523rd REPORT OF THE ACADEMIC POLICY COMMITTEE TO SENATE
on the APC meeting held on December 14th, 2023.

I. TO BE APPROVED BY SENATE

(A) NEW TEACHING PROGRAMS REQUIRING SENATE APPROVAL – *none*

(B) ACADEMIC PERFORMANCE ISSUES / POLICIES / GOVERNANCE/AWARDS

Office of the Provost and Executive Vice-President (Academic)
Revisions to the *Regulation on Conflict of Interest* – *appendix A*

At its meeting on November 23rd, 2023, the APC deliberated on the revisions to the Regulation on Conflict of Interest (COI Regulation). Subsequently, on December 6th, 2023, the COI Regulations underwent discussion at the Senate meeting. Following this, the COI Regulations returned to the APC for approval during its December 14th, 2023, meeting. The COI Regulation was called for revisions as it was last approved through governance in September 2011. The purpose of the revised COI Regulations is to streamline and optimize the reporting and reviewing process, along with reducing unnecessary steps in the approval process within central administration. In tandem with these changes, the companion document to the COI Regulation, *Recognizing Conflicts*, underwent a thorough review and revision. The objective was to broaden its scope by incorporating a more extensive array of contemporary examples that incite COI within the University.

Be it resolved that Senate, on the recommendation of the Academic Policy Committee, approve and recommend to the Board of Governors for approval, the Revisions to the Regulation on Conflict of Interest, as presented in Appendix A.

Office of the Vice-President (Research and Innovation)
Policy on the Ethical Conduct of Research Involving Human Participants – *appendix B*

APC reviewed and approved the proposed *Policy on the Ethical Conduct of Research Involving Human Participants*. The primary aim of the Policy is to advance and facilitate research with human participants, aligning with the highest scholarly and ethical standards. Two of the University's Ethics Boards (REBs) are designated by the provincial *Ministère de la Santé et des Services Sociaux* (MSSS) to review research: REB-3 and the Faculty of Medicine and Health Sciences REB. These REBs review research that falls under the auspices of Article 21 of the Quebec Civil Code which requires that research which could interfere with the integrity of a person who is a minor and or an adult unable to consent for themselves be reviewed by an REB that has been designated by the MSSS. Furthermore, several modifications have been introduced to the Policy to enhance its accuracy and to ensure that it aligns with current practices and protocols. These changes include the elimination of outdated processes and the incorporation of an updated appeals process.

Be it resolved that Senate, on the recommendation of the Academic Policy Committee, approve and recommend to the Board of Governors for approval, the revisions to the Policy on the Ethical Conduct of Research Involving Human Participants, as presented in Appendix B.

(C) CREATION OF NEW UNITS / NAME CHANGES / REPORTING CHANGES – *none*

(D) CHANGES IN DEGREE DESIGNATION – *none*

(E) INTER-UNIVERSITY PARTNERSHIPS – *none*

(F) OTHER

II. TO BE ENDORSED BY SENATE / PRESENTED TO SENATE FOR DISCUSSION – *none*

III. APPROVED BY APC IN THE NAME OF SENATE

(A) DEFINITIONS – *none*

(B) STUDENT EXCHANGE PARTNERSHIPS / CONTRACTS / INTERUNIVERSITY PARTNERSHIPS – *none*

(C) OTHER – *none*

IV. FOR THE INFORMATION OF SENATE

I. ACADEMIC REVIEWS – *none*

II. APPROVAL OF COURSES AND TEACHING PROGRAMS – *none*

1. Programs

a) APC Approvals (new options/concentrations and major revisions to existing programs)

i. New Programs - *none*

ii. Major Revisions of Existing Programs - *none*

b) APC Subcommittee on Courses and Teaching Programs (SCTP) Approvals
(Summary Reports: http://www.mcgill.ca/sctp/documents/)

i. Moderate and Minor Program Revisions

Approved by SCTP on November 9th, 2023; reported to APC on December 14th, 2023

School of Continuing Studies
Professional Development Certificate in Collaboration and Productivity (22-25 CEUs)

Faculty of Engineering
B.Eng. in Bioengineering (142-152 cr.)

Graduate and Postdoctoral Studies
Faculty of Medicine and Health Sciences
M.Sc. in Biochemistry; Chemical Biology (45 cr.)
Ph.D. in Biochemistry; Bioinformatics (0 cr.)
Ph.D. in Biochemistry; Chemical Biology (0 cr.)
M.Sc. in Biochemistry; Bioinformatics (45 cr.)
Ph.D. in Physiology; Chemical Biology (0 cr.)
M.Sc. in Physiology; Chemical Biology (45 cr.)

Desautels Faculty of Management
B.Com.; Concentration in Business Analytics (15 cr.)
B.Com.; Major in Information Technology Management (72 cr.)

ii. Program Retirements – *none*

2. Courses

a) **New Courses**

Reported as having been approved by SCTP on May 11th, 2023: 43
Faculty of Arts: 1
School of Continuing Studies:19
Faculty of Medicine and Oral Health Sciences: 1
Faculty of Education: 4
Faculty of Engineering: 2
Faculty of Law: 1
Desautels Faculty of Management: 1
Faculty of Medicine and Health Sciences: 7
Faculty of Science: 7

Reported as having been approved by SCTP on September 14th, 2023: 9
Faculty of Agricultural and Environmental Sciences: 1
School of Continuing Studies:1
Faculty of Engineering: 2
Desautels Faculty of Management: 1
Schulich School of Music: 4

Reported as having been approved by SCTP on October 12th, 2023: 11
Faculty of Agricultural and Environmental Sciences: 1
School of Continuing Studies:3
Desautels Faculty of Management: 1
Faculty of Medicine and Health Sciences: 6

Reported as having been approved by SCTP on November 9th, 2023: 14
Faculty of Arts: 3
School of Continuing Studies: 2
Faculty of Engineering: 2
Desautels Faculty of Management: 4
Faculty of Science: 3

b) **Course Revisions**
Reported as having been approved by SCTP on May 11th, 2023: 77
Faculty of Agricultural and Environmental Sciences: *2*
Faculty of Arts: 6
School of Continuing Studies: 49
Faculty of Education: 6
Faculty of Engineering: 3
Faculty of Law: 1
Faculty of Medicine and Health Sciences: 6
Faculty of Science: 4

Reported as having been approved by SCTP on September 14th, 2023: 6
Faculty of Agricultural and Environmental Sciences: 1
School of Continuing Studies: 2

Faculty of Engineering: 1
Schulich School of Music: 2

Reported as having been approved by SCTP on October 12th, 2023: 15
Faculty of Agricultural and Environmental Sciences: *5*
Faculty of Arts: 2
School of Continuing Studies: 7
Desautels Faculty of Management: 1

Reported as having been approved by SCTP on November 9th, 2023: 26
Faculty of Arts: 1
Faculty of Engineering: 1
Desautels Faculty of Management: 10
Faculty of Medicine and Health Sciences: 2
Schulich School of Music: 4
Faculty of Science: 8

c) **Course Retirements**
Reported as having been approved by SCTP on May 11th, 2023: 44
Faculty of Arts: 2
School of Continuing Studies: 36
Faculty of Education: 2
Faculty of Engineering: 4

Reported as having been approved by SCTP on September 14th, 2023: 2
School of Continuing Studies: 2

Reported as having been approved by SCTP on October 12th, 2023: 9
Faculty of Agricultural and Environmental Sciences: 7
Faculty of Arts: 2

Reported as having been approved by SCTP on November 9th, 2023: 2
Faculty of Medicine and Health Sciences: 2

III. OTHER

Faculty of Medicine and Health Sciences
Proposal to rename the Division of Experimental Medicine to the Division of Clinical and Translational Research – *appendix C*

APC reviewed and approved a proposal from the Faculty of Medicine and Health Sciences to rename the Division of Experimental Medicine to the Division of Clinical and Translational Research. The impetus behind this name change stems from the acknowledgment that the current nomenclature does not encompass the full spectrum of scientific advancements and graduate-level teachings within the faculty. The proposed change in the division name aims to better encapsulate the faculty's modern research initiatives, clinical practices, and the overarching vision for the program.

D23-36 Appendix A

MEMORANDUM

OFFICE OF THE PROVOST AND EXECUTIVE VICE-PRESIDENT (ACADEMIC)
James Administration Building
845 Sherbrooke Suite West, Suite 504
Tel: (514) 398-4177

DATE: 14 December 2023

TO: Academic Policy Committee (APC)

cc: Katharine Tiitson, Secretary of APC

FROM: Professor Angela Campbell, Associate Provost (Equity and Academic Policies)

RE: Regulation on Conflict of Interest

FOR: Approval

Purpose:

We are seeking approval from APC for the following regulation:

- Revisions to the *Regulation on Conflict of Interest* (COI Regulation), that will serve to render the process for COI review more effective and efficient.
- Revisions to the *Recognizing Conflicts* companion document to the COI Regulation to reflect a wider range of COI circumstances that emerge in our university context.

Background:

The COI Regulation was last approved through governance in September 2011. Given the extensive time that has since passed and the need to enhance efficiencies in COI review, a working group composed of stakeholders from VP (Research and Innovation) and Faculties was struck to review the COI Regulation.

Proposed revisions will make the reporting and review processes clearer and more efficient. This will prove beneficial for all staff covered by the COI Regulation, notably all faculty, many of whom annually declare COIs. Revisions will also eliminate unnecessary steps in approval processes within central administration.

The revised COI Regulation moves away from a distinction between "non-financial" (Form A), and "financial" (Form B) COIs to a more logical distinction between "non-research related" (Form A) or "research-related" (Form B) COIs. This is reflected by sections 3.3.3*ff* of the revised COI Regulation.

The process for approvals according to the new distinction is envisaged is as follows:

- For research-related COIs, the staff member submits the COI declaration to their chair/director and then to the VP-RI who decides whether to permit the COI and under which conditions. The Deans and Provost are no longer part of the approval path. This will save a great deal of time, something that is very important for PIs who need COI review/approval before proceeding with various initiatives.
- For non-research related COIs, the usual path of approval will proceed from staff to chair/director, dean, and Provost. These reviews are usually less complex and thus less time- and labour-intensive than research-related declarations.

In addition to these revisions, an important companion document to the COI Regulation, *Recognizing Conflicts*, has been reviewed and revised to reflect a wider range of circumstances that give rise to COI in our university setting.

Prior consultations/approvals:

The COI Regulation was reviewed by a Working Group, from June 2022 to January 2023, whose membership included:

- Prof. Angela Campbell (chair),
- Prof. Josephine Nalbantoglu (GPS),
- Prof. Benoit Boulet (Eng),
- Dr. Lesley Fellows (FMHS),
- Prof. David Stephens (Science),
- Prof. Michael Kokkolaras (Eng),
- Mark Weber (VP-RI),
- Me. Susanne Owen (Legal).

A consensus emerged to maintain the core of the COI Regulation in place, but to streamline the process and procedures.

Consultation on the proposed revisions:

- All Deans (spring 2023), who welcomed the changes.
- MAUT (summer 2023), who also welcomed the changes and only requested minor revisions.
- P7 (Fall 2023), minor revisions requested to Regulation and the document "Recognizing Conflicts" and process improvements outside the scope of the revision of the Regulation itself. Notably we will explore the possibility of having web-based long forms for disclosing COIs as we have for the annual disclosures.
- APC (Nov. 2023) for information and discussion.
- Senate (Dec. 2023) for information and discussion.

Next steps:

Presentation to Senate for approval in January, followed by Board approval.

Attachments:

- Appendix A. Side-by-side Regulation
- Appendix B. Recognizing Conflicts (companion document to the Regulation)

REGULATION NAME	REGULATION ON CONFLICT OF INTEREST
Approving Body	Senate Board of Governors
Initial Approval Date	Senate: May 9, 2009 Board of Governors: June 15, 2009
Date of last review	Senate: September 22, 2011 Board of Governors: September 27, 2011
Date of next review	Fall 2028
Executive Sponsor	Provost and Executive Vice-President (Academic)

Current version	Revised version
Preamble The University must pursue its mission in a manner that advances its goals, protects the integrity of all it does and maintains the confidence of all members of the University community, its affiliated institutions, granting agencies and its public and private sponsors, in an environment in which there is both increased attention to conflict of interest and an increase in apparent conflict situations. Trust is fundamental to the effective operation of the University. An assumption of personal integrity in every member of the University community underlies University policies and procedures, and those of granting agencies and the regulatory bodies who have oversight of many University based activities. The expectation is that all members of the University will conduct themselves with integrity in accordance with the trust and confidence that is reposed in them. Conflicts of interest may take various forms and may arise in various contexts. In essence a potential conflict of interest will exist whenever a member of the University community is in a position to influence the conduct of research, academic, human resource, business, financial, governance or other matters in ways that could lead to personal gain for the member or a related party, or give improper advantage to others, to the detriment of the University or other members of the University community. The purposes of this Regulation are to ensure that: • all affairs of the University are conducted in a manner that is free of actual and apparent conflict of interest and maintains the trust of the community in the University and its affiliated institutions; • at all times all members of the University Community act with integrity and adhere to the highest ethical standards; • the integrity of all members is protected in the performance of their University obligations and functions;	**Preamble** The University must pursue its mission in a manner that advances its goals, protects the integrity of all it does and maintains the confidence of all members of the University community, its affiliated institutions, granting agencies and its public and private sponsors, in an environment in which there is both increased attention to Conflict of Interest and an increase in ~~apparent~~ potential conflict situations. Trust is fundamental to the effective operation of the University. An assumption of personal integrity in every member of the University community underlies University policies and procedures, and those of granting agencies and the regulatory bodies who have oversight of many University-based activities. The expectation is that all members of the University will conduct themselves with integrity in accordance with the trust and confidence that is reposed in them. Conflicts of Interest may take various forms and may arise in various contexts. In essence, a potential Conflict of Interest will exist whenever a member of the University community is in a position to influence the conduct of research, academic, human resource, business, financial, governance or other matters in ways that could lead to personal gain for the member or a related party, or give improper advantage to others, to the detriment of the University or other members of the University community. The purposes of this Regulation are to ensure that: • all affairs of the University are conducted in a manner that ~~is free of actual and apparent conflict of interest and~~ maintains the trust of the community in the University and its affiliated institutions; • at all times all members of the University Community act with integrity and adhere to the highest ethical standards; • the integrity of all members is protected in the performance of their University obligations and functions;

