procedures and guidelines established by the McGill Advisory Council on Human Research Ethics and the individual Research Ethics Boards as well as all relevant federal and provincial regulations and laws, such as the Quebec Civil Code and the Canada Food and Drug Act.

All research projects involving research participants ~~the use of human subjects~~ conducted at or under the auspices of McGill University require ethics review and approval by a McGill Research Ethics Board (REB) or an REB of a McGill affiliated hospital or an REB recognized by a formal agreement with the University, before the research may begin.

1.0 RESPONSIBILITIES

Authority for ethics review according to this policy is established by the Board of Governors of the University. The ethical conduct of research involving human ~~subjects~~ participants is a responsibility that is shared by the various constituents of the University. Notwithstanding this shared responsibility, there are specific responsibilities that can be summarized as follows.

1.1 Responsibilities of the Administration

The Office of the Vice-Principal (Research and International Relations) bears the responsibility for the implementation of the University's policies on research involving human ~~subjects~~participants.

It must provide for the appropriate administrative oversight and the necessary resources to ensure that the University's adopted practices and procedures are being adhered to and are in compliance with all applicable ethical requirements. The Office of the Vice-Principal (Research and International Relations) is responsible for entering into any agreements with other institutions, such as the McGill affiliated hospitals, to conduct the ethics review and approval of the research of McGill members.
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.

1.2 Responsibilities of Researchers

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 ~~human~~ research ~~subjects~~participants.

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 ~~subjects~~ participants before starting the research. If there is any uncertainty about whether the research needs ethical review and approval, the researcher should consult the appropriate REB for advice.

All members of a research team who conduct research under the supervision of others also bear personal responsibility for the ethical conduct of research with human ~~subjects~~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 should ensure that the members of the research team are aware of the contents of this policy and of other applicable ethical guidelines that are relevant to their responsibilities. Researchers must ensure that all individuals under their supervision have the training and competence needed to carry out their responsibilities in an ethical manner.

1.3 Responsibilities of Faculty Members as Supervisors of Student Researchers

All student research must be supervised by a faculty member who accepts responsibility for overseeing 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 ensure that their students have the training and competence needed to carry out their responsibilities in an ethical manner. They must 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. 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, as described in Section 3.~~5~~4, the supervisor/instructor has full responsibility to ensure that a student's project receives the appropriate ethics approval. In the case of graduate or postdoctoral research, except for course research projects as described in Section 3.~~5~~4, it is the joint responsibility of the faculty supervisor and the student to ensure that the project receives the appropriate ethics approval. Supervisors are required to co-sign the student's submission to the REB to affirm their supervisory responsibilities.

1.4 Responsibilities of Student Researchers

Student research projects involving human ~~subjects~~ 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. As stated in Section 1.3, in the case of graduate or postdoctoral research, except for course research projects as described in Section 3.~~5~~4, it is the joint responsibility of the faculty supervisor and the student to ensure that the project receives the appropriate ethics approval. As 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 ~~subjects~~ 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 ~~subject~~ 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 ~~subjects~~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.

Membership

The ACHRE shall, at a minimum, consist of:

- the Chair, appointed by the Vice-Principal (Research and International Relations) in consultation with the other members of the ACHRE, who shall be a faculty member who is knowledgeable in research ethics
- the Associate Vice-Principal (Research and International Relations)
- the Chairs of the University REBs
- the Research Ethics Officer (~~Human Subjects~~OVPRIR), who will serve as Secretary
- the Senior Ethics Administrator, Faculty of Medicine
- one person representing community interests and concerns, who has no formal affiliation with the institution, appointed by the Vice-Principal (Research and International Relations) in consultation with the other members of the ACHRE
- one graduate student or postdoctoral fellow, to be named by the PGSS

Other members may be appointed on an ad-hoc basis as deemed necessary to carry out the mandate of the committee.

Responsibilities

The ACHRE shall be responsible for:

Advising and making recommendations to the Vice-Principal (Research and International Relations) on policies and procedures to be established or modified, in order to ensure that all research involving human ~~subjects~~ participants conducted at or under the auspices of McGill 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 Tri-Council Policy Statement *Ethical Conduct For Research Involving Humans*, federal and provincial regulations, and all other applicable guidelines.

Reviewing and advising the Vice-Principal (Research and International Relations) on the number, jurisdiction and responsibilities of the REBs at McGill University.

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 providing ethical and legal expertise to the REBs as needed.

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

Maintaining liaison with other organizations involved in the protection of human research ~~subjects~~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 at the call of the Chair, but not fewer than 2 times per year.~~ 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 ~~subjects~~participants, with the primary objective of protecting the rights and welfare of ~~these subjects~~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 conducted at the University and consistent with appropriate workloads. Researchers usually submit their projects to their designated REB (see Appendix ~~II~~I). Researchers may consult with the REB Chair to determine if another REB may be more appropriate for the review of their research project. The REB Chair has the authority to refer a project to another more appropriate REB, in consultation with the Chair of the other REB.

