MCGILL UNIVERSITY

POLICY ON THE ETHICAL CONDUCT OF RESEARCH INVOLVING HUMAN SUBJECTS

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POLICY ON THE ETHICAL CONDUCT OF RESEARCH INVOLVING HUMAN SUBJECTS

PREAMBLE

A fundamental commitment of the University is to the advancement of learning through scholarly activities, including research involving human subjects. 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 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.

The purpose of this policy is to promote and facilitate the conduct of human subject research 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 Tri-Council Policy Statement *Ethical Conduct For Research Involving Humans*. The guiding ethical principles are respect for human dignity, respect for free and informed consent, respect for vulnerable persons, respect for privacy and confidentiality, respect for justice and inclusiveness, minimizing harm and maximizing benefit. 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 at McGill University. All research involving human subjects must be in compliance with the 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 the use of human subjects conducted at or under the auspices of McGill University 1r8 0 0 70.0389 Tw -20.399 -1.153 Td[1ll Univ)-753P-53 cted 05d 062 b -1.15a007 TJ0.l as all R

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.

research projects as described in Section 3.5, 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 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 research.

2.1 Advisory Council on Human Research Ethics

The Advisory Council on Human Research Ethics (ACHRE) is the University body responsible

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, for faculty, staff and students.

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

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.

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.

- 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

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-

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

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 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 [illegible]

obtained when 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 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. When McGill members are conducting human subject research as part of a collaborative research team where the McGill member is the Principal Investigator, and the project will be conducted by a non-McGill collaborator, McGill REB approval is needed. In the case where the Principal Investigator is from another institution and has already obtained local REB approval, the McGill member must normally obtain McGill REB approval. 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.

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 go1cal research bsma8(viWo1[o r)]TJ0.1209 Tc 0.0d[resen1273 0 T((hougientowned Rnt, bsetu)Tj0.001 Tc 0.

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 as well as applicable federal and provincial requirements.

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 conflict of interest therefore, as appropriate, reference should also be made to existing University guidelines and regulations on conflict of interest.

5.0 RECORD-KEEPING FOR RESEARCHERS

The McGill *Policy on Research Ethics* recommends that all original data be maintained for a period of at least 5 years from the date of publication. 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 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 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 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, researchers, staff members, REB members and any other individuals who have concerns, complaints or recommendations related to human subjects research are encouraged to contact any of the offices listed in Appendix V. They will be directed to the appropriate office/individual. All inquiries will be taken seriously and dealt with in a timely manner.

Subjects 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 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. All complaints and actions taken, with confidentiality maintained, shall be reported in the ACHRE annual report. All founded complaints or cases of

investigator proposals and nominative information, shall be made available to authorized individuals for the purposes of auditing, monitoring and investigation of complaints or research

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APPENDIX I

Articles of the Tri-Council Policy Statement *Ethical Conduct For Research Involving Humans*

Article 1.1

a. All research that involves living human subjects requires review and approval by an REB in accordance with this Policy Statement, before the research is started, except as stipulated below.

b. Research involving human remains, cadavers, tissues, biological fluids, embryos or foetuses should also be reviewed by the REB.

c. Research about a living individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interviews, is not required to undergo ethics review. Such research only requires ethics review if the subject is approached directly for interviews or for access to private papers, and then only to ensure that such approaches are conducted according to professional protocols and to Article 2.3 of this Policy.

d. Quality assurance studies, performance reviews or testing within normal educational requirements should also not be subject to REB review.

Article 1.2

The institution in which research involving human subjects is carried out shall mandate the REB to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human subjects that is conducted within, or by members of, the institution, using the considerations set forth in this Policy as the minimum standard.

Article 1.3

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

a.

research within course requirements). A multiplicity of REBs with small workloads within the same institution should be avoided.

b. Large institutions may find it necessary to create more than one REB, usually to cover different areas of research. The jurisdiction of each REB should be clearly defined by the normal processes of governance within the institution, and a mechanism should be established to coordinate the practices of all REBs within the institution.

c. Small institutions may wish to explore regional cooperation or alliances, including the sharing of REBs.

Article 1.5

a. The REB shall satisfy itself that the design of a research project that poses more than minimal risk is capable of addressing the questions being asked in the research.

b. The extent of the review for scholarly standards that is required for biomedical research that does not involve more than minimal risk will vary according to the research being carried out.

c. 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.

d. Certain types of research, particularly in the social sciences and the humanities, may legitimately have a negative effect on public figures in politics, business, labour, the arts or other walks of life, or on organisations. Such research should not be blocked through the use of harms-benefits analysis or because of the potentially negative nature of the findings. The safeguard for those in the public arena is through public debate and discourse and, *in extremis*, through action in the courts for libel.