• all members can identify actual or apparent conflicts of interest; and • all actual and apparent conflicts of interest are properly managed in keeping with the law and best practices. The Regulation also recognizes that the existence of a potential conflict situation does not necessarily connote misconduct or preclude the involvement of a member in the situation in which the conflict has arisen – provided the conflict is recognized, disclosed, assessed and addressed. However, it must be recognized that not all conflicts of interest, even if disclosed in a timely manner, will be permitted. This Regulation applies to all members of the University community. It is part of a broader commitment by the institution to cultivate and reinforce a culture that will enable its members to identify and resolve conflicts of interest with the support and guidance of the administration and their units. To this end, opportunities to discuss and mentor members of the community on addressing conflict of interest will be enhanced. **Definitions** 1. For the purposes of this Regulation: 1.1 "Agency" includes a funding agency, granting council, foundation, organization or other entity, public or private, supporting in whole or in part, research and scholarly activities 1.2 "Conflict of Interest" means any situation in which: (i) a Member or a Related Party has a personal interest, whether direct or indirect, of which the Member is, or should be, aware, and that in the opinion of a reasonably informed and well advised Person is sufficient to put into question either the independence, impartiality, and objectiveness that the Member is obliged to exercise in the performance of his or her duties or the ability of the Member to act in the best interests of the University (actual Conflict of Interest); or (ii) a Member or a Related Party appears, in the opinion of a reasonably informed and well advised Person, to have a personal interest, whether direct or indirect, that is sufficient to put into question the independence, impartiality, and objectiveness that the Member is obliged to exercise in the performance of his or her duties or the ability of the Member to act in the best interests of the University (apparent Conflict of Interest);	• all members can identify actual or potential conflicts of interest; and • all actual and ~~apparent~~ potential conflicts of interest are properly managed in keeping with the law and best practices. The ~~Regulation also recognizes that the~~ existence of a potential or actual conflict situation does not necessarily connote misconduct or preclude the involvement of a member in the situation in which ~~the~~ a conflict has or might have arisen – provided the conflict is recognized, disclosed, assessed and addressed. However, it must be recognized that not all conflicts of interest~~, even if disclosed in a timely manner,~~ will be ~~permitted~~permissible even if disclosed in a timely matter. This Regulation applies to all members of the University community. It is part of a broader commitment by the ~~institution~~ University to cultivate and reinforce a culture that will enable its members to identify and resolve conflicts of interest with the support and guidance of the administration and their units. To this end, opportunities to discuss and ~~mentor~~ guide members of the community on addressing conflict of interest will be enhanced. **Section 1. Definitions** For the purposes of this Regulation: 1.1 "**Agency**" includes a funding agency, granting council, foundation, organization or other entity, public or private, supporting in whole or in part, research and scholarly activities. 1.2 "**Conflict of Interest (COI)**" means any situation in which: (i) a Member or a Related Party has a personal interest, whether direct or indirect, of which the Member is, or should be, aware, and that in the opinion of a reasonably informed and ~~well advised~~impartial Person is sufficient to put into question either the independence, impartiality, and objectiveness that the Member is obliged to exercise in the performance of ~~his or her~~their duties or the ability of the Member to act in the best interests of the University (actual Conflict of Interest); or (ii) a Member or a Related Party appears, in the opinion of a reasonably informed and ~~well advised~~impartial Person, to have a personal interest, whether direct or indirect, that is sufficient to put into question the independence, impartiality, and objectiveness that the Member is obliged to exercise in the performance of ~~his or her~~their duties or the ability of the Member to act in the best interests of the University (~~apparent~~ potential Conflict of Interest).~~;~~ 1.3 "**Days"** mean working days, which excludes weekends, statutory holidays, and other days during which the University is closed.

1.3 "Financial Interest" means any interest, or the opportunity to acquire any interest, in any business or Person or anything else of value including remuneration (such as salary, consulting fees, retainers, honoraria, bonuses, gifts, speaker's fees, advisory board remuneration, finders or recruitment fees), equity interests (such as stocks, stock options or other ownership interests), and intellectual property rights (such as patents, copyrights, royalties or other payments from such rights);	1.4 **Financial Interest**" means any interest, or the opportunity to acquire any interest, in any business or Person or anything else of value including remuneration (such as salary, consulting fees, retainers, honoraria, bonuses, gifts, speaker's fees, advisory board remuneration, finders or recruitment fees), equity interests (such as stocks, stock options or other ownership interests), and intellectual property rights (such as patents, copyrights, royalties or other payments from such rights).~~;~~
1.4 "Legal Person" includes corporations, partnerships, associations, foundations, organizations, government agencies, and any other entity or body.	1.5 "**Legal Person**" includes corporations, partnerships, associations, foundations, organizations, government agencies, and any other entity or body.
1.5 "Member," subject to section 8, means any member of the McGill University community: (i) who is an employee of the University; (ii) who holds office under the University Charter or Statutes or who serves on any body or committee of the University; (iii) who holds office on the board of an institution affiliated with McGill University or who serves on a committee established by such board; or (iv) who is an appointee (including a volunteer) of the University.	1.6 "**Member**," subject to section 8, means any member of the McGill University community: i. who is an employee of the University; ii. who holds office under the University Charter of Statutes or who serves on any body or committee of the University; iii. who holds office on the board of an institution affiliated with McGill University or who serves on a committee established by such board; or iv. who is an appointee (including a volunteer) of the University.
1.6 "New Member" means an individual who becomes a Member after the coming into effect of this Regulation;	1.7 "**New member**" means an individual who becomes a Member after ~~the coming into effect of this Regulation~~this Regulation is adopted.~~;~~
1.7 "Person" includes, where the context requires, both natural and Legal Persons.	1.8 "**Person**" includes, where the context requires, both natural and Legal Persons.
1.8 "Related Party" includes: (i) a Member's immediate family; (ii) a Person living in the Member's household; (iii) a Person with whom a Member has, or had, a close or intimate personal relationship; (iv) a Person with whom the Member shares, directly or indirectly, a financial or other interest; or (v) a Person to whom the Member owes a financial or moral obligation.	1.9 "**Related party**" includes: i. a Member's immediate family; ii. a Person living in the Member's household; iii. a Person with whom a Member has, or had, a close or intimate personal relationship; or iv. a Person with whom the Member shares or owes, directly or indirectly, a financial or other interest.~~; or~~ ~~a Person to whom the Member owes a financial or moral obligation~~.
1.9 "Reporting Officer" means: (i) for the Principal, the Chair of the Board of Governors; (ii) for the Provost, Deputy-Provost or a vice-principal, the Principal; (iii) for an assistant or associate provost, the Provost; (iv) for an assistant or associate vice-principal, that vice-principal to whom the Member reports; (v) for the Director or Dean of Libraries, the Provost; (vi) for a dean, the Provost; (vii) for the Secretary-General, the Principal;	1.10 "**Reporting Officer**" means: i. for the President, the Chair of the Board of Governors; ii. for the Provost and Executive Vice-President (Academic), Deputy-Provost or a vice-president, the President; iii. for an assistant or associate provost, the Provost and Executive Vice-President (Academic); iv. for an assistant or associate vice-president, that vice-president to whom the Member reports; v. for the Director or Dean of Libraries, the Provost and Executive Vice-President (Academic); vi. for a dean, the Provost and Executive Vice-President (Academic); vii. for the Secretary-General, the President;

(viii) for an assistant or associate dean, the dean; (ix) for the chair of a department or director of a centre, institute or school, the dean; (x) for the director of an administrative unit, the Provost, Deputy-Provost or vice-principal responsible for that unit; (xi) for a Member of the academic staff of a faculty having departments, centres, institutes or schools, the chair of the department or the director of the centre, institute or school to which the member has been appointed in his or her official letter of appointment; (xii) for a Member of the academic staff of a faculty without departments, centres, institutes or schools, the dean of the faculty to which the member has been appointed in his or her official letter of appointment; (xiii) for a Member of the librarian staff, the Director or Dean of Libraries; (xiv) for a postdoctoral fellow, the supervisor of the postdoctoral fellow; (xv) for a graduate student, the student's supervisor; (xvi) for any other Member, the holder of the office to whom the Member reports or who has supervisory responsibility over the Member; (xvii) for a Member of a committee other than a committee of the Board of Governors, the chair of the committee; (xviii) for the chair of a committee other than a committee of the Board of Governors, the individual or the chair of the body to which the committee reports; (xix) in the event that a Reporting Officer is also implicated in the Conflict of Interest situation, the first Reporting Officer's Superior not so implicated.	viii. for an assistant, ~~or~~ associate ~~dean~~, or vice-dean, the dean; ix. for the chair of a department or director of a centre, institute or school, the dean; x. for the director of an administrative unit, the Provost and Executive Vice-President (Academic), Deputy-Provost or vice-president responsible for that unit; xi. for a Member of the academic staff of a F~~f~~aculty having departments, centres, institutes or schools, the chair of the department or the director of the centre, institute or school to which the member has been appointed in ~~his or her~~their official letter of appointment; xii. for a Member of the academic staff of a faculty without departments, centres, institutes or schools, the dean of the faculty to which the member has been appointed in ~~his or her~~their official letter of appointment; xiii. for a Member of the librarian staff, the Director or Dean of Libraries; xiv. for a postdoctoral fellow, the supervisor of the postdoctoral fellow; xv. for a graduate student, the student's supervisor; xvi. for any other Member, the holder of the office to whom the Member reports or who has supervisory responsibility over the Member; xvii. for a Member of a committee other than a committee of the Board of Governors, the chair of the committee; xviii. for the chair of a committee other than a committee of the Board of Governors, the individual or the chair of the body to which the committee reports; xix. in the event that a Reporting Officer is also implicated in the Conflict of Interest situation, the first Reporting Officer's Superior not so implicated.
1.10 "Reporting Officer's Superior" means the individual to whom the Reporting Officer would personally report a Conflict of Interest.	1.11 "**Reporting Officer's Superior**" means the individual to whom the Reporting Officer would personally report a Conflict of Interest.
2. General Duties of Members	**2 Section 2. General Duties of Members**
2.1 A Member shall:	2.1 A Member shall:
(i) act responsibly, ethically and fairly with care, diligence, and loyalty and be accountable for his or her actions and decisions in the workplace; (ii) arrange their affairs in a manner that will bear public scrutiny; (iii) disclose Conflicts of Interest as soon as he or she is aware of them and address or manage them in the best interests of the University community; (iv) not act, after ceasing to be a Member, in such a manner as to take improper advantage of his or her prior association with the University.	i. act responsibly, ethically and fairly with care, diligence, and loyalty and be accountable for ~~his or her~~their actions and decisions in ~~the workplace~~performing their duties at or on behalf of the University; ii. arrange their affairs in a manner that will bear public scrutiny; iii. disclose Conflicts of Interest as soon as ~~he or she is~~they are aware of them and address or manage them in the best interests of the University community; iv. submit an updated Conflict of Interest declaration annually for all ongoing COIs;

3. Addressing Conflict of Interest

3.1 A Member, immediately upon becoming aware of a Conflict of Interest, shall make written disclosure of the facts material to the Conflict of Interest on a form approved by the Provost to:
(i) his or her Reporting Officer in accordance with these provisions; and
(ii) in the case of a Conflict of Interest situation arising in the context of research involving human subjects, to the Research Ethics Board in accordance with the University policies governing the ethical conduct of human subject research as exist from time to time.

3.1.1 The facts material to the Conflict of Interest may include as appropriate to the situation:
(i) the Persons or group of Persons likely to benefit from the Conflict of Interest;
(ii) any Persons or group of Persons whose interests may be adversely affected by the Conflict of Interest;
(iii) the nature and value of any advantage or benefit, monetary or other, direct or indirect, that may be derived by the Member or a Related Party from the Conflict of Interest situation;
(iv) any existing Financial Interest the Member or a Related Party may have in any Person involved in the Conflict of Interest situation;
(v) the relationship the Member or a Related Party has with the Person which is the source of the Conflict of Interest situation including whether the Member or Related Party is an officer or director of, or consultant to, or serves on an advisory or other board external to the University or its affiliated institutions;
(vi) the benefit, if any, that will be derived by the University from the situation; and
(vii) other relevant information that may be requested by the Reporting Officer or, where appropriate, a Research Ethics Board.

v. not act, after ceasing to be a Member, in such a manner as to take improper advantage of ~~his or her~~their prior association with the University.

2.2 In addition to the requirements of Section 2.1, the following Members shall submit an annual declaration related to Conflict of Interest on a form approved by the Provost and Executive Vice-President (Academic) by March 31st:
i. academic staff governed by the *Regulations Relating to the Employment of Tenure Track and Tenured Academic Staff*;
ii. academic staff governed by the *Regulations Relating to the Employment of Librarian Staff*; and
iii. salaried academic staff who are governed by the *Regulations Relating to the Employment of Contract Academic Staff*.

3 Section 3. Addressing Conflict of Interest

3.1 A Member, immediately upon becoming aware of a Conflict of Interest, shall make written disclosure of the facts material to the Conflict of Interest on a form approved by the Provost and Executive Vice-President (Academic) to:
i. ~~his or her~~their Reporting Officer in accordance with these provisions; and
ii. in the case of a Conflict of Interest ~~situation~~ arising in the context of research involving human subjects, to the Research Ethics Board in accordance with the University policies governing the ethical conduct of human subject research as exist from time to time.