Membership

REBs will be maximally effective to the extent that their members are selected on the basis of their interest in, commitment to, and suitability for the role.

An REB, shall, at a minimum, consist of five members, including both men and women, and have:
- at least one member~~s~~ who ~~are~~ is knowledgeable about the relevant ethical issues
- at least two faculty members who have broad expertise in the methods or in the areas of research that are covered by the REB; no REB may consist entirely of members of one discipline
- for biomedical research, and for all research reviewed by an REB designated by the Ministry of Health and Social Services, at least one member who is knowledgeable in the relevant law but is

not the legal counsel of the University; this is advisable but not mandatory for other areas of research
- at least one member who represents community interests and concerns, and has no formal affiliation with the Institution

The term of appointment for members will normally be 3 years, renewable, with staggered appointments. The Chair will be appointed by the Vice-Principal (Research and International Relations) in consultation with the Deans of the relevant Faculties. The other members of a REB are to be appointed by the relevant Faculties/Schools/Departments according to their regular nominating procedures, in consultation with the Chair of the REB. The number of members to be 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 protocols 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 ~~subject~~ participant representation, or other matters.

No member of a 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 ~~subjects~~ 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 ~~subjects~~ participants or that it deems to pose an unacceptable risk of harm to ~~subjects~~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.~~5~~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 ~~department~~ 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 ~~subjects~~ participants and can provide consultation to researchers at all stages of the application and review processes.

Is responsible for developing guidelines and 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. Such guidelines and procedures shall be formalized in writing and approved by the ACHRE.

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 ~~subjects~~participants.

Meetings

The REB shall meet at least annually, and as needed to review research proposals that are not assigned for delegated review ~~normally meet once a month or more frequently as needed~~.

As a minimum, a quorum of an REB must have five members, of which two members ~~with~~ 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. However, the Chair has the final authority to decide if the quorum present is adequate to properly conduct reviews.

Researchers ~~should~~ must be informed of submission deadline requirements. ~~the dates by which their projects must be received by the REB for consideration at the next scheduled meeting.~~

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.

Normally decisions will be 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.

Only regular members (or their alternates when replacing the regular member) have a vote.

Regular attendance by REB members at meetings is required.

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

REB records must be kept for a minimum of three years beyond the termination of a project.

~~**2.3 Research Ethics Boards of Affiliated Teaching Hospitals**~~

~~The REBs of the affiliated teaching hospitals report directly to the Board of Directors of each of the hospitals and have their own policies and procedures. Researchers conducting human subject research at a hospital usually apply to the hospital REB for ethics review and approval.~~

~~Multi-site projects conducted within the affiliated hospitals are normally reviewed by the Faculty of Medicine REB. The hospital REBs are recognized as acting on behalf of the University for conducting ethics reviews for McGill members conducting hospital-based research at any of the affiliated teaching hospitals. There shall be a written agreement between the University and the hospitals regarding the ethics review and approval of the research of McGill members.~~

~~The Faculty of Medicine coordinates the Research Ethics Committee of the Faculty (RECF). The RECF is a work group composed of the chair of the Faculty of Medicine REB and those of the affiliated hospitals, with the Associate Dean (Research) of Medicine acting as Chair. The purpose of the RECF is to provide a forum to address common issues across these REBs, and to discuss and share information and experiences regarding emerging ethical issues. The RECF will make recommendations for guidelines and procedures for the Faculty of Medicine and the affiliated hospital REBs to follow, and attempt to achieve, as far as possible, uniformity in function among these REBs. The Chair of the RECF will report to the ACHRE any issues of concern which pertain to University policy on research involving human subjects.~~

2.~~4~~ 3 Confidentiality

The desirability of openness with respect to the business of the various committee meetings must be limited by considerations of privacy of human ~~subjects~~ 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.

Attendance at Meetings - Normally, regular REB and other committee meetings are closed to the University community and the general public. Exceptions may be made by each committee when warranted.

Minutes of Meetings – Normally, minutes of these meetings are only accessible to the committee members. However, 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 institution, researchers and funding agencies.

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.

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 ~~subjects~~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 Definition of Research~~

~~Research is defined as the systematic investigation to establish and communicate facts, principles, understandings or generalizable knowledge. Research involving human subjects may include, but is not limited to, projects where data are derived from:~~

~~1) the collection of information through any interaction or intervention with a living individual~~
~~2) the secondary use of data previously collected from human subjects~~

3) identifiable private information about an individual
4) human remains, cadavers, human organs, tissues and biological fluids, embryos or fetuses

The examples listed are not intended to represent an exhaustive inventory of activities requiring review. The REB may also determine that some activities apparently falling into these categories may be exempted from review.

