

**AGENDA**

**NOTE: Members who wish to have items moved from the Consent to the Regular Agenda should contact the University Secretariat before the Senate meeting. Members may also request to have items moved when the Agenda is presented for approval.**

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School of Graduate Studies

1280 Main Street West  
Hamilton, Ontario, Canada  
L8S 4L8

Phone 905.525.9140  
Ext. 23679  
Fax 905.521.0689  
<http://www.mcmaster.ca/graduate>

**To : Senate**

**From : Christina Bryce  
Assistant Graduate Secretary**

**Re : Report from Graduate Council**

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At its meetings on December 4<sup>th</sup> and January 22<sup>nd</sup> Graduate Council approved the following for recommendation to Senate:

**For Information:**

**1. Faculty of Engineering**

**Design and Manufacturing (ADMI)**

Program Cancellation (M.Eng.)

The department proposed this cancellation as McMaster University is no longer affiliated with the ADMI (Advanced Design and Manufacturing Institute) program and it is now only offered as a collaboration between Queen's University and Western University.

This was also approved at the January 16<sup>th</sup> meeting of the University Planning Committee.

**2. Faculty of Health Sciences**

**Biomedical Discovery and Commercialization**

Change to Calendar Copy (M.B.D.C)

The program proposed a change to their calendar copy to remove a statement referring to unpaid internship opportunities. The rationale for removing this is that to date all internships have been paid and the program does not solicit/post unpaid opportunities.

**Health Research Methodology**

Change to Course Requirements (M.Sc. and Ph.D.)

The program proposed a change to their course requirements, removing 787 (which was cancelled) and replacing it with a cross-listed course from the Public Health program. They also proposed the creation of 753, a second Regression Analysis course that has been created to meet ever increasing demand.

**3. New Scholarship**

**NAME OF FUND: McMaster Graduate Students Association Emergency Bursary.**

**TERMS OF REFERENCE FOR FUND:**

Established in 2018 by the McMaster University Graduate Students Association Board of Directors and members of the McMaster Graduate Students Association. To be granted to full-time graduate students who are members of the GSA and who demonstrate urgent financial need due to exceptional circumstances as determined by the School of Graduate Studies.

**REPORT TO SENATE**  
**FROM THE**  
**UNIVERSITY PLANNING COMMITTEE**

**a. Advanced Design and Manufacturing Institute (ADMI) program cancellation**

At its meeting of January 16, 2019, the University Planning Committee approved, for recommendation to Senate, the cancellation of the Advanced Design and Manufacturing Institute (ADMI) program.

The University Planning Committee now recommends,

**that Senate approve the cancellation of the Advanced Design and Manufacturing Institute (ADMI) program, as circulated**

**Senate: FOR APPROVAL**  
**February 13, 2019**



**School of Graduate Studies**

1280 Main Street West  
Hamilton, Ontario, Canada  
L8S 4M2

Phone 905.525.9140  
Ext. 23679  
Fax 905.521.0689  
<http://www.mcmaster.ca/graduate>

To : University Planning Committee

From : Christina Bryce  
Assistant Graduate Secretary

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At its meeting on December 4<sup>th</sup>, Graduate Council approved the cancellation of the ADMI program.

Graduate Council now recommends that the University Planning Committee approve the cancellation of the ADMI program as outlined in the attached.

Attachment

**RECOMMENDATION FOR CHANGE IN GRADUATE CURRICULUM - FOR CHANGE(S) INVOLVING DEGREE PROGRAM REQUIREMENTS / PROCEDURES / MILESTONES**

**IMPORTANT: PLEASE READ THE FOLLOWING NOTES BEFORE COMPLETING THIS FORM:**

1. This form must be completed for **ALL** changes involving degree program requirements/procedures. **All** sections of this form **must** be completed.
2. An electronic version of this form (must be in MS WORD **not** PDF) should be emailed to the Assistant Secretary, School of Graduate Studies (cbryce@mcmaster.ca).
3. A representative from the department is **required to attend** the Faculty Curriculum and Policy Committee meeting during which this recommendation for change in graduate curriculum will be discussed.

DEPARTMENT		<b>Mechanical Engineering</b>	
NAME OF PROGRAM and PLAN		<b>Advanced Design and Manufacturing Institute (ADMI)</b>	
DEGREE	<b>Master's of Engineering (M.Eng.) Design and Manufacturing</b>		
<b>NATURE OF RECOMMENDATION (PLEASE CHECK APPROPRIATE BOX)</b>			
Is this change a result of an IQAP review? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
CREATION OF NEW MILESTONE <input type="checkbox"/>			
CHANGE IN ADMISSION REQUIREMENTS		CHANGE IN COMPREHENSIVE EXAMINATION PROCEDURE	CHANGE IN COURSE REQUIREMENTS
CHANGE IN THE DESCRIPTION OF A SECTION IN THE GRADUATE CALENDAR		EXPLAIN:	
OTHER CHANGES	(X)	EXPLAIN: <b>Removal of ADMI program and associated Master's degree from the Graduate Calendar (under "Faculty of Engineering", subheading "Mechanical Engineering - Programs")</b>	

DESCRIBE THE EXISTING REQUIREMENT/PROCEDURE:

PROVIDE A DETAILED DESCRIPTION OF THE RECOMMENDED CHANGE (*Attach additional pages if space is not sufficient.*)

RATIONALE FOR THE RECOMMENDED CHANGE (How does the requirement fit into the department's program and/or tie to existing Program Learning Outcomes from the program's IQAP cyclical review?):

McMaster University is no longer affiliated with the program; it is now only offered through a collaboration between Queen's University and Western University.

PROVIDE IMPLEMENTATION DATE: (*Implementation date should be at the beginning of the academic year*)

September 1, 2019.

ARE THERE ANY OTHER DETAILS OF THE RECOMMENDED CHANGE THAT THE CURRICULUM AND POLICY COMMITTEE SHOULD BE AWARE OF? IF YES, EXPLAIN.

PROVIDE A DESCRIPTION OF THE RECOMMENDED CHANGE TO BE INCLUDED IN THE CALENDAR (please include a tracked changes version of the calendar section affected if applicable):

CONTACT INFORMATION FOR THE RECOMMENDED CHANGE:

Name: **Dr. C. Ching**      Email: **chingcy@mcmaster.ca**      Extension: **24998**      Date submitted: **Oct. 9, 2018**



If you have any questions regarding this form, please contact the Assistant Secretary, School of Graduate Studies,  
cbryce@mcmaster.ca

SGS/2013

**REPORT TO THE SENATE**  
**FROM THE**  
**COMMITTEE ON APPOINTMENTS**

**Open Session (Regular Agenda)**

At its meeting on January 14, 2019, the Committee on Appointments approved the following recommendation and now recommends it to Senate for approval:

**a. Tenure and Promotion Policy**

On January 14, 2019, the Senate Committee on Appointments approved the amendment of Item 42 of the Tenure and Promotion Policy and now recommends it to Senate for approval:

It is now recommended,

**that Senate approve the amendment of Item 42 of the Tenure and Promotion Policy, as circulated.**

**SENATE: FOR APPROVAL**  
**February 13, 2019**

**MOTION: To amend Item 42 of the Tenure & Promotion Policy as described below.**

RATIONALE: In the previous version, the materials considered by the department (i.e., the external reviewers' letters) were released to the faculty member only after the faculty member requested to be reconsidered. But in most cases, their decision as to whether to request reconsideration would depend on having viewed the materials. The revision allows them to request the materials first and then decide whether to request reconsideration.