3.1.1 The facts material to the Conflict of Interest may include as appropriate to the situation:
i. the Persons or group of Persons likely to benefit from the Conflict of Interest;
ii. any Persons or group of Persons whose interests may be adversely affected by the Conflict of Interest;
iii. the nature and value of any advantage or benefit, monetary or other, direct or indirect, that may be derived by the Member or a Related Party from the Conflict of Interest ~~situation~~;
iv. any existing Financial Interest the Member or a Related Party may have in any Person involved in the Conflict of Interest ~~situation~~;
v. the relationship the Member or a Related Party has with the Person which is the source of the Conflict of Interest ~~situation~~ including whether the Member or Related Party is an officer or director of, or consultant to, or serves on an advisory or other board external to the University or its affiliated institutions;
vi. the benefit, if any, that will be derived by the University from the situation; and
vii. other relevant information that may be requested by the Reporting Officer, any authority charged with reviewing a Conflict of Interest pursuant to Section 3.3.3 or, where appropriate, a Research Ethics Board.

3.1.2 In addition to the requirements of sections 3.1 and 3.1.1, a disclosure of a Conflict of Interest by a Member pertaining to matters in his or her capacity as a Member of a University committee or board shall be recorded in the minutes of the body in question and the Member shall withdraw from the committee's or board's deliberations and abstain from voting on any resolutions pertaining to the matter in which the Member has a Conflict of Interest. A Member may also be required to resign his or her membership on the committee or board.	3.1.2 In addition to the requirements of sections 3.1 and 3.1.1, a Member who has a Conflict of Interest that arises in the context of membership in a University committee or other decision-making body shall disclose the Conflict of Interest to the Chair of the committee or other decision-making body concerned. The disclosure shall be recorded in the minutes of the decision-making body or committee. The Chair of the committee or other decision-making body shall determine whether the conflict can be managed through a conflict mitigation plan or whether the Member must withdraw from all or some of the activities of the decision-making body or committee concerned, including abstaining from deliberating and voting on the matter that has given rise to the Conflict of Interest. ~~a disclosure of a Conflict of Interest by a Member pertaining to matters in his or her capacity as a Member of a University committee or board shall be recorded in the minutes of the body in question and the Member shall withdraw from the committee's or board's deliberations and abstain from voting on any resolutions pertaining to the matter in which the Member has a Conflict of Interest. A Member may also be required to resign his or her membership on the committee or board~~. 3.1.2.1 Where, in a situation like that described in section 3.1.2, the Member in question is the Chair of the decision-making body or committee concerned, the Member's Reporting Officer shall determine the appropriate course to follow, consulting with appropriate University officers (e.g., Secretary-General, General Counsel) as appropriate.
3.2 If a Member is uncertain as to whether he or she is, or will be, in a Conflict of Interest with regard to some matter, such Member shall consult his or her Reporting Officer or, where appropriate, a Research Ethics Board, to clarify the issue.	3.2 If a Member is uncertain as to whether ~~he or she is~~they are, or will be, in a Conflict of Interest ~~with regard to some matter~~, such Member shall consult ~~his or her~~their Reporting Officer or, where appropriate, a Research Ethics Board, to clarify the issue.
3.3 Subject to section 3.5, the Reporting Officer, after reviewing the Member's disclosure, may determine: (i) there is no Conflict of Interest; (ii) there is a Conflict of Interest but it is permissible if appropriately addressed; or (iii) there is a Conflict of Interest and it is not permissible.	3.3 Subject to section 3.5, the Reporting Officer, after reviewing the Member's disclosure, may ~~determine~~decide: i. there is no Conflict of Interest; ii. there is a Conflict of Interest but it is permissible if appropriately addressed; or iii. there is a Conflict of Interest and it is not permissible.
3.3.1 When making a determination under section 3.3(ii) and (iii) the Reporting Officer shall meet with the Member and be guided by whether, if the Conflict of Interest is permitted: (i) the interests of the University can be adequately protected; (ii) the interests of other Persons affected by the Conflict of Interest can be adequately protected; (iii) the Conflict of Interest can be effectively addressed; (iv) the proposed Conflict of Interest may compromise the Member's judgment in fulfilling his or her obligations and duties to the University; (v) a reasonably informed and well advised Person would view the Conflict of Interest as appropriate.	3.3.1 When making a ~~determination~~ decision under section 3.3~~(ii) and (iii)~~ the Reporting Officer shall meet with the Member and be guided by whether, if the Conflict of Interest is permitted: i. the interests of the University can be adequately protected; ii. the interests of other Persons affected by the Conflict of Interest can be adequately protected; iii. the Conflict of Interest can be effectively addressed; iv. the proposed Conflict of Interest may compromise the Member's judgment in fulfilling ~~his or her~~their obligations and duties to the University; v. a reasonably informed and ~~well advised~~impartial Person would view the Conflict of Interest as ~~appropriate~~permissible.

3.3.2 The decision of the Reporting Officer shall be in writing and include: (i) his or her determination as to the existence of a Conflict of Interest together with supporting reasons; (ii) whether the Member is permitted to engage in the Conflict of Interest; (iii) the period for which permission is effective; (iv) the conditions, if any, under which permission is granted, which conditions shall as a minimum require: (a) disclosure of the Conflict of Interest to any and all other Persons who would be affected by it; and (b) that the Member promptly report any change in circumstances that may change the nature or scope of the Conflict of Interest or affect its management; and (v) where appropriate, the mechanism to be used to monitor the Conflict of Interest.	3.3.2 A Reporting Officer must make a decision under section 3.3 within 15 Days of receipt of the Member's disclosure. The decision will be recorded in writing and include: ~~The decision of the Reporting Officer shall be in writing and include~~: i. ~~his or her~~their determination as to the existence of a Conflict of Interest together with supporting reasons; ii. whether the Member is permitted to engage in the Conflict of Interest; iii. the period for which permission is effective; iv. the conditions, if any, under which permission is granted, which conditions shall as a minimum require: a) disclosure of the Conflict of Interest to any and all other Persons who would be affected by it; and b) that the Member promptly report any change in circumstances that may change the nature or scope of the Conflict of Interest or affect its management; and v. where appropriate, the ~~mechanism~~ measures to be ~~used~~ taken to monitor and/or manage the Conflict of Interest.
3.3.3 The Reporting Officer shall forward a copy of his or her determination to the Member, the Reporting Officer's Superior and, in research related matters, to the Office of the Vice-Principal (Research and International Relations) within ten (10) working days of receipt of the Member's disclosure or within ten (10) working days of receipt of the additional information requested pursuant to section 3.1.1(vii).	3.3.3 Upon making their decision, Reporting Officer shall forward a copy of their decision to the Member and: i. for research-related matters (including but not limited to situations involving research grants, spinoffs, partnered research or research contracts) to the Office of the Vice-President (Research and Innovation) who will have 15 Days to review the matter and record a decision before subsequently submitting the decision to the Member with a copy to their Reporting Officer's Superior and the Office of the Provost & Executive Vice-President (Academic) so that this can be re-tained in the Member's file with the Academic Per-sonnel Office; ii. for non-research related matters, to the Reporting Officer's Superior who will have 15 Days to review the matter and record a determination before subsequently referring the matter to the Provost & Executive Vice-President (Academic), who will have a further 10 Days to review and make a determination on the matter. The Provost & Executive Vice-President (Academic) shall then submit the decision to the Member, retaining with a copy for the Member's file within the Academic Personnel Office. ~~The Reporting Officer shall forward a cop y of his or her determination to the Member, the Reporting Officer's Superior and, in research related matters, to the Office of the Vice-Principal (Research and International Relations) within ten (10) working days of receipt of the Member's disclosure or within ten (10) working days of receipt of the additional information requested pursuant to section 3.1.1(vii)~~.

	3.3.3.1 Any University authority responsible for reviewing a Conflict of Interest disclosure may request additional information from the Member who made the disclosure. The time delays set out in section 3.3.3 are paused when such a request is made and resume when the additional information that can be provided has been delivered.
3.4.1 If a Member is of the opinion that permission to engage in the Conflict of Interest has been unreasonably withheld by the Reporting Officer he or she may, within fifteen (15) working days of receipt of the Reporting Officer's determination, request a review of the Reporting Officer's determination by the Reporting Officer's Superior.	3.4 If a Member is of the opinion that permission to engage in the Conflict of Interest has been unreasonably withheld by a University authority responsible, pursuant to this Regulation, for reviewing a Conflict of Interest disclosure, the Member may, within 15 Days of receipt of the decision, request a review of the matter by the Reporting Officer of the authority whose decision the Member contests. ~~If a Member is of the opinion that permission to engage in the Conflict of Interest has been unreasonably withheld by the Reporting Officer he or she may, within fifteen (15) working days of receipt of the Reporting Officer's determination, request a review of the Reporting Officer's determination by the Reporting Officer's Superior.~~
3.4.2 If the Reporting Officer's Superior is of the opinion that permission has unreasonably been granted or withheld, after consulting with the Member and the Reporting Officer, he or she may revoke or vary the Reporting Officer's determination in writing with accompanying reasons.	3.4.1 Upon receiving a review of a request to review a decision pursuant to section 3.4, the Reporting Officer of the authority who made the decision the Member contests will carry out a review by considering information deemed relevant and must consult with the staff member and with authority who made the decision concerned before making a determination. ~~If the Reporting Officer's Superior is of the opinion that permission has unreasonably been granted or withheld, after consulting with the Member and the Reporting Officer, he or she may revoke or vary the Reporting Officer's determination in writing with accompanying reasons.~~
3.4.3 The Reporting Officer's Superior shall forward a copy of his or her determination to the Member, the Reporting Officer and, in research related matters, to the Office of the Vice-Principal (Research and International Relations) within fifteen (15) working days of receipt of the Reporting Officer's determination or a Member's request for a review of that determination, as appropriate.	3.4.2 Further to the review described at section 3.4.1, the Reporting Officer of the authority who made the decision the staff member contests will make a determination that may uphold, reverse or modify the contested decision. This shall be communicated in writing, with accompanying reasons, to the staff member, the Reporting Officer, the Provost and Executive Vice-President (Academic), and, in the case of a research-related Conflict of Interest, to the Vice-President (Research &. Innovation). ~~The Reporting Officer's Superior shall forward a copy of his or her determination to the Member, the Reporting Officer and, in research related matters, to the Office of the Vice-Principal(Research and International Relations) within fifteen (15) working days of receipt of the Reporting Officer's determination or a Member's request for a review of that determination, as appropriate~~
3.5 Notwithstanding sections 3.3 through 3.4.3, where a Research Ethics Board has been charged with a Conflict of Interest situation the matter shall be dealt with in accordance with the provisions of University policies governing the ethical conduct of human subject research as exist from time to time.	3.5 Notwithstanding sections 3.3 through 3.4.~~3~~2, where a Research Ethics Board has been charged with a Conflict of Interest situation the matter shall be dealt with in accordance with the provisions of University policies governing the ethical conduct of human subject research as exist from time to time.

In addition to any filing requirements contained in University policies governing the ethical conduct of human subject research, a copy of the decision of the Research Ethics Board and, where appropriate, of the decision of the Research Ethics Appeals Committee shall be filed with the relevant chair and dean and the Office of the Vice-Principal (Research and International Relations).	In addition to any filing requirements contained in University policies governing the ethical conduct of human subject research, a copy of the decision of the Research Ethics Board and, where appropriate, of the decision of the Research Ethics Ap-peals Committee shall be filed with the relevant chair and dean and the Office of the Vice-President (Research and ~~International Relations~~ Innovation).
4. Confidentiality of Information	**Section 4. Confidentiality of Information**
4.1 Except as required by law, any confidential information disclosed by a Member pursuant to this Regulation shall be available only to those Persons who have a legitimate need to know, and to any Agency where disclosure is required to ensure compliance with the rules of that Agency.	4.1 Except as required by law, any confidential information disclosed by a Member pursuant to this Regulation shall be available only to those Persons who have a legitimate need to know, and to any Agency where disclosure is required to ensure compliance with the rules of that Agency.
5. Responsibility of Reporting Officers	**Section 5. Responsibility of Reporting Officers**
5.1 It is the responsibility of a Reporting Officer: (i) to ensure that those who report to them are aware of the provisions of this Regulation; (ii) to implement this Regulation by promptly initiating remedial or disciplinary action as appropriate on becoming aware of an undisclosed Conflict of Interest affecting a Member.	5.1 It is the responsibility of a Reporting Officer: i. to ensure that those who report to them are aware of the provisions of this Regulation; ii. to implement this Regulation by promptly initiating remedial or disciplinary action as appropriate on becoming aware of an undisclosed Conflict of Interest affecting a Member.
6. Responsibility of New Members	**Section 6. Responsibility of New Members**
6.1 A New Member shall disclose all Conflicts of Interest to his or her Reporting Officer as required by this Regulation within sixty (60) days following his or her becoming a Member.	6.1 A New Member shall disclose all Conflicts of Interest to ~~his or her~~their Reporting Officer as required by this Regulation within ~~sixty (60) days~~thirty (30) Days following ~~his or her~~their becoming a Member.
7. Cessation of Membership	**Section 7. Cessation of Membership**
7.1 A Member, upon ceasing to be a Member: (i) shall respect the confidentiality of all information received in the performance of his or her duties, as well as the confidentiality of the deliberations of any University board or committee or body on which the Member has served in any capacity; (ii) shall not make use of any University information that is not generally available to the public, in order to derive there from a benefit or advantage for the Member, a Related Party or his or her employer.	7.1 A Member, upon ceasing to be a Member: i. shall respect the confidentiality of all information received in the performance of ~~his or her~~their duties, as well as the confidentiality of the deliberations of any University board or committee or body on which the Member has served in any capacity; ii. shall not make use of any University information that is not generally available to the public, in order to derive there from a benefit or advantage for the Member, a Related Party or ~~his or her~~their employer.
8. Board of Governors	**Section 8. Board of Governors**
8.1 This Regulation does not apply to Members serving on the Board of Governors or its committees of the Board of Governors in so far as they are engaged in the official business of the Board of Governors. Such Members shall comply with the	8.1 This Regulation does not apply to Members serving on the Board of Governors or its committees of the Board of Governors in so far as they are engaged in the official business of the Board of Governors. Such Members shall comply with the