The researcher is responsible for consulting with the REB to clarify what types of activities must be reviewed and what exceptions may exist.

3.~~2~~ 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 ~~subject~~ 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 ~~subjects~~participants.

3.~~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) the researcher purports to represent the University in any way

3.~~4~~ 3 ~~Research Conducted Off Campus~~Multi-jurisdictional research

Much research is conducted by McGill members in locations outside of the institution whether in the field or within other institutions. Institutional accountability requires that each institution is responsible for research carried out under its auspices no matter where the research is conducted. There are also projects that may involve McGill members and researchers from other institutions. McGill REB approval is always needed in all circumstances before the research begins except in cases where McGill has formally delegated ethics review and approval to an external REB

Fieldwork Research - Research involving human ~~subjects~~ participants conducted in the field, whether in Canada or in foreign countries, must be reviewed and approved by the appropriate McGill REB before the research may begin. The investigator is responsible for being aware of any established mechanisms or guidelines ~~standard research protocol~~ to be followed or ethical approvals to be obtained when conducting research in other locations and/or dealing with particular groups or communities. The investigator is responsible for ensuring that all the required approvals have been obtained before starting the research, or for demonstrating to the REB why this is not feasible.

Research at Other Institutions – Research involving human ~~subjects~~ participants conducted by McGill members in other institutions must be reviewed and approved by the appropriate McGill REB before the research may begin~~, unless the institution's REB has been recognized by a formal agreement, such as in the case of the REBs of the affiliated teaching hospitals.~~ Researchers are also responsible for obtaining the necessary ethics approval from any ethics boards or authorities that oversee research at the other institutions. The investigator is responsible for ensuring that all the required approvals have been obtained before starting the research.

Team Research - When McGill members are ~~conducting human subject research as~~ part of a collaborative research ~~team~~ project involving human participants where the McGill member is the Principal Investigator, ~~and the project will be conducted by a non-McGill collaborator, McGill REB approval is needed~~ McGill REB approval is needed for all the human participant research to be conducted, even if the data will only be collected by the non-McGill member. The McGill member must also ensure that the collaborators have obtained their own institutional ethics approvals before collecting or accessing data. In the case where the Principal Investigator is from another institution and has already obtained ~~local~~ their institutional REB approval, the McGill member must normally also obtain McGill REB approval before collecting or accessing data. ~~However, the REB Chair has the discretion to expedite this review, based upon the nature of the project and the review of the other REB. The ACHRE may also develop guidelines specifying circumstances under which the approval of another REB constituted under the Tri-Council Policy Statement *Ethical Conduct For Research Involving Humans* may be sufficient without further McGill review required.~~

***Inter-institutional Agreements* -** McGill has agreements with several institutions authorizing the ethical review of research conducted by McGill members to be done by an external REB. See Appendix I for a complete listing.

a) Research Ethics Boards of Affiliated Teaching Hospitals **-** The REBs of the affiliated teaching hospitals report directly to the Board of Directors of each of the hospitals and have their own policies and procedures. Researchers conducting human participant research at a hospital usually apply to the hospital REB for ethics review and approval. Multi-site projects conducted within the Faculty of Medicine and an affiliated hospital(s) or in more than one of the affiliated hospitals are normally reviewed by the Faculty of Medicine REB and not by each hospital REB. The hospital REBs are recognized as acting on behalf of the University for conducting ethics reviews for McGill members conducting hospital-based research at any of the affiliated teaching hospitals.

The Faculty of Medicine coordinates the Research Ethics Committee of the Faculty (RECF). The RECF is a work group composed of the Chair of the Faculty of Medicine REB and the REB Chairs of the affiliated hospitals, with the Associate Dean (Research) of Medicine acting as the RECF Chair. The purpose of the RECF is to provide a forum to address common issues across these REBs, and to discuss and share information and experiences regarding emerging ethical issues. The RECF will make recommendations for guidelines and procedures for the Faculty of Medicine and the affiliated hospital REBs to follow, and attempt to achieve, as far as possible, uniformity in function among these REBs. The Chair, or the appointed delegate of the Chair, of the RECF will report to the ACHRE any issues of concern which pertain to University policy on research involving human participants

b) Team Research Involving Quebec Universities - The University is party to the Entente pour la reconnaissance des certificats d'éthique des projets de recherche à risque minimal (the 'Entente'). Under certain conditions, this Entente allows for the ethics review to be conducted by only one REB where there are researchers from several Quebec universities involved. See Appendix I for details.

***~~Multi-Centre Research~~* -** ~~Where multiple sites participate in the same research project, inter-institutional agreements may be developed and one REB designated to review the research. Although a delegated REB may approve a multi-centre project, the institution in which the research will take place may, through its own REB, subsequently disapprove or decline to participate in the study. However, a project that has been disapproved by a delegated REB may not subsequently be presented for review at the delegating institution's REB. Where no agreement exists, review and approval must be sought from the appropriate local REB and the REB of each participating institution. REBs reviewing multi-centre projects are expected to communicate any significant concerns they have~~

about the rights and welfare of the subjects with the other REBs reviewing the same project.