42.

- a. The Chair shall notify every candidate for re-appointment, tenure, or permanence of the Departmental recommendation in his or her case on or before October 1, and shall similarly notify every eligible candidate for promotion no later than December 1.
- b. A faculty member who believes that he or she has been unfairly treated because (i) he or she was not considered for tenure, permanence, and/or promotion by the Department, or (ii) he or she has been considered but no recommendation is being made, or (iii) an inappropriate recommendation is being made to the Faculty Tenure and Promotion Committee, may ~~request to be considered or reconsidered~~ view a copy of the material considered by the Departmental Committee, along with a copy of the Committee recommendation to the Faculty Committee by making a submission in writing to the Department Chair no later than October 7 (December 7 in the case of a faculty member being considered for promotion to Professor). It shall be the responsibility of the Chair of the Department to ensure that the confidentiality of the material is maintained. To this end, only unattributed copies of the originals of any external or internal letters of reference shall be provided. Any other written assessments shall be similarly redacted to maintain confidentiality.
- c. ~~Upon receiving such a request, the Chair shall discuss the matter with the faculty member concerned, and shall provide him or her with a copy of the material considered by the Departmental Committee, along with a copy of the Committee recommendation to the Faculty Committee. It shall be the responsibility of the Chair of the Department to ensure that the confidentiality of the material is maintained. To this end, only unattributed copies of the originals of any external or internal letters of reference shall be provided. Any other written assessments shall be similarly redacted to maintain confidentiality.~~ Having viewed the material considered by the Departmental Committee and the Committee recommendation to the Faculty Committee, the faculty member may request to be reconsidered. ~~desires it,~~ In this case, there shall be a meeting of the Departmental Committee to consider or re-consider the case. The faculty member shall have the right to appear before this Committee and make submissions thereto; the faculty member may be accompanied by a faculty colleague acting as an advisor.
- d. If, following such consideration of his or her case, the faculty member remains unsatisfied, he or she may convey this information, in writing, to the Faculty Dean, who shall apprise the Faculty Tenure and Promotion Committee of the case (see clause 50(c) below).

**REPORT TO THE SENATE**  
**FROM THE**  
**COMMITTEE ON APPOINTMENTS**

**Open Session (Regular Agenda)**

At its meeting on February 11, 2019, the Committee on Appointments approved the following recommendation and now recommends it to Senate for approval:

**a. Revised Terms of Reference – Health Sciences**

On February 11, 2019, the Senate Committee on Appointments approved the revised Terms of Reference for the Vice-Dean, Faculty of Health Sciences and Associate Dean, Graduate Studies (Health Sciences) and now recommends it to Senate for approval:

It is now recommended,

**That Senate approve, for recommendation to the Board of Governors, the revised terms of reference for the Vice-Dean, Faculty of Health Sciences and Associate Dean, Graduate Studies (Health Sciences), as circulated.**

**SENATE: FOR APPROVAL**  
**February 13, 2019**

February 1, 2019

Senate Committee of Appointments  
c/o University Secretariat  
Gilmour Hall  
Room 210

**Re: Recommendation for the approval of the Terms of Reference for the Vice-Dean,  
Faculty of Health Sciences and Associate Dean, Graduate Studies (Health Sciences)**

On behalf of the School of Graduate Studies and the Faculty of Health Sciences, we would like to recommend the attached updated terms of reference for approval.

Thank you for considering this request. If you need further information, please do not hesitate to contact us.

Yours sincerely,



Doug Welch  
Vice-Provost and Dean of Graduate Studies



Paul M. O'Byrne, MB, FRCPC, FRSC  
Dean and Vice President

Encl.

/rc

## **Terms of Reference**

### **Vice-Dean, Faculty of Health Sciences, Associate Dean of Graduate Studies (Health Sciences)**

The Vice-Dean, Faculty Health Sciences/Associate Dean of Graduate Studies (Health Sciences) (VD FHS/AD Graduate Studies (HS) has the primary responsibility within the Faculty of Health Sciences for furthering McMaster's goals regarding graduate education and research training, and provides leadership and coordination for all activities related to those goals. The VD FHS/ AD Graduate Studies (HS) will normally have a five-year term of office, with the possibility of reappointment for a second term.

The VD FHS/AD Graduate Studies (HS) reports both to the Dean and Vice-President (Health Sciences) and to the Vice-Provost and Dean of Graduate Studies. The VD FHS/AD Graduate Studies(HS) works in a coordinated way with the Assistant, Associate and Vice-Deans of both the Faculty of Health Sciences and the School of Graduate Studies to ensure that both Faculty-specific and University-wide goals are addressed.

Responsibilities include, but are not limited to:

- a) Working closely with the Dean and Vice-President Health Sciences and the Vice-Provost and Dean of Graduate Studies to assist with development, maintenance, and improvement of graduate programs in the Faculty of Health Sciences
- b) Maintaining ongoing liaisons with the Vice-Dean Research, (FHS) the Vice-Dean, Health Professional Education, (FHS), Vice-Dean, Undergraduate Education (FHS) and the Associate Deans of Graduate Studies (Engineering; Science; Business, Humanities and Social Sciences) for matters relating to these areas as they affect graduate programs and research training, including interdisciplinary programs.
- c) Providing input into and strategic planning for matters of graduate admissions, student enrolment, development of new disciplinary and interdisciplinary programs, and student recruitment and retention.
- d) Overseeing quality assurance for new and on-going graduate programs within the Faculty of Health Sciences, and facilitating internal and external reviews of graduate programs. The VD FHS/AD Graduate Studies (HS) oversees the graduate educational activities of the Assistant Deans and Program Directors who recognize a dual responsibility to consult and inform both the VD FHS/ AD Graduate Studies (HS) and the relevant Department Chair (or Vice Dean) within the Faculty of Health Sciences.
- e) Encouraging and facilitating innovation in graduate education and research training across campus within the Faculty of Health Sciences and in conjunction with other Faculties in interdisciplinary programs.
- f) Developing and overseeing financial strategies for the growth and enhancement of graduate studies in Health Sciences; managing financial resources allocated for graduate programs in

Health Sciences (as appropriate); and overseeing the administrative support in the office of the VD FHS/ AD Graduate Studies (HS).

- g) Serving as a member on, or Chair of, University-wide and Faculty-specific committees. (Including: chairing the Graduate Curriculum and Policy Council and the Graduate Admissions and Study Committee in the Faculty of Health Sciences; co-chairing the Scholarships Committee of the Graduate Council; chairing, when so delegated by the Dean of Health Sciences, selection committees for Assistant Deans (or equivalent) of graduate programs in the Faculty; ex officio member of search committees in Health Sciences as requested by the Dean of Health Sciences; membership on Graduate Council and Graduate Council Executive; membership on the Health Sciences Education and Research Councils and the Faculty of Health Sciences Executive Council; and membership on the School of Graduate Studies Executive).
- h) Interviewing candidates for tenured and tenure-track positions when requested, assessing the candidates' suitability for a faculty position at McMaster University, particularly regarding graduate supervision.
- i) Performing functions specified in such documents as the Student Appeal Procedures, including dealing with issues raised by individual students or problems involving their academic progress, conducting formal inquiries where required, participating in appeal hearings, and negotiating informal settlements to disputes to benefit students while upholding the regulations and standards of the School, Faculty, or Department.
- j) Performing functions specified in such documents as the Research Integrity Policy, including investigating allegations of research misconduct and, if found, represent the University's position at a Hearing.
- k) Serving from time-to-time on bargaining teams in the University's negotiations (e.g., regarding the TA or PDF collective agreements).
- l) Examining, and proposing revisions to policies, procedures, and regulations to improve the operation of graduate programs and graduate student success; and ensuring those policies, procedures, and regulations are implemented within the Faculty of Health Sciences.
- m) Working to enhance the quality of life and sense of community amongst the diverse group of graduate students and research trainees within the Faculty of Health Sciences and encourage their involvement in interdisciplinary activities.
- n) Communicate best practices in graduate supervision and provide oversight and resolutions for graduate supervision issues, when necessary.
- o) Discharging such duties as may be assigned by the Vice-Provost and Dean of Graduate Studies from time to time, including serving as the Acting Vice-Provost and Dean of Graduate Studies in the Dean's absence or as Acting AD (Graduate Studies) when the Associate Dean from another Faculty is away.