Code of Ethics and Conduct for Members of the Board of Governors of McGill University and Trustees of the Royal Institution for the Advancement of Learning.	*Code of Ethics and Conduct for Members of the Board of Governors of McGill University and Trustees of the Royal Institution for the Advancement of Learning*.
9. Failure to Comply with Regulation	**Section 9. Failure to Comply with Regulation**
9.1 The failure of a Member who knows, or who should reasonably know, that he or she is in a Conflict of Interest, to comply with the provisions of this Regulation may constitute a disciplinary offence under the regulations, policies, code or collective agreement to which the Member is subject.	9.1 The failure of a Member who knows, or who should reasonably know, that ~~he or she is~~they are in a Conflict of Interest, to comply with the provisions of this Regulation may constitute a disciplinary offence under the regulations, policies, code or collective agreement to which the Member is subject.
10. Review of Regulation	**Section 10. Review of Regulation**
10.1 The operation of this Regulation shall be reviewed at the end of its third year of operation by a working group comprised of: (i) one representative designated from within each of the following sectors: academic staff, support staff, administrative staff, trades and services staff, teaching assistants, undergraduate students, and graduate students and post-doctoral fellows; and (ii) one representative from each of: the Office of the Provost; the Office of the Vice-Principal (Research and International Relations); and the Office of the Vice-Principal (Administration and Finance).	10.1 The operation of this Regulation shall be reviewed at the end of its ~~third~~ fifth year of operation following its last amendment by a working group comprised of: i. one representative designated from within each of the following sectors: academic staff, ~~support staff, administrative staff, trades and services staff, teaching assistants, undergraduate students, and~~ graduate students and post-doctoral fellows appointed in consultation with employee associations (notably the McGill Association of University Teachers), employee unions, and student associations; and ii. one representative from each of: the Office of the Provost and Executive Vice-President (Academic); the Office of the Vice-President (Research and ~~International Relations~~ Innovation); and the Office of the Vice-President (Administration and Finance).

RECOGNIZING CONFLICT OF INTEREST

This document provides a series of brief scenarios that illustrate situations in which an ~~apparent or actual~~actual or potential conflict of interest may reasonably be seen to be present, and which require, at the very least, prompt disclosure to, and discussion with, the individual's reporting officer (as established in the *Regulation on Conflict of Interest*). Note that certain conflicts of interests can constitute other forms of misconduct (e.g., fraud); and it may not be sufficient to disclose the conflict in such cases. Engaging in these forms of misconduct could lead to discipline up to and including termination. The scenarios are drawn from situations that have occurred at McGill, from examples provided on the websites of other institutions of higher education, and from the literature on conflict of interest.

Please note that the list of scenarios does not purport to be exhaustive – from time-to-time other scenarios may be added to this document. The University conflict of interest regulations that these examples illustrate are ~~specifically~~ drafted in broad terms as it is never possible to enumerate all possible conflicts. Moreover, while the scenarios have been grouped for simplicity, some scenarios could be assigned to more than one category of conflict – however, they are not repeated under each heading which may be applicable.

Please also keep in mind when reviewing these illustrations that the mere existence of an ~~apparent or real~~actual or potential conflict situation does not necessarily connote misconduct. Conflicts of interest exist independently of the affected party's motives and intentions. Most conflicts of interest can be ~~approved~~ permitted when paired with a good mitigation plan. Therefore, appropriate consideration should be given to the following points:

- was there proper disclosure to the appropriate persons;
- was ~~consent~~ permission given by the proper authority;
- is the conflict being properly managed; and
- is the conflict one which should as a matter of principle never be permitted?

It is only when all relevant information has been gathered that a decision can be made as to the acceptability of the situation and the appropriate measures to mitigate the risks. It is important to keep in mind that conflicts of interest ~~have to~~must be disclosed~~,~~ and, where relevant, mitigation measures put in place, in order to protect the interests of all parties involved~~: the investigator(s), the participants, the students, McGill University, and the scientific validity of the research~~.

In reviewing the scenarios, please keep in mind that the *Regulation on Conflict of Interest* applies to Members of the University community defined by s. 1.6 of the *Regulation*; and as defined by s. 1.9, the term "Related party" includes:

i. a Member's immediate family;
ii. a Person living in the Member's household;
iii. a Person with whom a Member has, or had, a close or intimate personal relationship; or
iv. a Person with whom the Member shares or owes, directly or indirectly, a financial or other interest.

EXAMPLES OF CONFLICTS OF INTEREST

A. IN RELATION TO STUDENTS

A.1 A Member is involved in a teaching, supervisory or evaluative role with respect to a related party. For example, where:

- a teaching assistant forms a ~~close personal relationship~~friendship with a student in the group assigned to them;
- a faculty member or member of teaching staff begins an intimate relationship with a student and the situation is not covered by the Code of Conduct set by s. 8 of *Policy against Sexual Violence*;
- an instructor becomes their nephew's Ph.D. thesis supervisor or a member of their supervisory committee;
- a Ph.D supervisor launches a start-up with the student they supervise.

A.2 A member participates in an admission or any other University decision concerning a related party. For example, where:

- an administrator serving on a scholarships and awards committee participates in a discussion or decision concerning their daughter's application for a scholarship;
- an instructor, who also has external business interests, participates in the admission decision of their business partner's child.

A.3 A member takes part in any proceedings at any level that affect the academic standing of a related party. For example, where:

- an instructor re-reads an examination paper of their partner's child; or
- an academic administrator writes a letter of reference for their sister's child.

A.4 An instructor assigns course materials to students in circumstances in which he/she or a related party will benefit from the assignment. For example, where

- an instructor assigns students in their course a textbook he/she has written and for which he/she will receive royalties; or
- an instructor assigns students course materials prepared by a related party and for which the latter will receive royalties.

A.5 ~~A member receivesseeks remuneration from a student for~~

- ~~writing a letter of recommendation for the student;~~
- ~~reviewing the student's term paper; or~~
- ~~fast-tracking the review of the student's thesis manuscript.~~

A.6 A member enters into any contractual relationship (other than in a position explicitly sanctioned by the University such as research assistant or teaching assistant) with a student with whom the member has a teaching, supervisory or evaluative relationship. For example, where

- a researcher employs their Ph.D. student in their or a related party's private off-campus laboratory; or
- an instructor rents their house/apartment to a Ph.D. student who he/she is supervising.

A.7 A member and their spouse serve as the co-supervisors for a student's thesis.

A.8 A thesis supervisor delays the completion/publication of a student's thesis to allow the supervisor or a related party to be the first to publish the data/findings developed primarily by the student.

A.9 An instructor imposes as a mandatory course requirement that students registered in the course participate as research subjects in the instructor's research.

A.10 A thesis supervisor appears to gives priority to their or a related party's research or other activities to the detriment of their students' theses.

A.11 A graduate supervisor involves their students and/or trainees in their consulting activities.

B. IN RELATION TO RESEARCH

B.1 A researcher uses their, or a related party's, outside business interests to provide services to be charged to the researcher's research grants.

B.2 A researcher has an arrangement with a third party who has an interest in the outcome of the research wherein advantages (including the payment of money, royalties, or grants, or the transfer of shares or options in the sponsor) are promised, formally or informally, to the researcher or a related party.

B.3 A researcher diverts any research resources available to them through the University (e.g., space, equipment, materials) for their personal use, including in the context of consulting activities, or that of a related party.

B.4 A researcher enters into any commitments relating to proprietary research (i.e., which generates intellectual property) that are likely to interfere or overlapbe confused with the researcher's duties to the University.

B.5 A researcher receives, directly or indirectly, any payment, gift or other advantage or benefit from a third party in respect of the member's research activities.

B.6 A member uses for their personal benefit, or that of a related party, research conducted at the University.

B.7 A researcher recruits any member of the University community over whom the researcher or a related party has authority, to be a participant in medical testing or in clinical trials involving human subjects.

B.8 A member influences any research activities at the University so as to advance their personal interests or those of a related party.

B.9 A researcher enters into a private licensing agreement with a related party for the development of intellectual property generated as a result of University research without following McGill's Policy on Inventions and Software.

B.10 A researcher engages in research activities at McGill or an affiliated institution related to an invention for which they received a transfer of rights from McGill without a properly approved research agreement in place.

B.11 A researcher, for their benefit or that of a related party, unreasonably delays publication of, or prematurely announces, research results.

B.12 A researcher accepts research funding on terms that could be seen to compromise their ability to conduct the research freely or to publish promptly the results, whether positive or negative.

B.13 A member has a research relationship through McGill with an entity as well as another relationship with the same entity, such as:

- private consulting
- equity or financial interest
- intellectual property interest
- potential to receive revenue from the entity, including through a license signed by McGill

~~A researcher engages in private consulting activities as a private consultant or via a company they control (as defined in the Regulations on Consulting and Similar Activities by Academic Staff) for a third party with whom the University has a research contract or grant in which the researcher is a PI or co-PI.and under which the member is a part of the research team.~~

B.14 A researcher accepts to peer review a research proposal or funding application of

- another with whom the member or a related party is in direct competition; or
- a related party.

B.15 A researcher fails to disclose in a research publication that the research contained therein was funded by parties who have an interest in its outcome and where such relationship may raise questions about the researcher's objectivity or impartiality.

B.16 A researcher, or a related party, has a financial interest in the outcome of a clinical trial in which the researcher is participating.

B.17 A researcher does consulting work with an outside entity that might be perceived as compromising their objectivity on their research or other academic duties at the University.

B.18 A researcher carries out research with or within an entity (public, private, or non-governmental) whose interests conflict with McGill's best interests or academic mission.

C. IN RELATION TO HUMAN RESOURCES

C.1 A member employs a related party in a position funded, directly or indirectly, by the University or the member's research grant or contract.

C.2 A member is responsible for, or participates in, the appointment, employment, evaluation, advancement, or supervision of a related party.

C.3 A member is on the search committee for a position at McGill for which a former student or the student of a close collaborator is applying.

C.3 4 A member makes or contributes to a decision on the appointment, advancement or evaluation of the performance and other activities of another who is directly competing with a member or a related party. For example, where:

- a dean appoints a related party as chair of a department;
- a principal investigator employs a related party as a research associate; or
- an instructor employs a related party as their teaching assistant.

C.4 5 A member occupies a position in which a related party directly or indirectly reports to him/her.

C.5 6 A member, already on staff at the University, actively lobbies for and promotes the "spousal employment" of their spouse.

D. IN RELATION TO THE INSTITUTION

D.1 A member serves on a board of directors, advisory board~~, or the like,~~ of an outside organization which does, or is proposing to do, business with the University.

D.2 A member participates as a member of a board or committee of the University (or of an institution affiliated with the University) on a matter in which the member or a related party has an individual interest in the outcome of the deliberations of that board or committee.

D.3 A member accepts employment with, or undertakes any activities on or off campus for, a third party at times during which the member would normally be expected to be engaged in their duties to the University.

D.4 A member engages in a course of studies, or any other program or activity, that calls for attendance at or participation in lectures or other events at times during which the member would normally be expected to be engaged in their duties to the University.

D.5 A member uses University facilities, equipment, personnel or services for non-university activities or for the personal benefit of the member or a related party.

D.6 A member uses attributions or references to the name of the University, or of any member of the University, or of any affiliated institutions, associations or organizations (including the insignia of the University or of any unit or affiliated institution, association or organization), to promote the non-university activities of the member or a related party.

D.7 A member uses their official University position for publicity, endorsement or advertising purposes for a related party.

D.8 A member promotes or advertises their or a related party's products or services to the University or at a University event.

D.9 A member uses information that is not available to the general public and acquired as a result of their University position, for purposes unrelated to that position.

D.10 A member privately commercializes intellectual property they developed in the performance of their University duties without following McGill's Policy on Inventions and Software.

D.11 A member receives, directly or indirectly, any payment, gift or other advantage or benefit (except of a nominal value or as part of social entertainment considered in keeping with good professional ethics and which do not obligate the member) from a third party for the performance by the member of their University functions or duties.

D.12 ~~A member enters into any commitment with a third party that is likely to interfere or be confused with their duties to the University.~~

D.13 ~~A member competes with the University in any activity or matter.~~

D.14 A member associates in any manner with a third party (including through its name, publicity or operations) which falsely implies that the third party is associated with or benefits from a relationship with the University.

E. IN RELATION TO FINANCIAL MATTERS

E.1 A member participates in the purchase or sale by the University of any goods ~~or services~~ that they or a related party owns, or any services that they or a related party provides. ~~from or to him/herthem or a related party.~~

E.2 A member influences the decisions of a third party engaged in business with the University for the benefit of any party besides the University.

E.4 A member makes personal purchases, or purchases for a related party, through:

- the University purchasing department; or
- their Procurement card.

E.5 A member diverts any University resources or funds for personal use or the use of a related party.

E.6 A member approves the expense claims or expenditures of a related party.

E.7 A member accepts to teach or perform other duties for remuneration at another institution while on sabbatical or other paid leave from the University.

E.8 ~~A member accepts payment from any third party for the performance activities that fall within their duties at the University.~~

E.9 A member sells property acquired, in whole or in part, through research funds, to the University for personal profit.

E.10 A member donates property acquired, in whole or in part through research funds (or the proceeds received on the sale of such property), to the University for a charitable tax receipt.

E.11 A member solicits or accepts gifts that might be reasonably perceived to influence their duties at the University.

McGill

Memorandum
Note de service

Office of the Vice-Principal (Research and Innovation)

Date: December 14, 2023

To/Destinataire(s): Christopher Manfredi, Provost and Executive Vice-President (Academic), Chair of APC

From/De la part de: Martha Crago, Vice-President (Research and Innovation)

c.c. Katharine Tiitson, Academic Program Officer

Subject/Object: Policy on the Ethical Conduct of Research Involving Human Participants

For: Decision

Purpose:
Revisions to the *Policy on the Ethical Conduct of Research Involving Human Participants* is presented to APC for approval.