3.5 4 Student Research

All student research involving human subjectsparticipants, including but not limited to theses, independent research projects, and postdoctoral research, must receive ethics review and approval as described in Section 4.1 before the research may begin. Some student research projects are conducted in courses that require students to collect data from human subjectsparticipants, and these projects must also receive ethics review and approval. The intent of course research projects, however, is for the student to become more knowledgeable about the research process, rather than to contribute to generalizable knowledge, and the results of the data are not intended for publication or presentation outside the classroom. The REB may establish guidelines for delegating the review of course research projects to department review as described in Section 4.1. It is the responsibility of the course instructor to contact the REB if there is any uncertainty as to whether a course project needs ethics review or not. The applicable criterion for determining if ethics review is required is if an activity would be subject to ethics review in any other context, it is subject to review if it occurs in a teaching or training context. In the event that student research falls under the auspices of a research project that has already received ethics review and approval from a McGill approved REB, no further approval is necessary.

4.0 REVIEW OF RESEARCH

The review process is conducted in accordance with the standards and procedures within the Articles of the Tri-Council Policy Statement *Ethical Conduct For Research Involving Humans* in Appendix I TCPS as well as applicable federal and provincial requirements. The type of review depends upon the anticipated level of risk posed to research subjectsparticipants. Risks can include physical, psychological, or economic harms and can include injury to reputation or privacy. According to the TCPS, aA project may be considered to involve minimal risk if the risk possibleof harms anticipated by participation in the research areis not greater, considering probability and magnitude, than those ordinarily encountered in theby participants in those aspects of their everyday life that relate to the research.'s daily life.

4.1 Levels of Review

Full REB Review **-** Ethics review by a full REB is conducted at a convened meeting of the REB at which a quorum is present. The normal REB review process requires a convened meeting of the REB at which a quorum is present. 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. However, REB Chairs may designate any proposal for full review.. Generally, proposals involving more than minimal risk, that involve deception, or where the subjects are vulnerable or captive populations, require full review.

Expedited 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. The REB Chair will examine submissions to assess their appropriateness for review through an expedited process. Proposals eligible for expedited review may be reviewed and approved by the REB Chair or a designated member. Individual REBs may choose to form a subcommittee to conduct expedited reviews. All expedited reviews must be reported to the full REB on a regular basis. Submissions that may be eligible for expedited review include, but are not limited to, projects that involve no more than minimal risk or projects that have been previously approved but to which the researcher wishes to make minor modifications. The REB may delegate the review of course research projects, as described in Section 3.4, to individual REB members or to an REB designated departmental representative or committee. Course research projects may not involve greater than minimal risk. Jurisdiction of review is determined according to the department or faculty that offers the course, not by the department or faculty in

which the student is registered. All delegated reviews must be reported to the full REB on a regular basis.

~~***Department Review*** – The REB may delegate the review of course research projects, as described in Section 3.5, to department review by a REB designated departmental representative or committee. Department review may not be used for any projects involving greater than minimal risk, or for projects that are part of a faculty member's own research program. Jurisdiction of review is determined according to the department or faculty that offers the course, not by the department or faculty in which the student is registered. Department reviews must be reported to the full REB on at least an annual basis.~~

4.2 Scholarly Review as Part of Ethics Review

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 ~~subjects~~ participants and where risk of potential harm to ~~subjects~~ 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 ~~subjects~~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).

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.

4.3 Decision Making and Outcome of the Review Process

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. 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.

A decision on a submission can be categorized as follows:

a) Approved.
b) The REB endorses the submission with conditions that must be met before final approval is granted.

c) 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.
d) Not approved.

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

4.4 Appeals of Decisions

A. 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 REB decision following reconsideration is final.

A researcher who continues to dispute an REB decision after reconsideration by the REB may appeal that decision through the formal appeals process.

B. Appeals ~~Process -~~ Appeals can be made for procedural or substantive reasons. There will be two Research Ethics Appeal Committees, one serving the REB of the Faculty of Medicine and one serving the remaining REBs. The Advisory Council on Human Research Ethics is responsible for establishing the appeals process for the Research Ethics Committees in accordance with the requirements of the TCPS.

The Research Ethics Appeal Committee will serve as the final appeal committee whose decisions shall be final and binding in all respects for any appeal made by a researcher against a decision of an REB. ~~The Appeal Committee will only hear appeals based on procedural error, conflicts of interest, or bias.~~

~~There shall exist two standing Appeal Committees, one serving the Faculty of Medicine REB, and the other serving the remaining REBs. Appendix IV contains the procedures for appeals applicable to the Faculty of Medicine. Appendix III contains the procedures applicable for all other appeals.~~

There shall be no recourses, grievances or review process of matters decided upon by the Research Ethics Appeal Committee pursuant to other regulations or policies of the University.