The ideal candidate for this position will be an accomplished researcher, an excellent graduate mentor, and faculty member within the Faculty of Health Sciences. He or she should have extensive experience in graduate education and research training, a strong understanding of and

commitment to the role of graduate education in Health Sciences, demonstrated success in networking and collaboration, and excellent interpersonal and communication skills.

McMaster University is located on the traditional territories of the Haudenosaunee and Mississauga Nations and, within the lands protected by the “Dish With One Spoon” wampum agreement.

In keeping with its Statement on Building an Inclusive Community with a Shared Purpose, McMaster University strives to embody the values of respect, collaboration and diversity, and has a strong commitment to employment equity. The diversity of our workforce is at the core of our innovation and creativity and strengthens our research and teaching excellence. The University seeks qualified candidates who share our commitment to equity, diversity and inclusion. While all qualified candidates are invited to apply, we particularly welcome applications from women, persons with disabilities, First Nations, Métis and Inuit peoples, members of visible minorities, and LGBTQ+ persons.

Approved – FHS Faculty Executive – January 31.  
For Approval – SCA – February 11.



**REPORT TO SENATE**  
**FROM THE**  
**EXECUTIVE COMMITTEE**  
**Open Session (Regular Agenda)**

**a. McMaster Research Ethics Board Revised Terms of Reference**

On January 23, 2019, the Executive Committee approved the revised terms of reference for the McMaster Research Ethics Board and now recommends it to Senate for approval:

Senate Executive Committee now recommends,

**that Senate, on the recommendation of the Executive Committee, approve the proposed amendments to the McMaster Research Ethics Board Terms of Reference, as circulated.**

**b. Research Ethics Appeals Board Revised Terms of Reference**

On January 23, 2019, the Executive Committee approved the revised terms of reference for the Research Ethics Appeals Board and now recommends it to Senate for approval:

Senate Executive Committee now recommends,

**that Senate, on the recommendation of the Executive Committee, approve the proposed amendments to the Research Ethics Appeals Board Terms of Reference, as circulated.**


**Senate: For Approval**  
**February 13, 2019**

TO: Executive Senate Committee

FROM: Robert Baker, Vice-President, Research

RE: **McMaster Research Ethics Board Revisions**

DATE: January 15, 2019



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I am writing to inform the Senate Executive regarding proposed changes to the McMaster Research Ethics Board Terms of Reference and Appeal Board Terms of Reference. Please see below brief description of the proposed changes:

McMaster Research Ethics Board Terms of Reference

The impetus for the revision was to reduce the quorum requirements for approving minutes, guidelines, and other minor business. Therefore, the major change was to reduce quorum from 50% of membership to the minimum Tri-Council Policy Statement (TCPS) quorum requirements in order to facilitate the approval of minutes and other minor business at every meeting. Additionally, the quorum requirement for full board review of an ethics application was lowered from 50% to 40% of the membership (in addition to TCPS requirements) to decrease the likelihood of failing to meet quorum for the review (failure to meet quorum would cause the researcher(s) to have to wait an additional month to receive MREB feedback).

As the last change to the MREB ToR appears to have been in 2003, several other minor changes to update the document were included.

- Connected the membership and quorum requirements to the specific articles in the TCPS.
- Clarified that recruitment of new MREB Chairs is overseen by the Office of the VPR, and that it is not mandatory that a new Chair be appointment from the current MREB membership.
- Removed the mandate for MREB to serve as the appeal board for Student Research Ethics Committee decisions due to the conflict of interest.
- Clarified that HiREB reviews all Faculty of Health Science studies, with allowance for MREB to review in unique cases.
- Other minor changes to wording for clarity or to update to correct language (e.g. no longer VP Research and International Affairs).

Appeal Board Terms of Reference

The main reason for the revision was to update a document that predated the formation of the Hamilton Integrated REB (HiREB), as the document has outdated language referring to the old hospital REBs. Several other necessary changes were made through the revision process.

- Added a preamble that sets the context for appeal of an REB decision.
- Connected the membership and quorum requirements to the specific articles in the TCPS.
- Changed to a single membership structure for the Appeal Board that includes members from Hamilton Health Sciences and St. Joseph's Healthcare Hamilton. The original ToR only had this as a future possibility.
- Student Research Ethics Committee decisions to be appealed to the Appeal Board instead of MREB.
- Added a new section outlining the appeal procedure in detail.
- Increased the term length of board members to five years.

## McMaster Research Ethics Board Terms of Reference

### **Terms of Reference**

#### **Membership**

The MREB shall consist of at least 10 members, including both women and men, appointed by the President, on the recommendation of the Vice President, Research and International Affairs, following consultation with the current MREB Chair, Faculty Deans, and program and department Chairs. The Chair shall be appointed by the President from among the appointed members and shall serve, normally, for a term of three years, once renewable. MREB Members shall serve, normally, for staggered three year terms, once renewable. Members shall represent a broad range of disciplines and faculties, especially those in which research with human participants takes place. The Board membership will consist of at least one member knowledgeable in ethics and two members with no affiliation with McMaster University and recruited from the community served by McMaster University. All REB members shall be competent to judge the ethical acceptability of proposals and shall be knowledgeable about the McMaster University Policy and about the specific procedures of the REB of which they are members. Fifty percent of the appointed members (of which one shall be a community member) shall constitute a quorum. MREB members shall be without conflict of interest in the review process and shall disclose actual, perceived or potential conflicts of interest at the outset of a review.

#### **Mandate:**

The mandate of the MREB is

1. to keep current on ethical issues related to research involving human participants, to educate the University community on these issues and to formulate policies on these matters;
2. to review (using a proportionate approach), approve, reject, propose modifications to, or terminate any proposed or ongoing non medical research involving human participants conducted at McMaster or by members of McMaster University, including anyone affiliated with the University conducting such research at or under the auspices of McMaster University;
3. to assess and limit the risks to participants in research involving humans; and where there is more than minimal risk is identified, the REB shall satisfy itself that the design of a research project is capable of addressing the questions being asked in the research;
4. to monitor ongoing projects and to determine guidelines for the review of ongoing research projects and guidelines for reviewing requests for changes in previously approved research;
5. to develop policies and procedures for assessing and approving undergraduate student research;

6. to act as the Appeal Board for appeals of decisions rendered regarding undergraduate student research;
7. to serve as a resource to the research community, communicating and advising researchers on guidelines, procedures and other matters relating to the conduct of research with humans;
8. to meet regularly to discharge their responsibilities, and to keep and maintain minutes of such meetings; with the documentation being accessible to researchers, as it pertains to their application, and to "authorized" representatives of the institution and funding agencies;
9. to liaise with REBs of affiliated institutions to optimize efficiencies, co-ordinate activities and to ensure consistency of decisions;
10. to keep the Vice-President, Research & International Affairs informed of substantive issues in terms of policy, process and compliance and to submit a written report annually on the activities of the MREB to the Vice President, Research and International Affairs; and.
11. to implement and monitor the final decision of the Appeal Panel on behalf of the Research Ethics Appeal Board.