Background:
The Policy is undergoing revisions to remove outdated processes, move existing procedural content to a new Procedures document and incorporate an updated appeals process compliant with the Tri-Council Policy Statement (TCPS) within the new Procedures.

To provide some additional context, two of the University's Research Ethics Boards (REBs) are designated by the provincial Ministère de la Santé et des Services sociaux (MSSS) to review research that falls under the auspices of Article 21 of the Quebec Civil Code: REB-3 and the Faculty of Medicine and Health Sciences REB. Article 21 requires that research which could interfere with the integrity of a person who is a minor and or an adult unable to consent for themselves be reviewed by an REB that has been designated by the MSSS.

In 2021, the MSSS informed the University that the highest governing body of the University, the Board of Governors, must be responsible for appointing members to the University's REB-3 and the REB of the Faculty of Medicine and Health Sciences, and that the Policy had to be revised to reflect this appointment process. The required revisions were integrated and approved by the University's governance bodies to ensure compliance by the March 31, 2022, deadline.

In 2022, a deeper review and refresh of the Policy was initiated as the last in-depth review was in December 2012. A summary of the current changes proposed is below:

- Creation of a new Procedures document with existing content and text from the Policy, including text related to meetings, minutes, annual reports and other technical matters from previous Section 2 and all text from previous Sections 3 to 7.
- Including a clarified, updated appeals process within the new Procedures (Section 3.5). There were previously two different appeals processes that have now been merged and are now compliant with the TCPS.
- Reorganizing certain sections within the revised Policy.
- Including a new Section 6 with a review clause for the Policy.

Prior consultations/approvals

The changes were initiated by a working group composed of the Associate Director (Research Ethics) in the Office of the Vice-President (Research and Innovation), the Ethics Officer in the Faculty of Medicine and Health Sciences, and the Chair of the Advisory Council on Human Research Ethics (ACHRE) with guidance and input from Legal Services.

- Working Group; Spring 2022 to November 25, 2022
- Legal Services; Spring 2022 to November 25, 2022
- VP (RI) Leadership; December 2022
- Quebec Ministry; December 2022 – January 2023
- ACHRE Chairs; February 2023
- Secretary-General; February 2023
- PGSS, AMURE, AMPL; March 1 – March 31, 2023
- MAUT; March 1 – September 20, 2023
- Research Advisory Council; October 20, 2023
- Faculty Deans; November 6 – November 17, 2023
- P7; December 5, 2023

Next steps:

- Senate: January 17th, 2024
- Board of Governors: February 8th, 2024

Attachments

00. Memo
01. Side by Side *Policy on Ethical Conduct of Research Involving Human Participants*
02. New *Procedures for the Implementation of the Policy on Ethical Conduct of Research Involving Human Participants*

POLICY NAME	**POLICY ON THE ETHICAL CONDUCT OF RESEARCH INVOLVING HUMAN PARTICIPANTS**
Approving Body	To be filled by Secretary-General
Initial Approval Date	To be filled by Secretary-General
Date of last review	To be filled by Secretary-General
Date of next review	To be filled by Secretary-General
Executive Sponsor	Vice-President~~Principal~~ (Research and Innovation)

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

Current	**Proposed Revisions**
PREAMBLE A fundamental commitment of the University is to the advancement of learning through scholarly activities, including research involving human participants. The University recognizes that such activities flourish only in a climate of academic freedom, and therefore is committed to safeguarding, among others, the freedoms of inquiry and dissemination of research results. When these activities involve human participants these freedoms must be integrated with the responsibility to conduct the research in a manner that respects the dignity, rights and welfare, and above all protects from possible harm, the persons who are the research participants. The purpose of this policy is to promote and facilitate the conduct of research involving human participants in a manner consistent with the highest scholarly and ethical standards. To this end, McGill University is committed to adhering to the principles and articles stipulated in the most recent version of the Tri-Council Policy Statement Ethical	~~PREAMBLE~~**PURPOSE** A fundamental commitment of the University is to the advancement of learning through scholarly activities, including research involving human participants. The University recognizes that such activities flourish only in a climate of academic freedom, and therefore is committed to safeguarding, among others, the freedoms of inquiry and dissemination of research results. When these activities involve human participants these freedoms must be integrated with the responsibility to conduct the research in a manner that respects the dignity, rights and welfare, and above all protects from possible harm, the persons who are the research participants. The purpose of ~~this policy~~the Policy on the Ethical Conduct of Research Involving Human Participants ("Policy") is to promote and facilitate the conduct of research involving human participants in a manner consistent with the highest scholarly and ethical standards. To this end, ~~McGill~~ the

Conduct For Research Involving Humans (TCPS). The three core principles are respect for persons, concern for welfare, and justice. 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 research involving human participants at McGill University. All such research must be in compliance with the TCPS; 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 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 health and social services institution or an REB recognized by a formal agreement with the University, before the research may begin.	University is committed to adhering to the principles and articles stipulated in the most recent version of the Tri-Council Policy Statement: Ethical Conduct For Research Involving Humans (TCPS). The three core principles are respect for persons, concern for welfare, and justice. ~~Researchers are responsible for knowing about and adhering to the standards articulated therein.~~ This Ppolicy describes the administrative structures and responsibilities ~~and procedures~~ for the ethical review of research involving human participants at ~~McGill~~ the University. All such research must be in compliance with the TCPS; this Ppolicy; ~~the policies,~~ procedures and guidelines established by the McGill Advisory Council on Human Research Ethics and the individual Research Ethics Boards (REBs) as well as all relevant provincial, federal and ~~provincial~~ international ~~l~~ regulations and laws. ~~, such as the Quebec Civil Code and the Canada Food and Drug Act.~~ **SCOPE** This Ppolicy applies to all research involving human participants conducted at or under the auspices of ~~McGill~~the University and ~~.~~will be supported by Procedures for the Implementation of the Policy on the Ethical Conduct of Research Involving Human Participants ("Procedures"). ~~All research projects~~Research ~~-~~involving ~~research~~ human participants ~~conducted at or under the auspices of McGill University~~ requires ethics review and approval by a McGill ~~Research Ethics Board (~~REB~~)~~ before the research may begin. Research falling under Article 21 of the Quebec Civil Code must be reviewed by a REB that is designated by the Ministère de la Santé et des Services sociaux ~~Minister of Health and Social Services~~(MSSS). ~~.~~ In some instances of multi-jurisdictional research, a review done by an external REB may be accepted by the McGill REB , in accordance with the requirements of the TCPS and the Procedures.

	1. RESEARCH REQUIRING ETHICS REVIEW 1.1 The requirement for REB review applies to those activities described in the TCPS that meet the TCPS definition of 'research', defined as an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation, and 'human participants', defined as those individuals whose data, biological materials, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question(s). As per the TCPS, the following requires ethics review and approval by a REB before the research commences. Research involving: a. living human participants; b. human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials, and stem cells. This applies to materials derived from living and deceased individuals. Research involving human participants does not require REB review when: 1.It relies exclusively on information that is: a. made publicly available through a mechanism set out by legislation or regulation and that is protected by law; or b. is in the public domain and the individuals to whom the information refers have no reasonable expectation of privacy. 2. It involves the observation of people in public places where: a.) it does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups; b) .individuals or groups targeted for observation have no reasonable expectation of privacy; and c). any dissemination of research results does not allow identification of specific individuals.

	3. It relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information. Anonymous means the data or materials has never had personal identifiers associated with it. Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this Policy, and do not fall within the scope of REB review. If data are collected for the purposes of such activities are later proposed for research purposes, it would be considered secondary use of information not originally intended for research, and would require REB review in accordance with this Policy. 1.2 *REB review is also required for all* ~~R~~research conducted at or under the auspices of the University *which* includes: a. All research projects involving human participants conducted by or under the supervision of any member of the University, whether the research is funded or non-funded, or conducted on University premises or elsewhere. For the purpose of this document, a "member of the University" ~~is defined as including~~means: academic and non-academic staff;~~,~~ sessional instructors;~~,~~ students;~~,~~ visiting or adjunct scholars;~~,~~ postdoctoral ~~;s~~fellows, paid and unpaid research associates and assistants;~~,~~ and any person in a like position; all ~~,~~ when acting in connection with their institutional role(s).. This applies to arriving ~~new~~ faculty in respect of ongoing research even though their current research may have received ethics approval at a previous institution;~~,~~

	b. All student research projects conducted as part of thesis or course requirements;~~.~~ c. Pilot studies and feasibility studies;~~.~~ ~~a.~~ All research involving human participants (including recruitment and/or data collection) conducted by organizations or individuals who are not members of the University while on University premises or using University facilities, equipment, or resources (including human resources);~~.~~ ~~b.~~d. ~~; and~~ ~~c.~~e. Those aspects of c~~C~~ollaborative research involving researchers, data or participants from other institutions in which a McGill member is active, whether as ~~where the McGill member may, or may not be~~ the Principal Investigator or otherwise; and ~~d.~~f. 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 those members use ~~either~~ McGill facilities, equipment, or supplies, or rely on support from ~~support~~McGill staff ~~are used~~ ~~and~~ or ~~;~~ when the research data collected will be disseminated in association with the University and when~~;~~ ~~or~~ the researcher purports to represent the University in any way. ~~involving human participants~~
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 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.	**~~1.0~~2. RESPONSIBILITIES** ~~Authority for ethics review according to this policy is established by the Board of Governors of the University. ,, and ensuring that REBs are able to operate effectively and independently in their decision making.~~ The ethical conduct of research involving human participants is a responsibility that is shared by the various constituents of the University.

1.1 Responsibilities of the Administration

The Office of the Vice-~~Principal~~ President (Research and Innovation) bears the responsibility for the implementation of the University's policies on research involving human 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~~ President (Research and Innovation) is responsible for entering into any agreements with other institutions, such as the McGill affiliated health and social services institutions, 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 research 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 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.

Notwithstanding this shared responsibility, there are specific responsibilities. ~~that can be summarized as follows.~~

2.1 Responsibilities of the Board of Governors

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

2~~1~~.~~1~~ 2 Responsibilities of the Administration

a. The ~~Office of the~~ Vice-~~Principal~~ President (Research and Innovation) bears the responsibility for the implementation of this Policy~~the University's Ppolicyies on the Ethical Conduct of Research Involving Human Particiapnts~~~~research involving human participants~~. ~~It~~ They 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 Innovation) is responsible for entering into any agreements with other institutions, such as the McGill affiliated health and social services institutions, to conduct the ethics review and approval of the research of McGill members.~~

b. Academic administrators such as Deans, Directors and Department Chairs, have a responsibility for the conduct of research carried out within their jurisdictions. They have a responsibility to be aware of ongoing research and a duty to create a climate for ethical practice in research by

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 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 3.4, 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 3.4, it is the joint responsibility of the faculty supervisor and the student to ensure that the

promoting widespread general awareness and knowledge of this policy and the need for ethics review.

2~~1~~.~~2~~ 3 Responsibilities of Researchers

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

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

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

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 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 3.4, it is the joint responsibility of the faculty supervisor and the student to ensure that the project receives the appropriate ethics approval.

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

d.

e. Researchers are required to adhere with all conditions of approval of the ~~Research Ethics Board~~REB.

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

~~1~~2.~~3~~ 4 Responsibilities of Faculty Members as Supervisors of Student Researchers

a. All student research must be supervised by a faculty member who accepts responsibility for reasonable oversight of the ~~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~~ take reasonable measures to ensure that their students have the training and competence needed to carry out their responsibilities in an ethical manner. They must take reasonable efforts to ensure that the students are aware of and familiar with the contents of this Policy and of other applicable ethical guidelines that are

relevant to their responsibilities. Once a student's research project is approved, the supervisor must take further reasonable measures to ensure that the research is conducted in accordance with the provisions of this Policy and other applicable ethical requirements.

b. In the case of all undergraduate research, the supervisor has full responsibility to ensure that a student's project receives the appropriate ethics approval. In the case of course research projects, ~~as described in Section 3.4,~~ the supervisor/instructor has full responsibility to ensure that a student's project receives the appropriate ethics approval.

~~a.~~c. In the case of graduate or postdoctoral research, ~~except for course research projects as described in Section 3.4,~~ 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.~~

2~~1~~.4 ~~-~~5 Responsibilities of Student Researchers

a. Student research projects involving human participants must receive the appropriate ethics review and approval before the research may begin. Although a student's research must be supervised by a faculty member, this does not in any way relieve the obligation of the student to be familiar with and comply with the contents of this policy that are relevant to the student's responsibilities. ~~As stated in Section 1.3,~~

~~a.~~b. ~~I~~in the case of graduate or postdoctoral research, except for course research projects ~~as described in Section 3.4~~, it is the joint responsibility of the faculty supervisor and the student to ensure that

	the project receives the appropriate ethics approval.
2.0 STRUCTURE The overall responsibility for overseeing the ethical conduct of research involving human participants is entrusted to the Office of the Vice-~~Principal~~ President (Research and Innovation). The following bodies have been established for developing and implementing University policies and procedures related to human participant research. **2.1 Advisory Council on Human Research Ethics** The Advisory Council on Human Research Ethics (ACHRE) is the University body responsible for coordinating University-wide understanding of, and compliance with, the applicable requirements for the ethical conduct of research involving human participants. The ACHRE reports directly to the Board of Governors and to the Office of the Vice-~~Principal~~ President (Research and Innovation) and must submit an annual report of its activities. **Membership** The ACHRE shall, at a minimum, consist of: - the Chair, appointed by the Board of Governors, in consultation with the Vice-~~Principal~~ President (Research and Innovation) and with the other members of the ACHRE, who shall be a faculty member who is knowledgeable in research ethics - the Associate Vice-~~Principal~~ President (Research and Innovation) - the Chairs of the University REBs - the Associate Director, Research Ethics (OVPRI), who will serve as Secretary - the Ethics Officer, Faculty of Medicine and Health Sciences - one person representing community interests and concerns, who has no formal affiliation with the institution, appointed by the Board of Governors, in consultation with the Vice-~~Principal~~ President (Research and Innovation) and with the other members of the ACHRE - one graduate student or postdoctoral fellow, to be named by the PGSS	**~~2.0~~3. STRUCTURE** The overall responsibility for overseeing the ethical conduct of research involving human participants is entrusted to ~~the Office of~~ the Vice-~~Principal~~ President (Research and Innovation). The following bodies have been established for developing and implementing University policies and procedures related to human participant research. **~~3~~2.1 Advisory Council on Human Research Ethics** a. The Advisory Council on Human Research Ethics (ACHRE) is the University body responsible for coordinating University-wide understanding of, and compliance with, the applicable requirements for the ethical conduct of research involving human participants. b. The ACHRE reports directly to the Board of Governors and to the ~~Office of the~~ Vice-~~Principal~~ President (Research and Innovation) and must submit an annual report of its activities. c. The ACHRE ~~shall be~~is responsible for: - Advising and making recommendations to the Vice-President (Research and Innovation) on policies and procedures to be established or modified, in order to ensure that all research involving human participants conducted at or under the auspices of the University is carried out in a manner consistent with the highest ethical standards. The ACHRE will actively monitor the consistency of these policies and procedures with other McGill policies, the TCPS, provincial, federal and international regulations, and all other applicable guidelines.