Article 1.6

The REB should adopt a proportionate approach based on the general principle that the more invasive the research, the greater should be the care in assessing the research.

Article 1.7

REBs shall meet regularly to discharge their responsibilities.

Article 1.8

proposals, but those researchers may not be present when the REB is making its decision. When an REB is considering a negative decision, it shall provide the researcher with all the reasons for doing so and give the researcher an opportunity to reply before making a final decision.

Article 1.10

Researchers have the right to request, and REBs have an obligation to provide, reconsideration of decisions affecting a research project.

Article 1.11

(a) In cases when researchers and REBs can not reach agreement through discussion and reconsideration, an institution should permit review of an REB decision by an appeal board, provided that the board's membership and procedures meet the requirements of this Policy. No *ad hoc* appeal boards are permitted.

(b) Small institutions may wish to explore regional cooperation or alliances, including the sharing of appeal boards. If two institutions decide to

given and is maintained throughout their participation in the research. Articles 2.1(c), 2.3 and 2.8 provide exceptions to Article 2.1(a).

b. Evidence of free and informed consent by the subject or authorized third party should ordinarily be obtained in writing. Where written consent is culturally unacceptable, or where there are good reasons for not recording consent in writing, the procedures used to seek free and informed consent shall be documented.

c. The REB may approve a consent procedure[1] that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided that the REB finds and documents that:

   i. The research involves no more than minimal risk to the subjects;

   ii. The waiver or alteration is unlikely to adversely affect the rights and welfare of the subjects;

   iii. The research could not practicably be carried out without the waiver or alteration;

   iv. Whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation; and

   v. The waived or altered consent does not involve a therapeutic intervention.

d. In studies including randomization and blinding in clinical trials, neither the research subjects nor those responsible for their care know which treatment the subjects are receiving before the project commences. Such research is not regarded as a waiver or alteration of the requirements for consent if subjects are informed of the probability of being randomly assigned to one arm of the study or another.

Article 2.2

Free and informed consent must be voluntarily given, without manipulation, undue influence or coercion.

Article 2.3

REB review is normally required for research involving naturalistic observation. However, research involving observation of participants in, for example, political rallies, demonstrations or public meetings, should not require REB review since it can be expected that the participants are seeking public visibility.

Article 2.4

Researchers shall provide, to prospective subjects or authorized third parties, full and frank disclosure of all information relevant to free and informed consent. Throughout the process of free and informed consent, the researcher must ensure that prospective subjects are given adequate opportunities to discuss and contemplate their participation. Subject to the exception in Article 2.1(c), at the commencement of the process of free and informed consent, researchers or their qualified designated representatives shall provide prospective subjects with the following:

a. Information that the individual is being invited to participate in a research project;

b. A comprehensible statement of the research purpose, the identity of the researcher, the expected duration and nature of participation, and a description of research procedures;

c. A comprehensible description of reasonably foreseeable harms and benefits that may arise from research participation, as well as the likely consequences of non-action, particularly in research related to treatment, or where invasive methodologies are involved, or where there is a potential for physical or psychological harm;

d. An assurance that prospective subjects are free not to participate, have the right to withdraw at any time without prejudice to pre-existing entitlements, and will be given continuing and meaningful opportunities for deciding whether or not to continue to participate; and

e. The possibility of commercialization of research findings, and the presence of any apparent or actual or potential conflict of interest on the part of researchers, their institutions or sponsors.

In light of (b) and (c), REBs may require researchers to provide below:

participation in the study;

10. The ways in which the research results will be published, and how the subjects will be informed of the results of the research.

Article 2.5

Subject to applicable legal requirements, individuals who are not legally competent shall only be asked to become research subjects when:

a. the research question can only be addressed using the identified group(s); and

b. free and informed consent will be sought from their authorized representative(s); and

c. the research does not expose them to more than minimal risk without the potential for direct benefits for them.

Article 2.6

For research involving incompetent individuals, the REB shall ensure that, as a minimum, the following conditions are met:

a. The researcher shall show how the free and informed consent will be sought from the authorized third party, and how the subjects' best interests will be protected.

b. The authorized third party may not be the researcher or any other member of the research team.

c. The continued free and informed consent of an appropriately authorized third party will be required to continue the participation of a legally incompetent subject in research, so long as the subject remains incompetent.

d. When a subject who was entered into a research project through third-party authorization becomes competent during the project, his or her informed consent shall be sought as a condition of continuing participation.