## McMaster Research Ethics Board Terms of Reference

### **Mission**

The mission of the McMaster Research Ethics Board (MREB) is to ensure research involving human participants carried out under the auspices of McMaster University is of the highest quality, is conducted to protect the interests of human participants and of society and is in compliance with the Tri Council Policy Statement: Ethical Conduct for Research Involving Humans. The REB shall function as an autonomous entity.

### **Terms of Reference**

#### **Membership**

The MREB shall consist of at least 10 members and shall have a sufficient number of members to allow for a reasonable review workload for all members. The MREB membership shall comply with the TCPS membership requirements in [Article 6.4](#) and shall include adequate expertise in the relevant research disciplines. MREB members shall be without conflict of interest in the review process and shall disclose actual, perceived or potential conflicts of interest at the outset of a review.

The MREB members shall be appointed by the President, on the recommendation of the Vice-President, Research, following consultation with the current MREB Chair, and including consultation with Faculty Deans and program and department Chairs as applicable. MREB members shall serve, normally, for staggered three year terms, once renewable. The Chair and Vice-Chair(s) shall be appointed by the President and shall serve, normally, for a term of three years, once renewable. The recruitment of the Chair or Vice-Chair(s) shall be the responsibility of the Vice-President, Research, and may be in consultation with the current Chair and Vice-Chair(s) as well as the ethics office staff. It is preferable, but not mandatory, that the new Chair or Vice-Chair(s) be appointed from among the current, appointed MREB members.

#### **Quorum**

For full board ethics review of proposed research, quorum shall be constituted by meeting the TCPS quorum requirements ([Article 6.9](#)) and having at least 40% of the membership present for the discussion and vote.

MREB November 28, 2018

For conducting general business (e.g. approving agenda/minutes/guidelines), quorum shall be constituted by meeting the TCPS quorum requirements ([Article 6.9](#)).

The MREB will also meet any additional quorum requirements resulting from specific funding sources or local regulations on a case by case basis. For instance, for full board review of proposed research with United States government funding, MREB will meet the 50% plus one quorum threshold required by US regulations (in addition to the TCPS requirements).

### **Mandate**

1. To keep current on ethical issues related to research involving human participants, to educate the University community on these issues and to formulate policies and guidelines on these matters.
2. To review (using a proportionate approach), approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants conducted under the auspices of McMaster University. This includes research by anyone affiliated with McMaster and/or research making use of McMaster resources. Research conducted through the Faculty of Health Sciences is reviewed by the Hamilton Integrated Research Ethics Board (with an allowance for MREB to review FHS research, and HiREB to review non-FHS research, if appropriate based on the study details).
3. To assess and limit the risks to participants in research involving humans. Where there is more than minimal risk identified, the REB shall satisfy itself that the design of a research project is capable of addressing the questions being asked in the research.
4. To monitor ongoing projects, and to establish procedures for the review of ongoing research projects and requests for changes to previously approved research.
5. To develop policies and procedures for assessing and approving undergraduate student research.

MREB November 28, 2018

6. To serve as a resource to the research community, communicating and advising researchers on guidelines, procedures and other matters relating to the conduct of research involving human participants.
7. To meet regularly to discharge their responsibilities, and to keep and maintain minutes of such meetings; with the documentation being accessible to researchers, as it pertains to their application, and to "authorized" representatives of the institution and funding agencies, and in accordance with relevant legislation including, but not limited to, the Freedom of Information and Protection of Privacy Act (FIPPA).
8. To liaise with REBs of affiliated institutions to optimize efficiencies, co-ordinate activities and to ensure consistency of decisions.
9. To keep the Vice-President, Research informed of substantive issues in terms of policy, process and compliance, and to submit a written report annually on the activities of the MREB to the Vice President, Research.
10. To implement and monitor the final decision of the Appeal Panel on behalf of the Research Ethics Standing Appeal Board.



## McMaster Research Ethics Board Terms of Reference

### Mission

The mission of the McMaster Research Ethics Board (MREB) is to ensure research involving human participants carried out under the auspices of McMaster University is of the highest quality, is conducted to protect the interests of human participants and of society and is in compliance with the Tri Council Policy Statement: Ethical Conduct for Research Involving Humans. The REB shall function as an autonomous entity.

### Terms of Reference

#### Membership

The MREB shall consist of at least 10 members and shall have a sufficient number of members to allow for a reasonable review workload for all members. The MREB membership shall comply with the TCPS membership requirements in [Article 6.4](#) and shall include adequate expertise in the relevant research disciplines. MREB members shall be without conflict of interest in the review process and shall disclose actual, perceived or potential conflicts of interest at the outset of a review.

**Commented [NC1]: REVISED membership section:** The main change being the reference to the TCPS and Art. 6.4 – instead of spelling out all the requirements. This ties the membership to the article itself, in case there are changes in the TCPS.

The MREB members shall be appointed by the President, on the recommendation of the Vice-President, Research, following consultation with the current MREB Chair, and including consultation with Faculty Deans and program and department Chairs as applicable. MREB members shall serve, normally, for staggered three year terms, once renewable. The Chair and Vice-Chair(s) shall be appointed by the President and shall serve, normally, for a term of three years, once renewable. **The recruitment of the Chair or Vice-Chair(s) shall be the responsibility of the Vice-President, Research, and may be in consultation with the current Chair and Vice-Chair(s) as well as the ethics office staff. It is preferable, but not mandatory, that the new Chair or Vice-Chair(s) be appointed from among the current, appointed MREB members.**

**Commented [NC2]:** Made clear the recruitment of new Chairs is under the direction of the office of the VPR.

**Commented [NC3]:** Revised so it is not mandatory for the Chair to be from the current membership. As it may be the case that no one currently on the board wants to be Chair.

#### Quorum

For full board ethics review of proposed research, quorum shall be constituted by meeting the **TCPS quorum requirements ([Article 6.9](#))** and having at least 40% of the membership present for the discussion and vote.

**Commented [NC4]: NEW quorum section:** Major change to the ToR is the quorum section, which outlines three levels of quorum and drops the 50% requirement for regular non-review business (e.g. approving minutes). The full board review requirement dropped from 50% to 40%, to enable reviews to take place and avoid researchers having to wait another month.

**Commented [NC5]:** As with membership, just referring to the relevant article instead of listing every requirement. Links embedded for easy access to the TCPS requirements.

MREB November 28, 2018

For conducting general business (e.g. approving agenda/minutes/guidelines), quorum shall be constituted by meeting the TCPS quorum requirements (Article 6.9).

**Commented [NC6]:** With this change, to pass minutes, all that is needed is five people, both men and women, at least one member knowledgeable in ethics, at least one community member, and at least two members with expertise in relevant research fields (so at least two faculty/students). Basically art. 6.9 states minimum quorum = the art. 6.4 membership requirements.

The MREB will also meet any additional quorum requirements resulting from specific funding sources or local regulations on a case by case basis. For instance, for full board review of proposed research with United States government funding, MREB will meet the 50% plus one quorum threshold required by US regulations (in addition to the TCPS requirements).

**Commented [NC7]:** Revised to open up the possibility of modified quorum requirements for reasons beyond US funding, as per suggestion of the AVPR. Included the US example as it is the most likely scenario.