Researchers should recognize that decisions regarding appeals will be made in light of the primary objective of protecting the rights and welfare of the ~~subjects~~participants.

4.5 Continuing Review

Ongoing research shall be subject to continuing ethics review based on the associated risks to the ~~subjects~~participants. Normally, REBs will require at least annual reports on the status of all ongoing research projects. The greater the risk to the ~~subject~~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

a) requiring the researcher to submit status reports at various intervals as determined by the REB
b) requiring the researcher to propose an appropriate monitoring mechanism
c) requiring reports from an independent data and safety monitoring board

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.

The REB should be promptly notified by the researcher when the project is terminated.

4.6 Modification of an Approved Project

Researchers proposing any significant 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 ~~subject~~participant. The REB must then be immediately notified and the modification submitted for consideration immediately thereafter. ~~Such~~ M~~m~~odifications may include, but are not limited to, changes in research design, ~~subject~~ participant population, ~~,or~~ consent procedures or a change of principal investigator. Other minor modifications should be reported on a regular basis ~~including~~ such as a change of project title, additional funding sources, change of ~~principal or~~ co-~~principal~~ investigator(s) or other collaborators. Modifications involving minimal risk may be conducted by delegated review.

~~At the discretion of the Chair, these modifications may be approved by expedited review. However, significant revisions may require that the proposal be reviewed by the full committee.~~

4.7 ~~Adverse Events~~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. ~~serious or unexpected adverse event experienced by a subject which occurs in connection with the project or if data analysis or other review reveals undesirable outcomes for the subjects.~~. 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.

4.8 Conflicts of Interest

The researcher has 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. 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 ~~subject~~ participant to participate in the research. The REB has the responsibility to identify and 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 or ~~apparent~~ perceived conflict of interest is brought to the attention of the REB, the researcher may be required to disclose the conflict to potential ~~subjects~~participants, to abandon one of the interests in conflict, or to take some other action to address the conflict, as specified by the REB.

REB members must disclose to the REB 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.

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.

5.0 RECORD-KEEPING FOR RESEARCHERS

The McGill *Policy on Research Ethics* ~~recommends~~ states that that all original data be maintained for a period of at least ~~5~~ 7 years from the date of publication in the absence of any specific sponsor requirements.~~.~~ Researchers are responsible for ensuring that all data is maintained in accordance with the confidentiality and security promised to the study participants. Researchers are responsible for being aware of any specific data retention requirements applicable to their particular research (e.g. funding agencies, Health Canada). In particular, in compliance with measure 9 of the *Plan d'action ministériel* , a Principal Investigator conducting projects involving human ~~subjects~~ participants within institutions that fall under the responsibility of the Ministry of Health and Social Services, such as hospitals or CSSSs, as well as in institutions where there is a Ministry of Health and Social Services designated REB, is required to maintain a list of ~~subjects~~ participants for at least a period of one year after the project ends. The list must include the name of the person, contact information for the subject; the REB project number, and the start and end date of the project. This requirement doesn't extend to projects where ~~subjects~~ participants will be completely anonymous, or where only a records review will be conducted (e.g. examining school records, medical chart reviews).

6.0 COMPLAINTS, CONCERNS AND RECOMMENDATIONS

Research ~~subjects~~participants, researchers, staff members, REB members and any other individuals who have concerns, complaints or recommendations related to ~~human subjects~~ research involving human participants are encouraged to contact any of the offices listed in Appendix ~~V~~II. They will be directed to the appropriate office/individual. All inquiries will be taken seriously and dealt with in a timely manner. Complaints regarding research conducted under the auspices of affiliated hospitals follows the complaint procedures established by those institutions.

~~Subjects~~ Participants who have specific complaints or concerns about any aspect of their participation in a research study should contact the Research Ethics Officer in the Office of the

Vice-Principal (Research and International Relations). The Chair of the Advisory Council on Human Research Ethics will be notified immediately for investigation of the complaint. Once all the information is received, the Chair of the Advisory Council on Human Research Ethics will determine if any further action is necessary. The ~~subject~~ participant and the Principal Investigator will be notified of any decision and the justification for any actions taken. If research misconduct is suspected, as defined under the University's Regulations Concerning Investigation of Research Misconduct, the Chair of the Advisory Council on Human Research Ethics shall immediately initiate the reporting process described in said Regulations. The REB involved must be notified of any investigation in progress to allow the REB to take any safety measures that may be necessary to protect the welfare of the research ~~subjects~~participants. All complaints and actions taken, with confidentiality maintained, shall be reported in the ACHRE annual report. All founded complaints or cases of research misconduct, 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 includes the Dean/Chair of the Faculty, School or Department, the Vice-Principal (Research and International Relations), the REB that approved the research , and where relevant, 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 investigator proposals and nominative information, shall be made available to authorized individuals for the purposes of auditing, monitoring and investigation of complaints or research misconduct.