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~~ President (Research and Innovation) on policies and procedures to be established or modified, in order to ensure that all research involving human participants conducted at or under the auspices of 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~~ President (Research and Innovation) 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~~ President (Research and Innovation) and the REBs to develop and implement educational resources and programs on the ethics of research involving human participants, for faculty, staff and students.

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

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

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

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

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

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

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

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~~Membership~~

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

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~~The ACHRE shall, at a minimum, consist of:~~

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

Receiving the annual reports of the REBs and submitting them to the Board of Governors and the Office of the Vice-~~Principal~~ President (Research and Innovation).

Meetings

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

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

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

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

2.2 Research Ethics Boards

The mandate of an REB is to determine the ethical acceptability of research involving human participants, with the primary objective of protecting the rights and welfare of the participants. Each REB reports directly to the Board of Governors, 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 I). Researchers may consult with the REB Chair to determine if another REB may be more appropriate for the review of

~~- the Chair, appointed by the Board of Governors, in consultation with the Vice-Principal (Research and Innovation) and with the other members of the ACHRE, who shall be a faculty member who is knowledgeable in research ethics~~
~~- the Associate Vice-Principal (Research and Innovation)~~
~~- the Chairs of the University REBs~~
~~- the Associate Director, Research Ethics (OVPRI), who will serve as Secretary~~
~~- the Ethics Officer, Faculty of Medicine and Health Sciences~~
~~- one person representing community interests and concerns, who has no formal affiliation with the institution, appointed by the Board of Governors, in consultation with the Vice-Principal (Research and Innovation) and 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 Innovation) on policies and procedures to be established or modified, in order to ensure that all research involving human participants conducted at or under the auspices of 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 Innovation) on the number, jurisdiction and responsibilities of the REBs at McGill University.~~

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 who 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 Board of Governors is responsible for the appointment, reappointment and removal of REB members. The term of appointment for members will normally be 3 years, renewable, with staggered appointments. The Chair will be appointed by the Board of Governors in consultation with the Vice-~~Principal~~ President (Research and Innovation) and in consultation with the Deans of the relevant Faculties.

The other members will be appointed by the Board of Governors in consultation with the REB Chair. The other members of an REB may be nominated by the relevant Faculties/Schools/Departments according to their regular nominating procedures, in consultation with the Chair of the REB and presented to the Board of Governors for

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

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

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

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

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

~~Receiving the annual reports of the REBs and submitting them to the Board of Governors and the Office of the Vice-Principal (Research and Innovation).~~

~~Providing an annual report of its activities to the Board of Governors and the Vice-Principal (Research and Innovation).~~

~~**Meetings**~~

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

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

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

appointment. 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 projects have an opportunity to be represented. The REB Chair may deem that other regular members may be necessary to carry out the mandate of the REB. Such members will be presented to the Board of Governors for appointment.

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

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

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

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

Responsibilities

Each REB:

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

~~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~~3.2 Research Ethics Boards

a. ~~The mandate of an REB is to determine the ethical acceptability of research involving human participants, with the primary objective of protecting the rights and welfare of the participants. Each~~ The REB remains accountable to the highest body of the institution that established it for the integrity of its processes. The University REB~~s~~ report~~s~~ directly to the Board of Governors, ~~and~~ must submit an annual report of ~~its~~ their activities.

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

c. Each REB:

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

- Is responsible for reviewing research projects involving human participants in a manner consistent with this policy. The REB conducts reviews in an independent manner, and the REB decisions are not subject to review by

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 ongoing research that is not being conducted in accordance with the REB's requirements or other ethical requirements. Has the authority to suspend or terminate approval of any ongoing research that has been associated with unexpected serious harm to participants or that it deems to pose an unacceptable risk of harm to participants. In this regard, the REB Chair is authorized to act on behalf of REB members in exigent circumstances. Actions taken by the REB Chair in relation to exceptional circumstances should be brought to the full REB for ratification as soon as is practicable and in all cases, no later than 30 days after the action was taken. Is responsible for promptly reporting the suspension or termination of approval of a research project to the Principal Investigator, the Vice-~~Principal~~ President (Research and Innovation) and other institutional officials as deemed appropriate by the REB, providing a statement of the reasons for the action taken. Is responsible for establishing and overseeing mechanisms for delegated review of course research projects (as described in Section 3.4) in units within its jurisdiction. Is responsible for serving as the initial appeals committee for any appeal taken by an individual against a decision of a delegated review of course research projects. Acts as a resource to the University community on matters pertaining to the ethical conduct of research involving human participants and can provide consultation to researchers at all stages of the application and review processes.	any other body or person except as allowed by the TCPS. - Has the authority to approve, require modification of, or disapprove research projects. - Has the authority to suspend or terminate approval of any ongoing research that has been associated with unexpected serious harm to participants or that it deems to pose an unacceptable risk of harm to participants. In this regard, the REB Chair is authorized to act on behalf of REB members in exigent circumstances. - Is responsible for promptly reporting the suspension or termination of approval of a research project to the Principal Investigator, and the Vice-President (Research and Innovation) and other institutional officials as deemed appropriate by the REB, providing a statement of the reasons for the action taken. - Has the authority to transfer the responsibility for ethics review to another McGill REB that is determined to have the relevant competencies to evaluate the submitted research, in consultation with the other REB. - Is responsible for establishing and overseeing mechanisms for delegated review of course research projects in units within its jurisdiction. - Is responsible for informing the ACHRE of issues arising that may affect the review process of the REBs, or any other issues of concern that may affect University policy relating to research involving human participants.

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 participants.

Meetings

The REB shall meet at least annually, and as needed to review research proposals that are not assigned for delegated review.

As a minimum, a quorum of an REB must have five members, of which two members have broad expertise in the methods or areas of research under review, one member who is knowledgeable about the relevant ethical issues, one member with no formal affiliation with the institution and, for biomedical research and all research under the auspices of Article 21 of the Quebec Civil Code, one member who is knowledgeable in the relevant law. However, the Chair has the final authority to decide if the quorum present is adequate to properly conduct reviews.

Researchers must be informed of submission deadline requirements.

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.

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

~~Researchers usually submit their projects to their designated REB (see Appendix 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.~~

~~**b. Membership**~~

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

d.

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

~~d. 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.~~

~~e.~~

~~f. An REB, shall, at a minimum, consist of five members, including both men and women, and have:~~

~~g. - at least one member who is knowledgeable about the relevant ethical issues~~

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 Confidentiality

The desirability of openness with respect to the business of the various committee meetings must be limited by considerations of privacy of human participants or of third parties, the confidentiality of proprietary data, the need to encourage free discussion at these meetings, and the desire to promote cooperation in carrying out the purposes of these committees.

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.

~~h. - 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~~

~~i. - 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~~

~~j. - at least one member who represents community interests and concerns, and has no formal affiliation with the Institution~~

~~k.~~

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

~~m.~~

~~n.~~ The other members will be appointed by the Board of Governors in consultation with the REB Chair. ~~. The other members of an REB may be nominated by the relevant Faculties/Schools/Departments according to their regular nominating procedures, in consultation with the Chair of the REB and presented to the Board of Governors for appointment. 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 projects have an opportunity to be represented. The REB~~

Research Proposal – Each committee shall consider a research proposal and all accompanying information to be confidential documents.	~~Chair may deem that other regular members may be necessary to carry out the mandate of the REB. Such members will be presented to the Board of Governors for appointment.~~ f. g. REB Office Personnel may be appointed by the REB ~~-~~as non-voting members to serve in accordance with the requirements of the TCPS. REB Office Personnel serving as REB members shall have the knowledge, experience and training comparable to what is expected of all REB members. The REB shall ensure that REB Office Personnel can fulfill their responsibilities as REB members independently. ~~Alternate members may be appointed for each of the regular members so as not to prohibit the functioning of the REB in case of illness or other unforeseen circumstances.~~ ~~When membership of an REB extends beyond 5 members, the community representation should increase proportionately.~~ ~~The REB Chair may appoint ad hoc members or seek outside advice when reviewing a project that requires specific expertise regarding methodology, community or research participant representation, or other matters.~~ ~~No member of an REB may participate in the review of any project in which the member has a conflicting interest, such as their own or their student's project. Members must disclose to the REB possible conflicts of interest arising out of personal relationships, financial interests, multiple roles, or other factors. When the REB determines that a conflict exists, the member may be requested to provide information to the REB but may not be present during the consideration of the project.~~ ~~**Responsibilities**~~**Mandate and Authority**

	~~Each The REB:~~ ~~Is mandated to determine the ethical acceptability of research involving human participants, with the primary objective of protecting the rights and welfare of the participants. The ethics review process is conducted in accordance with the standards and procedures of the TCPS as well as applicable provincial, federal, and international requirements.~~ ~~Is responsible for reviewing research projects involving human participants in a manner consistent with this policy. The REB conducts reviews in an independent manner, and the REB decisions are not subject to review by any other body or person except as allowed by the TCPS~~ ~~Has the authority to approve, require modification of, or disapprove research projects 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 ongoing research that is not being conducted in accordance with the REB's requirements or other ethical requirements.~~ ~~Has the authority to suspend or terminate approval of any ongoing research that has been associated with unexpected serious harm to participants or that it deems to pose an unacceptable risk of harm to participants. In this regard, the REB Chair is authorized to act on behalf of REB members in exigent circumstances. Actions taken by the REB Chair in relation to exceptional circumstances should be brought to the full REB for ratification as soon as is practicable and in all cases, no later than 30 days after the action was taken.~~ ~~Is responsible for promptly reporting the suspension or termination of approval of a research project to the Principal Investigator, the~~

	~~Vice-Principal (Research and Innovation) and other institutional officials as deemed appropriate by the REB, providing a statement of the reasons for the action taken.~~ ~~Is responsible for establishing and overseeing mechanisms for delegated review of course research projects (as described in Section 3.4) in units within its jurisdiction.~~ ~~Is responsible for serving as the initial appeals committee for any appeal taken by an individual against a decision of a delegated review of course research projects.~~ ~~Acts as a resource to the University community on matters pertaining to the ethical conduct of research involving human participants and can provide consultation to researchers at all stages of the application and review processes.~~ ~~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 participants.~~ ~~**Meetings**~~ ~~The REB shall meet at least annually, and as needed to review research proposals that are not assigned for delegated review.~~ ~~As a minimum, a quorum of an REB must have five members, of which two members have broad expertise in the methods or areas of research under review, one member who is knowledgeable about the relevant ethical issues, one member with no formal affiliation with the institution and,~~

	~~for biomedical research and all research under the auspices of Article 21 of the Quebec Civil Code, one member who is knowledgeable in the relevant law. However, the Chair has the final authority to decide if the quorum present is adequate to properly conduct reviews.~~ ~~Researchers must be informed of submission deadline requirements.~~ ~~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 Confidentiality**~~ ~~The desirability of openness with respect to the business of the various committee meetings must be limited by considerations of privacy of human participants or of third parties, the confidentiality of proprietary data, the need to encourage free discussion at these meetings, and the desire to promote cooperation in carrying out the purposes of these committees.~~ ~~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 participants conducted at or under the auspices of McGill University, must be reviewed and approved by the appropriate McGill approved REB. The requirement for REB review applies to those activities that meet the TCPS definition of 'research' and 'human participants'. Researchers must consult the TCPS for discussion of what activities need ethics review and what exceptions may exist. Researchers are responsible for consulting with the REB for verification as to whether their research needs ethics review or not. **3.1 Scope of Review** The requirement for ethics review and approval by a McGill approved REB applies to • all research projects involving human participants 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	~~**3.0 RESEARCH REQUIRING ETHICS REVIEW**~~ ~~All research involving human participants conducted at or under the auspices of McGill University, must be reviewed and approved by the appropriate McGill approved REB. The requirement for REB review applies to those activities that meet the TCPS definition of 'research' and 'human participants'. Researchers must consult the TCPS for discussion of what activities need ethics review and what exceptions may exist. Researchers are responsible for consulting with the REB for verification as to whether their research needs ethics review or not.~~ ~~**3.1 Scope of Review**~~ ~~The requirement for ethics review and approval by a McGill approved REB applies to~~ ~~•~~ ~~Aall research projects involving human participants conducted by or under the supervision of any member of McGill University, whether the research is funded or non-funded, or conducted on~~

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 involving human participants conducted as part of thesis or course requirements
- pilot studies and feasibility studies involving human participants
- all research involving human participants (including recruitment and/or data collection) conducted by organizations or individuals who are not members of McGill University while on University premises or using University facilities, equipment, or resources (including human resources)
- research that involves the use of the University's non-public information to identify or contact human research participants.