### Mandate

**Commented [NC8]:** The original #6 below was removed. This was MREB serving as the appeal board for SREC decisions.

1. To keep current on ethical issues related to research involving human participants, to educate the University community on these issues and to formulate policies and guidelines on these matters.

The revised appeal Board ToR makes the appeal board the board that reviews all appeals. MREB will no longer be the appeal board for SREC reviews due to COI. (as stated during the appeal board ToR revisions – the chances of a SREC review being appealed are essentially nil since anything more sensitive/complex gets bumped to MREB anyway).

2. To review (using a proportionate approach), approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants conducted under the auspices of McMaster University. This includes research by anyone affiliated with McMaster and/or research making use of McMaster resources.

**Commented [NC9]:** Mandate based on TCPS, Art. 6.1, see also interpretation #1 in multi-jurisdictional research for definition of university "resources".

Research conducted through the Faculty of Health Sciences is reviewed by the Hamilton Integrated Research Ethics Board (with an allowance for MREB to review FHS research, and HiREB to review non-FHS research, if appropriate based on the study details).

<http://www.pre.ethics.gc.ca/eng/policy-politique/interpretations/multi-jurisdictional-plusieurs-autorites/>

3. To assess and limit the risks to participants in research involving humans. Where there is more than minimal risk identified, the REB shall satisfy itself that the design of a research project is capable of addressing the questions being asked in the research.

**Commented [NC10]:** This longer statement replaces the "non-medical" designation. Originally, it was non-medical in that FHS studies that didn't involve a medical procedure (e.g. pedagogical study) were reviewed by MREB. But at some point FHS decided that all FHS research should be reviewed by their board – so the "non-medical" distinction on what is reviewed by which REB is not really accurate anymore.

4. To monitor ongoing projects, and to establish procedures for the review of ongoing research projects and requests for changes to previously approved research.

5. To develop policies and procedures for assessing and approving undergraduate student research.

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6. To serve as a resource to the research community, communicating and advising researchers on guidelines, procedures and other matters relating to the conduct of research involving human participants.

7. To meet regularly to discharge their responsibilities, and to keep and maintain minutes of such meetings; with the documentation being accessible to researchers, as it pertains to their application, and to "authorized" representatives of the institution and funding agencies, and in accordance with relevant legislation including, but not limited to, the Freedom of Information and Protection of Privacy Act (FIPPA).

Commented [NC11]: Added at the suggestion of the Privacy Officer.

8. To liaise with REBs of affiliated institutions to optimize efficiencies, co-ordinate activities and to ensure consistency of decisions.

9. To keep the Vice-President, Research informed of substantive issues in terms of policy, process and compliance, and to submit a written report annually on the activities of the MREB to the Vice President, Research.

10. To implement and monitor the final decision of the Appeal Panel on behalf of the Research Ethics Standing Appeal Board.

MREB November 28, 2018

# McMaster University & Affiliated Hospitals Appeals Board Terms of Reference

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## **Structure of Research Ethics Appeal Board**

### **1. Research Ethics Appeal Board Membership**

The Appeal Board, from which the Appeal Panel will be formed, shall consist of a minimum of eight (8) members, including both women and men, drawn from the broad range of disciplines and faculties in which research with human participants takes place. All members of the Appeal Board will have the appropriate background and be without conflict of interest. Membership will include at least:

1. three McMaster University faculty members with broad expertise in the methods or in the areas of research that are covered by the REB(s);
2. one McMaster University faculty member knowledgeable in ethics;
3. one member knowledgeable in the law relevant to biomedical research;
4. a previous member of the MREB; and
5. two members from the community external to the University.

Members shall be appointed by The President, upon the recommendation of the Vice President, Research and International Affairs, for staggered terms of three years, renewable.

### **2. Quorum**

For meetings of the Board, at least 50 per cent of the membership of the Board shall constitute a quorum.

### **3. Chair and Vice-Chair**

A Chair and a Vice Chair shall be appointed from the Board membership by the President, upon the recommendation of the Vice President, Research and International Affairs. These appointments will be for two years, renewable terms.

## **Appeal Board's Terms of Reference**

The mandate of the Appeal Board is:

1. to hear, through an Appeal Panel, appeals of decisions reached by the MREB, HHS/FHS REB or the SJH REB, provided that decisions rendered by the latter two REBs are specific to an appeal by a McMaster University faculty member under the auspices of their University appointment;

2. to submit annually to the Vice President, Research & International Affairs a written report on the appeals received and considered by the Appeal Panel and
3. to assess periodically the appeal process and to make recommendations to the President through the Vice President, Research & International Affairs, for modifications, as appropriate.

#### **Appeal Panel's Structure**

To hear an appeal, the Chair or Vice-Chair shall select four members, including both women and men, with a minimum of one and up to two McMaster University appointed faculty members, from the Appeal Board membership and, together, these five shall constitute the Appeal Panel. Composition of the Appeal Panel shall meet the requirements of the Tri-Council Policy Statement. Chairs of the REBs may serve only on an Appeal Panel reviewing a decision not made by their respective REB.

The members of the Appeal Panel shall have appropriate background and be without conflict of interest. In the case of a conflict of interest or absence on the part of the Chair, the Vice Chair will chair the Appeal Panel.

#### **Appeal Panel's Terms of Reference**

The mandate of the Appeal Panel is:

1. to review the decision made by the REB which has been appealed by a researcher;
2. to conduct a full review of the application and associated documentation<sup>(1)</sup> in order to reach an independent decision;
3. to render a final and binding decision, by majority vote, which may either
  - a) uphold the original decision,
  - b) modify the original decision or
  - c) impose specific conditions for approval of the project.

In the event a majority vote is not rendered, the Chair or the Vice-Chair shall cast the deciding vote.

4. to communicate the decision, in writing and with reasons, to the researcher, Chair of the REB and to all members of the Appeal Board, and
5. to provide advice, in the event of 3.b) or 3.c) above, to the REB charged with the responsibility for implementing and monitoring the final decision of the Appeal Panel.

**(1)** may include the original ethics application, the original REB decision, all subsequent written communications, documents and records, including REB Minutes pertaining to the submission, a copy of a research proposal for funding of the proposed research, if applicable, relevant references or copies of pertinent guidelines, internal and external policies and legislation.

### **Single, Regional University/Hospital Appeal Process**

Recognizing the merits of and mutual interest expressed in having a single, university/hospital appeal process for McMaster University, Hamilton Health Sciences (HHS) and St. Joseph's Healthcare, Hamilton (SJH), provision is made for McMaster University to broaden, through agreements with its affiliated hospitals, the mandate and structure of the Standing Appeal Board. Such agreements between McMaster University and its affiliated hospitals will enable the mandate and structure of and terms of reference for the Standing Appeal Board and Appeal Panel to be expanded to include the adjudication of any appeal of a decision reached by the joint HHS/FHS REB and the SJH REB and to include appropriate representation from these REBs and from HHS and SJH.

#### **1. McMaster University and Affiliated Hospital Agreements**

The agreement(s) between McMaster University and its affiliated hospital(s) shall define communication and repository procedures and designated administrative resources.

#### **2. Ex-officio Members**

Subject to the execution of agreement(s) with the affiliated hospital(s), the Chairs of the MREB, HHS/FHS REB and SJH REB will serve as ex-officio members on the Appeal Board. Chairs of the REBs may serve only on an Appeal Panel reviewing a decision not made by their respective REB.