Complaints regarding a REB should be made 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. All complaints, with confidentiality maintained, must be reported in the ACHRE Annual Report.

Any REB member or other individual involved in the review of ~~human subject~~ 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 ~~subjects~~ 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 ~~adverse~~ unanticipated issues ~~events~~ or protocol changes to the REB, failure to provide ongoing progress reports, or significant deviation from the approved protocol.

Actions taken by a 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 on research projects involving human ~~subjects~~participants, freezing of research funds, or academic penalties in accord with the Code of Student Conduct and Disciplinary Procedures and the Regulations Related to the Employment of Academic Staff. Graduate students who do not have REB approval for projects involving human ~~subjects~~ participants risk non-acceptance of their thesis work.

Any action taken by the REB or the University administration will be reported promptly, in writing, to the investigator.

APPENDIX ~~II~~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 ~~subjects~~ participants in accordance with this policy. A researcher's designated REB is usually determined according to the unit of the researcher's primary academic appointment, although researchers may consult with the REB Chair to determine if another REB may be more appropriate for the review of their research project. Faculties and departments are assigned to specific boards as follows:

Faculty of Agricultural and Environmental Sciences Research Ethics Board– for members in the Faculty of Agricultural and Environmental Sciences for research involving competent adults

Faculty of Medicine Research Ethics Board (also referred to as the Institutional Review Board or the IRB) – for members in the Faculties of Medicine and Dentistry

University Research Ethics Board I – for members in the Faculty of Law, Faculty of Arts except Linguistics and Social Work, Faculty of Engineering, Desautels Faculty of Management, School of Continuing Studies, Faculty of Religious Studies, Faculty of Science except Psychology, and any other unit not specifically assigned to another REB, for the review of research involving competent adults.
~~in Anthropology, CDAS, Economics, Geography, Political Science, Sociology, and in the Faculties of Engineering, Law, Management, Religious Studies and any other unit not specifically assigned to another board~~

University Research Ethics Board II – for members in Linguistics, Psychology, Schulich School of Music, the School of Social Work and the Faculty of Education, for research involving competent adults ~~Linguistics, Psychology, Social Work, the Faculty of Music and the Faculty of Education~~

University Research Ethics Board III - for members in all units except the Faculties of Medicine and Dentistry for the review of research involving minors or adults not competent to consent ~~faculties except the Faculties of Medicine and Dentistry, for the review of all non biomedical research (i.e. research which does not involve medically invasive measures, procedures or interventions) involving minors and cognitively impaired adults,~~

2) Affiliated Hospital Research Ethics Boards – ~~As described in Section 2.3, T~~the University recognizes the Research Ethics Boards of the affiliated hospitals as acting on behalf of the University for conducting ethics reviews for McGill members conducting research in the following affiliated hospitals:

- the McGill University Health Center
- the Douglas Hospital
- the SMBD Jewish General Hospital
- St. Mary's Hospital Center

3) Other - a) The University recognizes the Research Ethics Board of the Centre de recherché interdisciplinaire en réadaptation du Montréal métropolitain(CRIR) as acting on behalf of the University for conducting ethics reviews for McGill members conducting research within an establishment of CRIR.

b) The University is party to the *Entente pour la reconnaissance des certificats d'éthique des projets de recherche à risque minimal* (the 'Entente'). When a research project involves only minimal risk and involves a member(s) from McGill and an investigator(s) from a Quebec university who is also party to the Entente, the ethics review will be undertaken by the REB (REB PI) for the university under whose auspices the Principal Investigator carries out the research. The ethics approval from the REB PI will be recognized by the REB of the co-investigator without further ethics approval needed. The co-investigator's REB retains the option to conduct a full ethics review if it determines that the research involves greater than minimal risk. This does not apply to any research conducted under Article 21 of the Quebec Civil Code. Procedural details should be obtained from the REB.

*****Procedure to be revised by ACHRE in accordance with TCPS requirements, not included in appendices**

~~APPENDIX III~~

~~PROCEDURES FOR APPEALS OF DECISIONS OF RESEARCH ETHICS BOARDS SERVING ALL FACULTIES (EXCEPT THE FACULTY OF MEDICINE)~~

~~The Research Ethics Appeal Committee (hereafter "Appeal Committee") is established in accordance with Article 1.11 of the Tri-Council Policy Statement ***"Ethical Conduct for Research Involving Humans"*** to hear appeals of decisions of Research Ethics Boards (REBs) serving all faculties of McGill University, except the Faculty of Medicine.~~

~~1 Notice of Appeal~~

~~1.1 A Notice of Appeal must be filed with the Chair of the Advisory Council on Human Research Ethics (ACHRE) within 6 months of the rejection of a project by a REB. The notice must clearly state the grounds upon which the appeal is filed.~~

