

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 documentation¹ 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.

¹documents 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.