#### **3. Chair and Vice-Chair of Research Ethics Appeal Board**

Subject to the execution of agreement(s) with the affiliated hospital(s), the Vice-President, Research and International Affairs shall consult with the heads of the affiliated hospitals prior to making appointment recommendations.

#### **4. Affiliated Hospital Representation on the Research Ethics Appeal Board**

Representation from affiliated hospitals will be added to the membership of the Appeal Board under separate agreements and will include at least:

- a. a previous member from the joint HHS/FHS REB and SJH REB;
- b. one member from each hospital and
- c. the Chairs of the joint HHS/FHS and the SJH REBs, as per 2. Ex-officio Members above.

The members from the hospitals (item 4. above) will be appointed by their respective Trustees, upon the recommendation of their respective Chief of Staff.

**5. Composition of the Complete Single Regional University / Hospital Appeal Board**

Subject to the execution of agreements between McMaster University and its affiliated hospitals, the full composition of the Single Regional University / Hospital Appeal Board shall constitute at least the following 15 positions:

Ex-Officio Members:

The chairs of the MREB, the HHS/FHS REB and the SJH/REB

Appointed Members:

Three faculty members expert in methods of research

One faculty member knowledgeable in ethics

One faculty member knowledgeable in the law relevant to biomedical research

One previous member of the MREB

One previous member of the HHS/FHS REB

One previous member of the SJH REB

One faculty member from HHS

One faculty member from SJH

Two community members

# **MCMASTER UNIVERSITY**

## **Appeal of a Research Ethics Board Decision**

### **Terms of Reference – Research Ethics Standing Appeal Board**

A Standing Appeal Board shall be established by the President of McMaster University to adjudicate any appeal of a negative decision, concerning a research protocol, reached by the McMaster University Research Ethics Board (MREB), one of the Student Research Ethics Committees (SRECs), the Hamilton Integrated Research Ethics Board (HiREB), or the Student Research Committee (SRC) of the HiREB.

The Research Ethics Boards and Appeal Board are guided by the Tri-Council Policy Statement (TCPS) in its most current form and principles of natural justice in their decision-making. Such principles include providing a reasonable opportunity for the researcher to be heard, a written explanation of the reasons for opinions or decisions, an opportunity for rebuttal, fair and impartial judgment, and reasoned and written grounds for the decisions. The appeal process is not a substitute for Research Ethics Boards (REBs) and researchers to work closely together to ensure high-quality ethical research, nor is it a forum to merely seek a second opinion.

To this end, the TCPS and REBs encourage ongoing discussion with researchers prior to the submission of a new human ethics application and during the review process, with the provision for reconsideration of a Research Ethics Board decision affecting a research project. The researcher and the REB must have fully exhausted the reconsideration process, and the REB must have issued a final decision before the researcher initiates an appeal through the established appeal mechanism. Such appeals will be considered by an Appeal Panel, drawn from the membership of the Standing Appeal Board as defined below. The Terms of Reference and the Structure of the Appeal Panel are outlined later in this document.

The mandate of the Standing Appeal Board is:

1. to hear appeals, through a panel of the Standing Appeal Board, of negative decisions reached by the MREB, the HiREB, or the Student Research Committee (SRC) of the HiREB, made by the researcher (i.e. the Applicant for MREB applications, and designated Local Principal Investigator [LPI]/faculty advisor for HiREB applications);
2. to submit to the McMaster University Vice President (Research), a written report on each appeal received and considered by the Standing Appeal Board; and
3. to assess periodically the appeal process and to make recommendations to the McMaster University President through the Vice President (Research) , for modifications, as appropriate.



## Structure of the Research Ethics Standing Appeal Board

### 1. Membership

The Appeal Board (from which an Appeal Panel is formed), shall consist of a minimum of nine (9) members, reflect the human diversity of the institutions, be drawn from the broad range of disciplines and Faculties in which research involving human participants takes place, and be in compliance with the TCPS membership requirements in [Article 6.4](#).

All members of the Standing Appeal Board will have the appropriate background as specified below. Membership will include at least:

- a. one member knowledgeable in ethics;
- b. one member knowledgeable in the law relevant to biomedical research;
- c. one previous member of the MREB;
- d. one previous member of the HiREB;
- e. one member from Hamilton Health Sciences Corporation (HHS);
- f. one member from St. Joseph's Healthcare Hamilton (SJHH);
- g. two faculty members from McMaster University (non-Faculty of Health Science appointment and);
- h. one member from the community external to the University, HHS, and SJHH;

At a minimum, McMaster faculty members, and HHS and SJHH members should have broad expertise in the methods or in the areas of research that are covered by the MREB and HiREB.

Members shall be appointed by the McMaster University President, upon the recommendation of the Vice-President (Research), for staggered terms of five years, once renewable. The members from the hospitals (items 1e and 1f above) will be appointed by their respective Trustees/Governors, upon the recommendation of their respective Chief/VP/Director/Chair.

### 2. Ex-officio Members of the Standing Appeal Board

The current Chairs of the MREB and HiREB will serve as ex-officio members on the Appeal Board, with non-voting privileges, and may only serve in this capacity on an Appeal Panel reviewing a decision not made by their respective REB.

### 3. Chair and Vice-Chair of the Standing Appeal Board

The Appeal Board Chair and a Vice-Chair shall be appointed from the membership of the Appeal Board by the University President, upon the recommendation of the Vice-President (Research). These appointments will be for five-year, once renewable terms. The community member external to the University, HHS, and SJHH cannot serve as Chair or Vice-Chair.

### 4. Quorum of the Appeal Board

Quorum shall be constituted by meeting the TCPS quorum requirements ([Article 6.9](#)) and having at least 50 per cent of the membership of the Board present.

## Appeal Panel Structure

To hear an appeal, the Chair of the Appeal Board (provided s/he is free of a conflict of interest regarding the REB decision under appeal), shall serve as the Panel Chair and select four members from the general Appeal Board membership. The Panel should meet the TCPS requirements for REB membership ([Art. 6.4](#)). The Panel members should have the appropriate background and be without conflict of interest relative to the research ethics decision under appeal.

If the Appeal Board Chair has a conflict of interest in relation to the REB decision under appeal, or in the absence of the Appeal Board Chair; the Vice-Chair will serve as Panel Chair.

The current HiREB Chair or current MREB Chair may only serve as a non-voting ex-officio member on an Appeal Panel that is reviewing a decision not made by their respective REB.

## Appeal Panel Terms of Reference

The mandate of the Appeal Panel is:

1. to review the decision made by the REB which has been appealed by a researcher;
2. to conduct a full review of the application and associated documentation<sup>1</sup> in order to reach an independent decision and to make every effort to reach consensus.
3. to render on behalf of the institution a final and binding decision, by majority vote, which may
  - a. approve;
  - b. approve with modifications; or
  - c. disapprove the project.

A decision should be reached by majority vote of the five individuals comprising the Appeal Panel (four members plus the Chair).

4. to communicate the Appeal Panel decision, in writing and with reasons, to the researcher; Chair of the REB; and to all members of the Appeal Board; and to fulfill the mandate of the Appeal Board, by submitting to the Vice President (Research), a written report on the appeal received and considered by the Appeal Panel of the Appeal Board. This report will be completed by the Chair or Vice-Chair of the Appeal Panel.
5. to provide advice to the REB charged with the responsibility for implementing and monitoring the final decision of the Appeal Panel, in the event the Appeal Panel's decision is to a) approve the research; or b) to approve the research with modifications.