3.2 Research Projects in Which the Researcher is a Consultant

Research projects involving human participants 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

3.3 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

~~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.~~

- ~~Aall student research projects involving human participants conducted as part of thesis or course requirements~~
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~~**3.3 Multi-jurisdictional Research**~~

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 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 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 participants conducted by McGill members in other institutions must be reviewed and approved by the appropriate McGill REB before the research may begin. 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. Research with non-McGill collaborators- When McGill members are part of a collaborative research project involving human participants where the McGill member is the Principal Investigator, 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	~~McGill REB approval is always needed in all circumstances before the research begins except as allowed for in the TCPS and in accordance with Procedures as approved by the Vice-Principal (Research and Innovation).~~ ~~McGill researchers are required to obtain a McGill REB approval whether the research is conducted on or off campus and are responsible for obtaining any approvals required by the institution or location where the research will take place. A McGill REB approval is needed whether the McGill member is the lead Principal Investigator or not. Researchers involved in collaborative research with researchers from other institutions, will need to obtain a McGill REB approval, whether they are the lead Principal Investigator or not, even if the non-McGill collaborator/co-investigator has obtained approval from their institution.~~ ~~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 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 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.~~

institution and has already obtained their institutional REB approval, the McGill member must normally also obtain McGill REB approval before collecting or accessing data.

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 at affiliated health and social services institutions - Where the University has agreements in place with affiliated institutions, the University mandates the institution's REB to conduct the ethics review of McGill members on behalf of the University, and no further review is needed by a McGill REB. Researchers must adhere to the requirements of the affiliated institution's REB. When the human participant research will take place at both the affiliated institution and on the McGill campus, the researcher must also obtain a feasibility review and final authorization by the University for the portion of the research undertaken on the McGill campus.

b) Research Involving collaborators from 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.

3.4 Student Research

All student research involving human participants, 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 participants, and these projects must also receive ethics review and approval. The intent of course research projects, however, is for the student to

~~Research at Other Institutions - Research involving human participants conducted by McGill members in other institutions must be reviewed and approved by the appropriate McGill REB before the research may begin. 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.~~

~~Research with non-McGill collaborators- When McGill members are part of a collaborative research project involving human participants where the McGill member is the Principal Investigator, 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 their institutional REB approval, the McGill member must normally also obtain McGill REB approval before collecting or accessing data.~~

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~~a) Research at affiliated health and social services institutions - Where the University has agreements in place with affiliated institutions, the University mandates the institution's REB to conduct the ethics review of McGill members on behalf of the University, and no further review is needed by a McGill REB. Researchers must adhere to the requirements of the affiliated institution's REB. When the human participant research will take place at both the affiliated institution and on the McGill campus, the researcher must also obtain a feasibility review and final authorization~~

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 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.	~~by the University for the portion of the research undertaken on the McGill campus.~~ ~~b) Research Involving collaborators from 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.~~ ~~**3.4 Student Research**~~ ~~All student research involving human participants, 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 participants, 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 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	~~**4.0 REVIEW OF RESEARCH**~~

The review process is conducted in accordance with the standards and procedures of the TCPS as well as applicable federal and provincial requirements. The type of review depends upon the anticipated level of risk posed to research participants. Risks can include physical, psychological, or economic harms and can include injury to reputation or privacy. According to the TCPS, a project may be considered to involve minimal risk if the possible harms anticipated by participation in the research are not greater, considering probability and magnitude, than those ordinarily encountered by participants in those aspects of their everyday life that relate to the research.

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. 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.

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 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.

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

~~The review process is conducted in accordance with the standards and procedures of the TCPS as well as applicable federal and provincial requirements. The type of review depends upon the anticipated level of risk posed to research participants. Risks can include physical, psychological, or economic harms and can include injury to reputation or privacy. According to the TCPS, a project may be considered to involve minimal risk if the possible harms anticipated by participation in the research are not greater, considering probability and magnitude, than those ordinarily encountered by participants in those aspects of their everyday life that relate to the research.~~

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~~**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~~

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

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

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

~~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**~~

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 – Appeals can be made for procedural or substantive reasons. There will be two Research

~~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.~~

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~~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.~~

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Ethics Appeal Committees, one serving the REB of the Faculty of Medicine and Health Sciences and one serving the remaining REBs. The Advisory Council on Human Research Ethics is responsible for establishing the appeals process for the Research Ethics Appeals 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. 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 participants. **4.5 Continuing Review** Ongoing research shall be subject to continuing ethics review based on the associated risks to the participants. Normally, REBs will require at least annual reports on the status of all ongoing research projects. The greater the risk to the participant, the greater the scrutiny of the continuing review process. The design of this process will depend upon the particular circumstances of the project and might include but is not limited to 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.	~~b) Appeals – 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 Health Sciences and one serving the remaining REBs. The Advisory Council on Human Research Ethics is responsible for establishing the appeals process for the Research Ethics Appeals 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.~~ ~~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 participants.~~ ~~**4.5 Continuing Review**~~ ~~Ongoing research shall be subject to continuing ethics review based on the associated risks to the participants. Normally, REBs will require at least annual reports on the status of all ongoing research projects. The greater the risk to the participant, the greater the scrutiny of the continuing review process. The design of this process will depend upon the particular circumstances of the project and might include but is not limited to~~ ~~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~~

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 participant. The REB must then be immediately notified and the modification submitted for consideration immediately thereafter. Modifications may include, but are not limited to, changes in research design, participant population, consent procedures, change of principal investigator, new funding, or new co-investigators. Modifications involving minimal risk may be conducted by delegated review.

4.7 Unanticipated Issues

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

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 participant to participate in the research. The REB has the responsibility to identify and seek clarification of situations where

~~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.~~

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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 perceived conflict of interest is brought to the attention of the REB, the researcher may be required to disclose the conflict to potential participants, to abandon one of the interests in conflict, or to take some other action to address the conflict, as specified by the REB. 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.	~~unduly influence the 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 perceived conflict of interest is brought to the attention of the REB, the researcher may be required to disclose the conflict to potential participants, to abandon one of the interests in conflict, or to take some other action to address the conflict, as specified by the REB.~~ ~~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 Regulation on the Conduct of Research states that research data be maintained for a period of 7 years from the date of first 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.	~~**5.0 RECORD-KEEPING FOR RESEARCHERS**~~ ~~The McGill Regulation on the Conduct of Research states that research data be maintained for a period of 7 years from the date of first 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.~~
6.0 COMPLAINTS, CONCERNS AND RECOMMENDATIONS	~~a. 6.0 COMPLAINTS, CONCERNS AND RECOMMENDATIONS~~ ~~a.~~

Research participants, researchers, staff members, REB members and any other individuals who have concerns, complaints or recommendations related to research involving human participants are encouraged to contact any of the offices listed in Appendix 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 health and social services institutions follow the complaint procedures established by those institutions.	~~Research participants, researchers, staff members, REB members and any other individuals who have concerns, complaints or recommendations related to research involving human participants are encouraged to contact any of the offices listed in Appendix 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 health and social services institutions follow the complaint procedures established by those institutions.~~
Participants who have specific complaints or concerns about any aspect of their participation in a research study should contact the Associate Director, Research Ethics in the Office of the Vice-Principal (Research and Innovation). 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 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 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 Innovation), the REB that approved the research, and where relevant, the Board of Governors and the Ministry of Health and Social	~~Participants who have specific complaints or concerns about any aspect of their participation in a research study should contact the Associate Director, Research Ethics in the Office of the Vice-Principal (Research and Innovation). 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 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 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 Innovation), the REB that approved the research, and where relevant, the Board of Governors and the Ministry of Health and~~

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 an 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 Innovation) 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 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 Innovation) for appropriate action.	~~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 an 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 Innovation) 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 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 Innovation) for appropriate action.~~
7.0 NONCOMPLIANCE Instances of noncompliance with policies or procedures for research involving human participants should be brought to the attention of the Chair of the appropriate REB for review and resolution. When deemed appropriate, serious instances of noncompliance will be forwarded to the appropriate institutional officials for disposition. Noncompliance can include, but is not limited to, failure to obtain prior REB approval before starting a research project, inadequate supervision of the research, failure to report unanticipated issues or protocol changes to the REB, failure to provide ongoing progress reports, or significant deviation from the approved protocol.	~~**7.0 NONCOMPLIANCE**~~ ~~**All researchers conducting human participant research are required to comply with this Policy and all applicable regulations and procedures. Instances of alleged noncompliance with policies or procedures for research involving human participants shouldmust be brought to the attention of the REB Chair of the appropriate REB for review and resolution. When deemed appropriate, serious instances of noncompliance will be forwarded to the appropriate institutional officials for disposition.**~~ ~~**Noncompliance can include, but is not limited to, failure to obtain prior REB approval before starting a research project, inadequate supervision of the research, failure to report unanticipated issues or protocol changes to the REB, failure to provide ongoing progress reports,**~~

Actions taken by an REB or the University administration, as appropriate, may include, but are not limited to, education measures, compliance audits, terminating or suspending REB approval of active studies, restrictions on the ability to serve as an investigator on research projects involving human participants, freezing of research funds, or academic penalties in accord with the Code of Student Conduct and Disciplinary Procedures and the Regulations Relating to the Employment of Academic Staff. Graduate students who do not have REB approval for projects involving human 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.	~~or significant deviation from the approved protocol.~~ ~~Actions taken by an REB or the University administration, will be in proportion to the nature, impact and severity of the noncompliance, and 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 participants, freezing of research funds. Other actions may be taken in accordance with the regulations, policies, codes or collective agreement to which the researcher is subject., or academic penalties in accord with the Code of Student Conduct and Disciplinary Procedures and the Regulations Relating to the Employment of Academic Staff. Graduate students who do not have REB approval for projects involving human participants risk non-acceptance of their thesis work.~~**4.** **4. NONCOMPLIANCE** a. All researchers conducting human participant research are required to comply with this Policy and all applicable regulations and procedures. Instances of alleged noncompliance must be brought to the REB Chair for review and resolution. b. When deemed appropriate, serious instances of noncompliance will be forwarded to the appropriate institutional officials for disposition. c. If research misconduct is suspected, as defined under the University's Regulations Concerning Investigation of Research Misconduct, the Chair of the ACHRE shall immediately initiate the process described in said Regulations. ~~Any action taken by the REB or the University administration will be reported promptly, in writing, to the investigator.~~
APPENDIX I	**5. AUTHORITY TO APPROVE PROCEDURES**

MCGILL APPROVED RESEARCH ETHICS BOARDS

1) McGill Research Ethics Boards - The University currently has 5 Research Ethics Boards formally approved to conduct the ethics review of research involving human participants in 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 Medicine and Health Sciences Research Ethics Board (also referred to as the Institutional Review Board or the IRB) – for members in the Faculties of Medicine and Health Sciences and Dentistry and any research involving biomedically invasive measures, procedures, interventions or genetic research.

University Research Ethics Board 1 – 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 research involving competent adults

University Research Ethics Board 2 – for members in Linguistics, Psychology, Schulich School of Music, School of Social Work and the Faculty of Education, for research involving competent adults

University Research Ethics Board 3 - for members in all units except the Faculties of Medicine and Health Sciences and Dentistry for research involving minors or adults not competent to consent

University Research Ethics Board 4 – for members in the Faculty of Agricultural &Environmental Sciences for research involving competent adults

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

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

~~b.~~

~~c. MCGILL APPROVED RESEARCH ETHICS BOARDS~~

~~d.~~

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

~~f.~~

~~g. Faculty of Medicine and Health Sciences Research Ethics Board (also referred to as the Institutional Review Board or the IRB) – for members in the Faculties of Medicine and Health Sciences and Dentistry and any research involving biomedically invasive~~

2) Affiliated Health and Social Services Institutions – The University recognizes the REBs of the following institutions as acting on behalf of the University for conducting ethics reviews for McGill members in accordance with the terms of the agreement in place with each of them:

- the CIUSSS CODIM
- the CIUSSS ODIM
- the McGill University Health Centre

3) Other

a) The University recognizes the Research Ethics Board of the Centre de recherche 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.9.