Article 2.7

Where free and informed consent has been obtained from an authorized third party, and in those circumstances where the legally incompetent individual understands the nature and consequences of the research, the researcher shall seek to ascertain the wishes of the individual concerning participation. The potential subject's dissent will preclude his or her participation.

Article 2.8

Subject to all applicable legislative and regulatory requirements, research involving emergency health situations shall be conducted only if it addresses the emergency needs of individuals involved, and then only in accordance with criteria established in advance of such research by the REB. The REB may allow research that involves health emergencies to be carried out without the free and informed consent of the subject or of his or her authorized third party if ALL of the following apply:

a. A serious threat to the prospective subject requires immediate intervention; and

b. Either no standard efficacious care exists or the research offers a real possibility of direct benefit to the subject in comparison with standard care; and

c. Either the risk of harm is not greater than that involved in standard efficacious care, or it is clearly justified by the direct benefits to the subject; and

d. The prospective subject is unconscious or lacks capacity to understand risks, methods and purposes of the research; and

e. Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and

f. No relevant prior directive by the subject is known to exist.

When a previously incapacitated subject regains capacity, or when an authorized third party is found, free and informed consent shall be sought promptly for continuation in the project and for subsequent examinations or tests related to the study.

Article 3.1

Subject to the exceptions in Article 1.1(c), researchers who intend to interview a human subject to secure identifiable personal information shall secure REB approval for the interview procedure used and shall ensure the free and informed consent of the interviewee as required in Article 2.4. As indicated in Article 1.1c, REB approval is not required for access to publicly available information or materials, including archival documents and records of public interviews or performances.

Article 3.2

Subject to Article 3.1 above, researchers shall secure REB approval for obtaining identifiable personal information about subjects. Approval for such research shall include such considerations as:

a. The type of data to be collected;

b. The purpose for which the data will be used;

c. Limits on the use, disclosure, and retention of the data;

d. Appropriate safeguards for security and confidentiality;

e. Any modes of observation (e.g., photographs or videos) or access to information (e.g., sound recordings) in the research that allow identification of particular subjects;

f. Any anticipated secondary uses of identifiable data from the research;

g. Any anticipated linkage of data gathered in the research with other data about subjects, whether those data are contained in public or personal records; and

h. Provisions for confidentiality of data resulting from the research.

Article 3.3

If identifying information is involved, REB approval shall be sought for secondary uses of data. Researchers may gain access to identifying information if they have demonstrated to the satisfaction of the REB that:

a. Identifying information is essential to the research;

b.

Article 5.2

Article 8.4

c. Embryos exposed to manipulations not directed specifically to their ongoing normal development will not be transferred for continuing pregnancy; and

d. Research involving human embryos takes place only during the first 14 days after their formation by combination of the gametes.

Article 9.5

It is not ethically acceptable to undertake research that involves ectogenesis, cloning human beings by any means including somatic cell nuclear transfer, formation of animal/human hybrids, or the transfer of embryos between humans and other species.

Article 10.1

Research proposing the collection and use of human tissues requires ethics review by an REB. Among other things, the researcher shall demonstrate the following to the REB:

a. That the collection and use of human tissues for research purposes shall be undertaken with the free and informed consent of competent donors;

b. In the case of incompetent donors, free and informed consent shall be by an authorized third party;

c. In the case of deceased donors, free and informed consent shall be expressed in a prior directive or through the exercise of free and informed consent by an authorized third party.

Article 10.2

For the purpose of obtaining free and informed consent, researchers who seek to collect human tissue for research shall, as a minimum, provide potential donors or authorized third parties information about:

a. The purpose of the research;

b. The type and amount of tissue to be taken, as well as the location where the tissue is to be taken;

c. The manner in which tissue will be taken, the safety and invasiveness of acquisition, and the duration and conditions of preservation;

d. The potential uses for the tissue including any commercial uses;

e. The safeguards to protect the individual's privacy and confidentiality;

f. Identifying information attached to specific tissue, and its potential traceability; and

g. How the use of the tissue could affect privacy.

Article 10.3

a. When identification is possible, researchers shall seek to obtain free and informed consent from individuals, or from their authorized third parties, for the use of their previously collected tissue. The provisions of Article 10.2 also apply here.

b. When collected tissue has been provided by persons who are not individually identifiable (anonymous and anonymized tissue), and when there are no potential harms to them, there is no need to seek donors' permission to use their tissue for research purposes, unless applicable law so requires.

APPENDIX II

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 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:

APPENDIX III

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 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.

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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.

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

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

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

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

Research Ethics Officer (Human Subjects) – (514) 398-6831