All documents pertaining to the appeal of a MREB decision will be housed at the administrative offices of HiREB. All documents pertaining to the appeal of a HiREB decision will be housed in the administrative offices

of MREB. Paper records will be kept a minimum of one year and digital documents, including copies of paper documents, will be retained permanently.

<sup>1</sup>documents may include the original ethics application, the original REB decision, all subsequent written communications, documents and records, including portions of the REB Minutes pertaining to the submission, relevant references or copies of pertinent guidelines, internal and external policies, and legislation.

## **Appeal Procedure**

1. While the Appeal Board will be provided administrative support by the ethics office personnel of both the HiREB and the MREB, the Appeal Panel will be provided administrative support by the ethics office personnel of the REB not undergoing an appeal of one of its decisions.
2. The researcher/applicant, within thirty (30) working days of receiving a REB's final negative decision, must submit a written appeal of that decision to the administrator of the ethics office supporting that REB. That written appeal shall outline the grounds of the appeal and be accompanied by any supporting documentation held by the researcher/applicant.
3. The administrator of the ethics office supporting the REB that made the decision under appeal will in a timely manner: a) acknowledge receipt of the appeal in writing to the researcher/applicant; b) forward a copy of the written appeal to the Chair of the Appeal Board and to the Chair of the REB that made the decision.
4. The REB will be required to provide a written response to the appeal within ten (10) working days of receipt of the appeal request. The REB's written response to the appeal must be sent to the administrator of the alternate REB supporting the Appeal Board who will send it to the Appeal Board Chair.
5. The Appeal Board Chair or, the Vice-Chair as described in the section above entitled "Appeal Panel Structure", will select members of the Panel.
6. The ethics office administrative staff providing administrative support to the Appeal Panel will request the REB whose decision is being appealed, to provide all relevant documentation and then assemble and distribute that supporting documentation, including the response by the REB whose decision is being appealed; to the Appeal Panel Chair and members for review, along with a copy of the complete documents package sent to the researcher/applicant and the REB. Additional appeal-related documents may include the original ethics application, original REB decision, all subsequent written communications, documents and records, including REB Minutes pertaining to the submission, relevant references or copies of pertinent guidelines, internal and external policies, and legislation.
7. A meeting of the Appeal Panel, with provision for presentations by the researcher/applicant and the REB Chair/REB representative, will be convened by the Appeal Panel, within thirty (30) working days of receipt of the appeal by the REB that rendered the decision. Both parties may be accompanied by a colleague of their choice.
8. Meetings of an Appeal Panel will be conducted in accordance with the principles of natural justice. Both

the researcher/applicant and the REB will have the right to speak to the Panel regarding the issues raised in the distributed documentation. The Appeal Panel is free to ask questions at any time during the presentations.

9. The following procedure is a natural sequence, which any Appeal Panel may vary at its discretion.
  - a. The researcher presents the reasons for the appeal and speaks to the issues.
  - b. The REB Chair presents the reasons for the decision of the REB and speaks to the issues.
  - c. Neither the researcher/applicant nor the REB Chair/REB representative shall be present when the Appeal Panel deliberates and makes a decision.
10. The Appeal Panel, having heard the oral presentations of both parties and having reviewed the written supporting documentation, shall be the sole judge of the facts and shall render a decision which is fair and just in the circumstances.
11. The majority decision of the Appeal Panel will be final and binding and will be communicated to the researcher/applicant and the REB within ten (10) working days of the meeting.
12. The Chair or Vice-Chair of the Appeal Panel will communicate the decision of the Appeal Panel in writing, including a summary of issues, factual findings, conclusions and reasons for the decision to the researcher, the Appeal Board, and the Chair of the REB. The Chair of the REB that rendered the original decision will be responsible for implementation and follow-up through the REB and such other parties as it deems appropriate.
13. The Chair or Vice-Chair of the Appeal Board shall submit to the McMaster University Vice President, Research, a written report on each appeal received and considered by the Appeal Board.

## MCMASTER UNIVERSITY Appeal of a Research Ethics Board Decision

### Terms of Reference – Research Ethics Standing Appeal Board

A Standing Appeal Board shall be established by the President of McMaster University to adjudicate any appeal of a negative decision, concerning a research protocol, reached by the McMaster University Research Ethics Board (MREB), one of the Student Research Ethics Committees (SRECs), the Hamilton Integrated Research Ethics Board (HiREB), or the Student Research Committee (SRC) of the HiREB.

The Research Ethics Boards and Appeal Board are guided by the Tri-Council Policy Statement (TCPS) in its most current form and principles of natural justice in their decision-making. Such principles include providing a reasonable opportunity for the researcher to be heard, a written explanation of the reasons for opinions or decisions, an opportunity for rebuttal, fair and impartial judgment, and reasoned and written grounds for the decisions. The appeal process is not a substitute for Research Ethics Boards (REBs) and researchers to work closely together to ensure high-quality ethical research, nor is it a forum to merely seek a second opinion.

To this end, the TCPS and REBs encourage ongoing discussion with researchers prior to the submission of a new human ethics application and during the review process, with the provision for reconsideration of a Research Ethics Board decision affecting a research project. The researcher and the REB must have fully exhausted the reconsideration process, and the REB must have issued a final decision before the researcher initiates an appeal through the established appeal mechanism. Such appeals will be considered by an Appeal Panel, drawn from the membership of the Standing Appeal Board as defined below. The Terms of Reference and the Structure of the Appeal Panel are outlined later in this document.

The mandate of the Standing Appeal Board is:

1. to hear appeals, through a panel of the Standing Appeal Board, of negative decisions reached by the MREB, the HiREB, or the Student Research Committee (SRC) of the HiREB, made by the researcher (i.e. the Applicant for MREB applications, and designated Local Principal Investigator [LPI]/faculty advisor for HiREB applications);
2. to submit to the McMaster University Vice President (Research), a written report on each appeal received and considered by the Standing Appeal Board; and
3. to assess periodically the appeal process and to make recommendations to the McMaster University President through the Vice President (Research), for modifications, as appropriate.

**Commented [NC1]:** In addition to the specific comments on revisions below, the main revisions were updates to language that pre-dated the formation of HiREB, permanent inclusion of hospital representatives on the standing appeal board, and increase in the term length of the board members from 2/3 to 5 years, and the addition of an appeal procedure section.

**Commented [NC2]:** Following Christi Garneau's advice, and after confirming with the MREB Chairs, appeals for SREC decisions will go straight to the appeal board and not to MREB. This also then follows the same procedure as HiREB's SRC.

## Structure of the Research Ethics Standing Appeal Board

### 1. Membership

The Appeal Board (from which an Appeal Panel is formed), shall consist of a minimum of nine (9) members, reflect the human diversity of the institutions, be drawn from the broad range of disciplines and Faculties in which research involving human participants takes place, and be in compliance with the TCPS membership requirements in [Article 6.4](#).

All members of the Standing Appeal Board will have the appropriate background as specified below. Membership will include at least:

- a. one member knowledgeable in ethics;
- b. one member knowledgeable in the law relevant to biomedical research;
- c. one previous member of the MREB;
- d. one previous member of the HiREB;
- e. one member from Hamilton Health Sciences Corporation (HHS);
- f. one member from St. Joseph's Healthcare Hamilton (SJHH);
- g. two faculty members from McMaster University (non-Faculty of Health Science appointment and;
- h. one member from the community external to the University, HHS, and SJHH;

At a minimum, McMaster faculty members, and HHS and SJHH members should have broad expertise in the methods or in the areas of research that are covered by the MREB and HiREB.

