

PROCEDURES FOR APPEALS OF DECISIONS OF RESEARCH ETHICS BOARDS I, II, III AND THE FACULTY OF AGRICULTURAL AND ENVIRONMENTAL SCIENCES RESEARCH ETHICS BOARD

The Research Ethics Appeal Committee (hereafter “Appeal Committee”) is established in accordance with the requirements of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) and the McGill Policy on the Ethical Conduct of Research Involving Human Participants to hear appeals of decisions of Research Ethics Boards (REBs) I, II, III and the Faculty of Agricultural and Environmental Sciences REB.

1. Notice of Appeal

1.1 Researchers have the right to request, and the REB has an obligation to provide, reconsideration of an REB decision. Researchers and REBs are expected to engage in meaningful discussion together to ensure high-quality ethical research. The appeal process is not a forum to merely seek a second opinion. Researchers and the REB must have fully exhausted the reconsideration process and the REB must have issued a final decision before a researcher initiates an appeal.

1.2 A Notice of Appeal must be filed with the Chair of the Advisory Council on Human Research Ethics (ACHRE) within 20 working days of the final decision of the REB. The appeal must be made in writing (in print or electronically) and must clearly state the grounds upon which the appeal is filed. An appeal made by a Principal Investigator who is a student must be supported by the faculty supervisor.

2. Composition of the Appeal Committee

The ACHRE Chair shall act as the Chair of the Appeal Committee. The Appeal Committee shall consist of the members of all the 5 McGill REBs. Members for hearing an appeal will be drawn from the Appeal Committee by the Chair of the Appeal Committee with membership configuration in accordance with the TCPS and consisting of a minimum of 8 members. When the Principal Investigator making the appeal is a student, then the ACHRE student member will also serve on the Appeal Committee. No member of the Appeal Committee hearing a particular appeal can be a member of the REB whose decision is being appealed, or can have been a member of the REB when the decision being appealed was made. The Appeal Committee may appoint *ad hoc* experts as required.

3. The Appeal

3.1 An appeal can be launched for procedural or substantive reasons. The onus is on the Principal Investigator making the appeal to justify the grounds on which the appeal is requested and to indicate any breaches to the research ethics review process or any elements of the REB decisions that are not supported by the TCPS or the McGill Policy on the Ethical Conduct of Research Involving Human Participants.

3.2 Upon receipt by the Chair of the Appeal Committee of all supporting documentation including the Notice of Appeal, all documentation provided to the REB, all correspondence between the REB and the investigator and the minutes of the REB, the Appeal Committee will normally have 30 working days to review the file and a meeting will be convened on or before the final working day.

3.3 The meeting date will be announced one week prior and both the investigator and the REB Chair or other REB member designated by the REB may appear before the Appeal Committee. Each of the parties

has the right to be assisted by an advisor who shall be a member of the McGill University community and will not receive any remuneration for acting as an advisor. None of these people can be present during the deliberations and decision-making by the Appeal Committee.

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

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

3.6 The Chair of the Appeal Committee shall provide a written decision of the Appeal Committee concerning the grounds of the appeal with copies to the investigator and the REB and within 7 working days after the meeting at which a decision was reached. The Appeal Committee may find the following:

- Approved as submitted and the negative decision of the REB is overturned.
- Declined as submitted and the negative decision of the REB is upheld.
- Modifications are proposed and the final decision is pending. In this case the investigator has 10 working days to make the requested modifications and resubmit the application to the Appeals Committee for re-review.

If the investigator does not respond to the request for modifications within the 10 working days, the Notice of Appeal will be declared declined and the negative decision of the REB upheld.

3.7 The decision of the Appeal Committee is final.

4. Responsibilities

The original REB assumes the sole responsibility for administering and monitoring a project approved by the Appeal Committee.

5. Reporting

The number of appeals made and the final decision of each will be reported in the ACHRE Annual Report.

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