~~measures, procedures, interventions or genetic research.~~

~~h.~~

~~i. University Research Ethics Board 1 – 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 research involving competent adults~~

~~j.~~

~~k. University Research Ethics Board 2 – for members in Linguistics, Psychology, Schulich School of Music, School of Social Work and the Faculty of Education, for research involving competent adults~~

~~l.~~

~~m. University Research Ethics Board 3 - for members in all units except the Faculties of Medicine and Health Sciences and Dentistry for research involving minors or adults not competent to consent~~

~~n.~~

~~o. University Research Ethics Board 4 – for members in the Faculty of Agricultural &Environmental Sciences for research involving competent adults~~

~~p.~~

~~q. 2) Affiliated Health and Social Services Institutions – The University recognizes the REBs of the following institutions as acting on behalf of the University for conducting ethics reviews for McGill members in accordance with the terms of the agreement in place with each of them:~~

~~r. - the CIUSSS CODIM~~

~~s. - the CIUSSS ODIM~~

~~t. - the McGill University Health Centre~~

~~u.~~

~~v. 3) Other~~

~~w.~~

~~x. a) The University recognizes the Research Ethics Board of the Centre de recherche 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.~~ ~~y.~~ ~~z.~~b. ~~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.~~9.
APPENDIX II Contact Information for Complaints, Concerns and Recommendations Related to Research Involving Human Participants Associate Director, Research Ethics, Office of the Vice-Principal (Research & Innovation) – (514) 398-6831 Chair, University Advisory Council on Human Research Ethics – (514) 398-6831 Vice-Principal (Research and Innovation) – (514) 398-3991 www.mcgill.ca/research/researchers/compliance/human/ - lists all REB Chairs and contact information	**6. REVIEW** ~~**APPENDIX II**~~ After five years, this Policy shall be reviewed by a working group comprised of the Vice-President (Research and Innovation) or delegate; the Chair of the ACHRE; and one member from each University REB. The working group may make recommendations for modification to this Policy. ~~Contact Information for Complaints, Concerns and Recommendations Related to Research Involving Human Participants~~ ~~Associate Director, Research Ethics, Office of the Vice-Principal (Research & Innovation) – (514) 398-6831~~ ~~Chair, University Advisory Council on Human Research Ethics – (514) 398-6831~~

	~~Vice-Principal (Research and Innovation) – (514) 398-3991~~ ~~www.mcgill.ca/research/researchers/compliance/human/ - lists all REB Chairs and contact information~~

PROCEDURE TITLE	PROCEDURES FOR THE IMPLEMENTATION OF THE POLICY ON THE ETHICAL CONDUCT OF RESEARCH INVOLVING HUMAN PARTICIPANTS
Executive Sponsor	Vice-~~Principal~~ President (Research and Innovation)
Initial Approval Date	Date that the Procedure was originally approved by Executive Sponsor
Date of Last Review	N/A

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

PURPOSE

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

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

1. ADVISORY COUNCIL ON HUMAN RESEARCH ETHICS

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

1.1 Membership

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

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

1.2 Meetings

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

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

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

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

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

2. RESEARCH ETHICS BOARDS

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

2.1 Membership

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

b. The REB Chair must monitor the composition of the membership for appropriate ~~membership~~representation. The number of members needed from each unit within an REB's jurisdiction is to be determined by the Chair of the REB and should be approximately in proportion to the number of submissions from that unit. For REBs that cover a large number of units, REB membership should be rotated to ensure that all units submitting projects have an opportunity to be represented. ~~As the number of members at a convened meeting increases beyond 6-8 internal members, there should be a proportionate number of community members present.~~

c. The REB Chair must be an experienced REB member and is responsible for ensuring adherence to the applicable policies, regulations, procedures and guidelines. The REB Chair provides overall leadership to the REB and ensures consistency of review decisions. The REB Chair can delegate any of their responsibilities, as appropriate, to a Vice-Chair or other qualified REB members~~individual(s)~~. Any responsibilities that are delegated by the REB Chair must be documented.

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

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

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

2.2 Meetings

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

~~As a minimum, a quorum of an REB must have five members, of which two members have broad expertise in the methods or areas of research under review, one member who is knowledgeable about the relevant ethical issues, one member with no formal affiliation with the institution and, for biomedical research and all research under the auspices of Article 21 of the Quebec Civil Code, one member who is knowledgeable in the relevant~~

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

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

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

~~e. 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.~~

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

~~g.~~ f. 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 or as required by applicable regulations.~~

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

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

2.3 Resignations and Removals

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

a.

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

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

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

~~**2.3 Confidentiality**~~

~~a. The desirability of openness with respect to the business of the various committee meetings must be limited by considerations of privacy of human participants or of third parties, the confidentiality of proprietary data, the need to encourage free discussion at these meetings, and the desire to promote cooperation in carrying out the purposes of these committees.~~

~~**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.~~

2.~~4~~3 Documentation Management

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

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

2.~~5~~3~~4~~ Annual Reports

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

~~**2.5 Record Keeping**~~

~~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. 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 University, researchers and funding agencies. REB records must be kept for a minimum of three years beyond the termination of a project or as required by applicable regulations.~~

3. REVIEW OF RESEARCH

The review process is conducted in accordance with the standards and procedures of the TCPS as well as applicable provincial, federal and ~~provincial~~ international requirements. ~~The type of review depends upon the anticipated level of risk posed to research participants. Risks can include physical, psychological, or economic harms and can include injury to reputation or privacy. According to the TCPS, a project may be considered to involve minimal risk if the possible harms anticipated by participation in the research are not greater, considering probability and magnitude, than those ordinarily encountered by participants in those aspects of their everyday life that relate to the research.~~

3.1 Levels of Review

a. Full REB Review

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

b. Delegated Review

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

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

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

c. Unit Level Review

The ethics review of course-based research projects with a primarily pedagogical purpose may , under prescribed circumstances as established by the REB, be delegated by the REB ~~may delegate the review of course research projects to individual REB members or to an REB~~ to non-REB members at the department/school/faculty level. To be delegated, the unit level representatives must have the necessary experience, expertise and training required to review and approve the course projects in accordance with the TCPS. All such members must, at a minimum, complete

the TCPS tutorial. Training will be provided by the REB. The representative(s) must fulfill the function throughout the academic year (September-August). ~~designated departmental representatives or committee who are not current REB members.~~ Reporting ~~of~~ the actions and decisions must be made on a regular basis, the timing and format as established by the REB. Accountability requires that, regardless of the review strategy, the REB continues to be responsible for the ethics of all research involving humans within its jurisdiction.

3.2 Scholarly Review as Part of Ethics Review

a. As stated in the TCPS, as part of research ethics review, the REB shall review the ethical implications of the methods and design of the research. When evaluating if the potential gains of the research warrant the costs and risks to be incurred by the participants and where risk of potential harm to participants exists, the REB must satisfy itself that the design of a research project is capable of addressing the questions being asked in the research. REBs may therefore require that research be peer reviewed, particularly when the research involves greater than minimal risk to participants. The extent of the scholarly review that is required for biomedical research that does not involve more than minimal risk will vary according to the research being carried out. Research in the humanities and the social sciences that poses, at most, minimal risk shall not normally be required by the REB to be peer reviewed. REBs must respect the relevant guidelines that require REBs to evaluate the scientific aspects of the research as part of ethics review for specific types of research (e.g. clinical trials).

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

3.3 Decision Making and Outcome of the Review Process

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

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

c. A decision of 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~~ University may however, refuse to allow certain types of research within its jurisdiction, even though it has been found to be ethically acceptable.

3.4 Reconsideration

~~–~~Researchers have the right to request, and the REB has an obligation to provide, reconsideration of an REB decision. The researcher must provide a written rebuttal in response to the concerns identified by the initial REB review. The researcher has the right to appear and be heard in a meeting with the REB to discuss the rebuttal. ~~The REB decision following reconsideration is final~~. The r~~R~~esearcher and the REB must have fully exhausted the formal reconsideration process and the REB must have issued its final decision before the Researcher may initiate an appeal.

3.5 Appeals of Decisions

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

~~a.~~ ~~–~~The ACHRE Chair shall act as the Chair of the Appeal Committee. The Appeal Committee shall consist of the members of all the McGill REBs. Members for hearing an appeal will be drawn from the Appeal Committee by the Chair with the composition of the committee hearing the appeal satisfying the REB requirements set out in Section 2.1(d) of these Procedures. No member of the Appeal Committee who is hearing a particular appeal of a decision can be a member of the REB

who made or reconsidered such decision. The Appeal Committee may appoint *ad hoc* experts as required.

b.

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

c.

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

d.

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

f. The decision made by the Appeal Committee on behalf of the University shall be final and shall be communicated in writing to the researcher and to the REB whose decision was appealed within ten (10) working days of the meeting at which the decision was reached. An Appeal Committee decision may be categorised as follows:

- Approved as submitted and the decision of the REB is overturned.
- Declined as submitted and the decision of the REB is upheld.
- Modifications are proposed and the final decision is pending. In this case the appealing researcher has 10 working days to make the requested modification and resubmit the application to the Appeals Committee for re-review. If the researcher does not respond to the request for modifications within the 10 working days, the appeal will be declined and the decision of the REB upheld.
-

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

~~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 Health Sciences and one serving the remaining REBs. The Advisory Council on Human Research Ethics is responsible for establishing the appeals process for the Research Ethics Appeals Committees in accordance with the requirements of the TCPS.~~

3.5 Continuing Review

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

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

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

3.6 Modification of an Approved Project

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

3.7 Unanticipated Issues

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

responsibility of a researcher to share any new knowledge with the REB that may affect a participant's welfare or have other ethical implications.

3.8 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 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, potential or perceived conflict of interest is brought to the attention of the REB, the researcher may be required to disclose the conflict to potential participants, to abandon one of the interests in conflict, or to take some other action to address the conflict, as specified by the REB.

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

~~T~~This section does not attempt to address all matters relating to conflicts of interest therefore, as appropriate, reference should also be made to existing University guidelines and regulations on conflicts of interest.

~~**4. RECORD KEEPING FOR RESEARCHERS**~~

~~The McGill Regulation on the Conduct of Research states that research data be maintained for a period of 7 years from the date of first 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 approved by the REB and in compliance with relevant University policies and any applicable legislation. Researchers are responsible for being aware of any specific data retention requirements applicable to their particular research.~~

~~5~~4. COMPLAINTS AND CONCERNS

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

a.

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

b.

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

c.

d.

e. 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 may include the Dean/Chair of the Faculty, School or Department, the Vice-Principal (Research and Innovation), the REB that approved the research, and where relevant, the study sponsor, the Board of Governors and the Ministry of Health and Social Services, and to other persons who have a legitimate need to know. All REB records, including 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.

d.

f.

g. Complaints regarding an REB should be made to the Chair of the Advisory Council on Human Research EthicsACHRE. The Chair is responsible for investigating the allegationcomplaint and must reporting such allegations complaints to the Vice-Principal (Research and Innovation) for appropriate action. All complaints, with confidentiality maintained, must be reported in the ACHRE Annual Report.

e.

h.

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

56. NONCOMPLIANCE

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

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

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

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

~~6~~7. ~~AGREEMENTS~~Multi-jurisdictional Research

Commented [LM1]: This section would be better placed as a heading under 3.0 Review of Research,

As described in the Policy, research involving human participants conducted at or under the auspices of the University requires ethics review and approval by a McGill REB before the research may begin. However, in some instances of multi-jurisdictional research, a review done by an external REB may be accepted by the McGill REB , in accordance with the Policy and the requirements of the TCPS.

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

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

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

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

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

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

McGill | Faculty of Medicine and Health Sciences

D23-36 - Appendix C

MEMORANDUM

Office of the Vice-President, Health Affairs and Dean of Medicine and Health Sciences 3605 de la Montagne, Room 117
Montreal, QC H3G 2M1
Phone: 514-398-3524 Fax: 514-398-4423

TO: Professor Christopher Manfredi
Provost and Executive Vice-President (Academic)
Chair of Academic Policy Committee (APC)

CC: Marc Rodger, Chair Department of Medicine

FROM: Dr. Lesley Fellows MDCM, DPhil
Vice-President (Health Affairs)
Dean of Medicine and Health Sciences

DATE: December 12, 2023

SUBJECT: **Request to change the name of divisions within the Department of Medicine**

FOR: information discussion decision action

Dear Professor Manfredi:

This request is made on behalf of the Department of Medicine, Faculty of Medicine and Health Sciences, for the Academic Policy Committee (APC) to consider and approve a change in the name of the following Division:

Current Division Name: Experimental Medicine
New Suggested Name: Division of Clinical and Translational Research

Background and Rationale/issues to address
Experimental Medicine traces its roots back to the **1950s** when the Department of Experimental and Investigative Medicine was created. Experimental Medicine was absorbed in the Department of Medicine (DOM) of McGill University in 1975.

Currently, Experimental Medicine includes **over 350 graduate students** enrolled in one of its 6 thesis-based degree programs by over 250 Faculty members (both Full-Time and Associate members):

1. M.Sc. in Experimental Medicine
2. M.Sc., Environment Option
3. M.Sc., Bioethics Option

4. M.Sc., Digital Health Innovation Option
5. Ph.D. in Experimental Medicine
6. Ph.D., Environment Option

While the "Experimental Medicine" includes wide-ranging areas of research spanning from fundamental bench to translational to bedside to policy research the name, historically based, does not reflect the breadth of the science our faculty advance or teach their graduate students.

The purpose of this rebranding is to have a graduate program title that reflects our contemporary research, clinical practices and vision for the program.

Alignment with mission and strategic priorities
The Department of Medicine (DOM) undertook a community-building participatory strategic planning exercise over the last year (10/2022- 10/2023). All our DOM members were asked to provide at least 1 aspiration that they had for their Department in the next 5 years. These aspirations were then ranked through DOM wide surveys. The most important/highest ranked aspiration theme for the Department was to be "the most research intensive DOM in Canada." Through a similar process, the community told us that to reach this aspiration we needed to train/grow our clinician scientist ranks. This re-focusing of our Graduate Program to a Graduate Program in Clinical and Translational Research, along with programmatic and structural changes (e.g. a PhD in Digital Innovation and a MSc/PhD in Clinical Research) will allow us to create dual (clinical and research) training paths to bolster our clinician scientist numbers.

Consultations
As described above, we extensively consulted the Department to establish our strategic plan. The Strategic Plan consultation phase included soliciting feedback/refining the strategic plan based on feedback from our affiliated hospital leadership, the hospital-based research institutes and foundations. We also consulted the School of Population and Global Health who were supportive of the re-vamp and re-focus of our Graduate Program. Finally, the proposed change was presented to the Dean's Operations Committee of the Faculty of Medicine and Health Sciences.

Risk factors
None apparent

Impact of Decision, next steps
Once the Division name change is approved, we will re-brand the graduate program and expect that it will lead to greater interest from medical residency, sub-specialty and fellowship trainees and ultimately more clinician scientists working at McGill. More clinician scientists will lead to better patient care through delivering tomorrow's innovation today to our local community. We will continue the path of developing our PhD programs in Digital Innovation and Clinical Research as key strategic priorities for the Department.

Following approval by APC, the Department of Medicine will immediately adjust all internal and external communication media (including website and letterhead, etc.) to reflect the new Division name. We will ensure communication of a succinct but impactful supporting statement as to the purpose and intent of this change.

Formal and final approval of the Division name change will be announced at the first Faculty of Medicine and Health Sciences Faculty Council meeting scheduled after approval and

communicated via Health-E news and other news media within the Faculty of Medicine and Health Sciences.

On behalf of the Faculty of Medicine and Health Sciences, I hope that the APC will be favorable to our request.

Sincerely,

Lesley Fellows MDCM, DPhil