Members shall be appointed by the McMaster University President, upon the recommendation of the Vice-President (Research), for staggered terms of five years, once renewable. The members from the hospitals (items 1e and 1f above) will be appointed by their respective Trustees/Governors, upon the recommendation of their respective Chief/VP/Director/Chair.

### 2. Ex-officio Members of the Standing Appeal Board

The current Chairs of the MREB and HiREB will serve as ex-officio members on the Appeal Board, with non-voting privileges, and may only serve in this capacity on an Appeal Panel reviewing a decision not made by their respective REB.

### 3. Chair and Vice-Chair of the Standing Appeal Board

The Appeal Board Chair and a Vice-Chair shall be appointed from the membership of the Appeal Board by the University President, upon the recommendation of the Vice-President (Research). These appointments will be for five-year, once renewable terms. The community member external to the University, HHS, and SJHH cannot serve as Chair or Vice-Chair.

### 4. Quorum of the Appeal Board

Quorum shall be constituted by meeting the TCPS quorum requirements ([Article 6.9](#)) and having at least 50 per cent of the membership of the Board present.

**Commented [NC3]:** Revised to remove the TCPS gender requirements for membership as trying to merge the "both men and women" TCPS clause with gender inclusive language was problematic. It seemed to prioritize gender above other diversity and still retained a binary gender focus. Instead, this document can just refer to the TCPS article containing the gender clause, and let the phrase "reflect the human diversity of the institutions" call for inclusivity in membership for not only gender, but ethnicity, ability, etc. Similar edits made below.

**Commented [NC4]:** Simplified this section by linking directly to TCPS quorum requirements. In practice, the board is unlikely to meet as a full board – as the appeals are handled through the panel process.

## Appeal Panel Structure

To hear an appeal, the Chair of the Appeal Board (provided s/he is free of a conflict of interest regarding the REB decision under appeal), shall serve as the Panel Chair and select four members from the general Appeal Board membership. The Panel should meet the TCPS requirements for REB membership (Art. 6.4). The Panel members should have the appropriate background and be without conflict of interest relative to the research ethics decision under appeal.

Commented [NCS]: As above, simplified to just refer to Art. 6.4.

If the Appeal Board Chair has a conflict of interest in relation to the REB decision under appeal, or in the absence of the Appeal Board Chair; the Vice-Chair will serve as Panel Chair.

The current HiREB Chair or current MREB Chair may only serve as a non-voting ex-officio member on an Appeal Panel that is reviewing a decision not made by their respective REB.

## Appeal Panel Terms of Reference

The mandate of the Appeal Panel is:

1. to review the decision made by the REB which has been appealed by a researcher;
2. to conduct a full review of the application and associated documentation<sup>1</sup> in order to reach an independent decision and to make every effort to reach consensus.
3. to render on behalf of the institution a final and binding decision, by majority vote, which may
  - a. approve;
  - b. approve with modifications; or
  - c. disapprove the project.

A decision should be reached by majority vote of the five individuals comprising the Appeal Panel (four members plus the Chair).

4. to communicate the Appeal Panel decision, in writing and with reasons, to the researcher; Chair of the REB; and to all members of the Appeal Board; and to fulfill the mandate of the Appeal Board, by submitting to the Vice President (Research), a written report on the appeal received and considered by the Appeal Panel of the Appeal Board. This report will be completed by the Chair or Vice-Chair of the Appeal Panel.
5. to provide advice to the REB charged with the responsibility for implementing and monitoring the final decision of the Appeal Panel, in the event the Appeal Panel's decision is to a) approve the research; or b) to approve the research with modifications.

All documents pertaining to the appeal of a MREB decision will be housed at the administrative offices of HiREB. All documents pertaining to the appeal of a HiREB decision will be housed in the administrative offices

of MREB. Paper records will be kept a minimum of one year and digital documents, including copies of paper documents, will be retained permanently.

**Commented [NC6]:** There was some confusion about record retention as this section said indefinitely and #14 below said a minimum of one year. I've put them together here, differentiated between paper and digital, and deleted #14.

<sup>1</sup>documents may include the original ethics application, the original REB decision, all subsequent written communications, documents and records, including portions of the REB Minutes pertaining to the submission, relevant references or copies of pertinent guidelines, internal and external policies, and legislation.

### Appeal Procedure

1. While the Appeal Board will be provided administrative support by the ethics office personnel of both the HIREB and the MREB, the Appeal Panel will be provided administrative support by the ethics office personnel of the REB not undergoing an appeal of one of its decisions.
2. The researcher/applicant, within thirty (30) working days of receiving a REB's final negative decision, must submit a written appeal of that decision to the administrator of the ethics office supporting that REB. That written appeal shall outline the grounds of the appeal and be accompanied by any supporting documentation held by the researcher/applicant.
3. The administrator of the ethics office supporting the REB that made the decision under appeal will in a timely manner: a) acknowledge receipt of the appeal in writing to the researcher/applicant; b) forward a copy of the written appeal to the Chair of the Appeal Board and to the Chair of the REB that made the decision.
4. The REB will be required to provide a written response to the appeal within ten (10) working days of receipt of the appeal request. The REB's written response to the appeal must be sent to the administrator of the alternate REB supporting the Appeal Board who will send it to the Appeal Board Chair.
5. The Appeal Board Chair or, the Vice-Chair as described in the section above entitled "Appeal Panel Structure", will select members of the Panel.
6. The ethics office administrative staff providing administrative support to the Appeal Panel will request the REB whose decision is being appealed, to provide all relevant documentation and then assemble and distribute that supporting documentation, including the response by the REB whose decision is being appealed; to the Appeal Panel Chair and members for review, along with a copy of the complete documents package sent to the researcher/applicant and the REB. Additional appeal-related documents may include the original ethics application, original REB decision, all subsequent written communications, documents and records, including REB Minutes pertaining to the submission, relevant references or copies of pertinent guidelines, internal and external policies, and legislation.
7. A meeting of the Appeal Panel, with provision for presentations by the researcher/applicant and the REB Chair/REB representative, will be convened by the Appeal Panel, within thirty (30) working days of receipt of the appeal by the REB that rendered the decision. Both parties may be accompanied by a colleague of their choice.
8. Meetings of an Appeal Panel will be conducted in accordance with the principles of natural justice. Both



the researcher/applicant and the REB will have the right to speak to the Panel regarding the issues raised in the distributed documentation. The Appeal Panel is free to ask questions at any time during the presentations.

9. The following procedure is a natural sequence, which any Appeal Panel may vary at its discretion.
  - a. The researcher presents the reasons for the appeal and speaks to the issues.
  - b. The REB Chair presents the reasons for the decision of the REB and speaks to the issues.
  - c. Neither the researcher/applicant nor the REB Chair/REB representative shall be present when the Appeal Panel deliberates and makes a decision.
10. The Appeal Panel, having heard the oral presentations of both parties and having reviewed the written supporting documentation, shall be the sole judge of the facts and shall render a decision which is fair and just in the circumstances.
11. The majority decision of the Appeal Panel will be final and binding and will be communicated to the researcher/applicant and the REB within ten (10) working days of the meeting.
12. The Chair or Vice-Chair of the Appeal Panel will communicate the decision of the Appeal Panel in writing, including a summary of issues, factual findings, conclusions and reasons for the decision to the researcher, the Appeal Board, and the Chair of the REB. The Chair of the REB that rendered the original decision will be responsible for implementation and follow-up through the REB and such other parties as it deems appropriate.
13. The Chair or Vice-Chair of the Appeal Board shall submit to the McMaster University Vice President, Research, a written report on each appeal received and considered by the Appeal Board.