~~1.2 The Chair of the ACHRE shall determine that a definite impasse exists between the researcher and the REB whose decision has been appealed.~~

~~1.3 The Chair of the ACHRE shall then charge the Chair of the Appeal Committee to call the committee to hear the case. The Chair of the ACHRE shall ensure that all parties have copies of the notice of appeal.~~

~~2 Composition of the Appeal Committee~~

~~2.1 The Appeal Committee shall be named annually by the Vice-Principal (Research and International Relations) in consultation with the President of the McGill Association of University Teachers or the designate of the President. Normally, no member should serve more than three consecutive terms.~~

~~2.2 The composition of the Appeal Committee shall be the Chair, who will be a Chair of one of the REBs, two faculty members who have experience serving on an REB, an individual~~

knowledgeable about the relevant ethical issues, a lawyer, and a community member who is currently serving on a McGill REB. When the Principal Investigator making the appeal is a student, then the ACHRE student member will also serve on the Appeal Committee. No member of the Appeal Committee hearing a particular appeal can be a member of the REB whose decision is being appealed, or can have been a member of the REB when the decision being appealed was made. The Vice-Principal (Research and International Relations) will normally name alternate committee members who can substitute for any members who must be recused or cannot otherwise attend.

2.3 The whole committee must be present for a quorum to exist. The Appeal Committee shall appoint *ad hoc* experts as required.

3 The Appeal

3.1 It is not the intention that the appeal process should simply substitute the opinion of one group of reasonable individuals with that of another. The Appeal Committee shall therefore have the jurisdiction to hear appeals based only on failure to follow proper procedures, a conflict of interest or evidence of bias.

3.2 The appeal shall involve two distinct stages; i) to determine whether grounds exist that would require that the protocol be considered anew and ii) a *de novo* consideration of the protocol if grounds for appeal are established.

3.3 In the first stage, the mandate of the Appeal Committee is to determine whether the protocol received fair and reasonable consideration, and not to make a *de novo* decision on the ethical merits of the protocol.

The Appeal Committee shall receive for its consideration the notice of appeal, all the documentation provided to the REB, and the minutes of the REB regarding the project. The investigator shall appear expressly to present evidence to establish the grounds for appeal as outlined in 3.1. The Chair of the REB or representative shall also appear simultaneously. Each of the parties has the right to be assisted by an advisor who shall be a member of the McGill University community and will not receive any remuneration for acting as an advisor.

3.3.1.1 At the hearing, the investigator presents evidence to support grounds (article 3.1) that would invalidate the REB decision. The Chair of the REB responds. The Appeal Committee can question both parties. Each party is given a single opportunity for brief summation, with the investigator speaking last.

3.3.1.2 The Appeal Committee may elect to hear witnesses if, in its opinion, it is relevant to reaching a decision on the grounds of the appeal.

3.3.2 The Chair of the Appeal Committee shall provide a written decision of the Appeal Committee concerning the grounds of the appeal with copies to the investigator, the REB and the Chair of the ACHRE.

3.4 If the Appeal Committee finds that there has been a failure to follow proper procedures, or evidence to support a possible conflict of interest or bias, it proceeds to the second instance.

3.4.1 In a second meeting the committee shall undertake a *de novo* decision on the ethical merits of the protocol in question. All the documents made available to the local REB and the relevant minutes of the REB are to be available to the Appeal Committee. The Appeal Committee must afford the investigator an opportunity to appear to answer questions.

3.5 The Appeal Committee shall meet within 30 days of receipt of the written notification of the appeal, and shall render a written decision on the grounds of appeal within 30 days of that meeting. If grounds are established, a written decision on the ethical merits of the protocol shall be provided within an additional 60 days.

3.6 The decision of the Appeal Committee is final and a written decision is provided to the investigator, the REB and the Chair of the ACHRE.

4 Responsibilities

4.1 The original Research Ethics Board assumes the sole responsibility for administering and monitoring a project approved by the Appeal Committee.

5 Reporting

5.1 The Chair of the Appeal Committee shall make an annual report on the activities of the Appeal Committee to the Vice-Principal (Research and International Relations).

*** - To be revised by RECF in accordance with TCPS and brought to ACHRE, not included in appendices

APPENDIX IV

PROCEDURES FOR APPEALS FROM THE DECISIONS OF RESEARCH ETHICS BOARDS IN THE FACULTY OF MEDICINE, MCGILL UNIVERSITY

March 1, 1999

The Research Ethics Appeal Committee of the Faculty (hereafter "Appeal Committee") is established in accordance with Article 1.11 of the Tri-Council Policy Statement ***"Ethical Conduct For Research Involving Humans"*** to hear appeals of decisions of Research Ethics Boards (hereafter "REBs") of the Faculty and those of Affiliated Hospitals.

1 Notice of appeal

1.1 Notice of Appeal must be filed with the Associate Dean (Research) of the Faculty of Medicine within 6 months of the rejection of a protocol by a Research Ethics Board. The notice must clearly state the grounds upon which the appeal is filed.

1.2 The Associate Dean shall determine that a definite impasse exists between the researcher and the REB whose decision has been appealed.

1.3 The Associate Dean shall then charge the Chair of the Appeal Committee (or the Co-chair as appropriate) to call the Appeal Committee to hear the case. The Associate Dean shall ensure that all parties have copies of the notice of appeal.

2 Composition of the Appeal Committee

2.1 The Appeal Committee shall be named annually by the Dean of Medicine with consideration to recommendations received from the Research Ethics Committee of the Faculty. With the exception of the Chair of the Institutional Review Board, no member can serve more than three consecutive terms.

2.2 The composition of the Appeal Committee shall be as follows: The Chair shall be the current Chair of the Institutional Review Board of the Faculty of Medicine. The Dean of Medicine shall name the following members: three Chairs and alternate of hospital-based Research Ethics Boards, one of whom is designated as co-chair; a lawyer and alternate; an ethicist and alternate; two community members and alternate from different Research Ethics Boards. The Co-chair shall act as Chair if the appeal is from a decision of the Institutional Review Board. No members of the Appeal Committee hearing a particular appeal can be affiliated with that REB.

2.3 A quorum consists of the Chair (or Co-Chair), two hospital-based REB Chairs, a lawyer, an ethicist, and one community member. The appeal committee shall appoint *ad hoc* experts as required and described in the Tri-Council Statement ***"Ethical Conduct for Research Involving Humans"***.

3 The Appeal

3.1 It is not the intention that the appeal process should simply substitute the opinion of one group of reasonable individuals with that of another. The Appeal Committee shall therefore have jurisdiction to hear appeals based only on failure to follow proper procedures, a conflict of interest or evidence of bias.

3.2 The appeal shall involve two distinct stages; i) to determine whether grounds exist that would require that the protocol be considered anew and ii) a *de novo* consideration of the protocol if grounds for appeal are established.

3.3 In the first stage, the mandate of the Appeal Committee is to determine whether the protocol received fair and reasonable consideration, and not to make a *de novo* decision on the ethical merits of the protocol.

3.3.1 The Appeal Committee shall receive for its consideration the notice of appeal, all the documentation provided to the Research Ethics Board, and the minutes of the REB regarding the protocol. The investigator shall appear expressly to present evidence to establish the grounds for appeal as outlined in 3.1. The Chair of the REB or representative shall also appear simultaneously. The parties are not assisted by advisors.

3.3.1.1 At the hearing, the Investigator presents evidence to support grounds (article 3.1) that would invalidate the Research Ethics Board decision. The Chair of the REB responds. The Appeal Committee can question both parties. Each party is given a single opportunity for brief summation, with the Investigator speaking last.

3.3.1.2 The Appeal Committee may elect to hear witnesses if, in its opinion, it is relevant to reaching a decision on the grounds of the appeal.

3.3.2 The Chair of the Appeal Committee shall provide a written decision of the Appeal Committee concerning the grounds of the appeal with copies to the investigator, the REB and the Associate Dean (Research).

3.4 If the Appeal Committee finds that there has been a failure to follow proper procedures, or evidence to support a possible conflict of interest or bias, it proceeds to the second instance.

3.4.1 In a second meeting the committee shall undertake a *de novo* decision on the ethical merits of the protocol in question. All the documents made available to the local REB and the relevant minutes of the REB are to be available to the Appeal Committee. The Appeal Committee must afford the researcher an opportunity to appear to answer questions.

3.5 The Appeal Committee shall meet within 30 days of receipt of the written notification of the appeal, and shall render a written decision on the grounds of appeal within 30 days of that meeting. If grounds are established, a written decision on the ethical merits of the protocol shall be provided within an additional 60 days.

3.6 The decision of the Committee is final and a written decision is provided to the researcher, the REB and the Associate Dean Research of the Faculty of Medicine.

4 Responsibilities

4.1 The Institutional Review Board of the Faculty of Medicine and each Hospital Research Ethics Board, with the approval of the Board of Directors of the Hospital, agree that the decisions of the Appeal Committee are binding.

4.2 The original Research Ethics Board assumes the sole responsibility for administering and monitoring a protocol approved by the Appeal Committee.

5 Reporting

~~5.1 The Dean of Medicine shall make an annual report on the activities of the Appeal Committee to the Vice Principal Research.~~

~~5.2 Hospital-based Research Ethics Review Boards are responsible for reporting to the Board of Directors of their Hospital any Appeal Committee decisions relevant to their own function.~~

Appendix ~~V~~II

Contact Information for Complaints, Concerns and Recommendations Related to ~~Human Subjects Research~~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