

TITLE	408: Reconsideration of HREB Decisions and Appeal Process
SCOPE	All health research submitted to the Health Research Ethics Board (HREB) operating under the direct authority of the Health Research Ethics Authority (HREA)
APPROVAL AUTHORITY	Ethics Director
EFFECTIVE DATE	April 2024

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the process by which a Researcher may seek reconsideration of an REB decision or appeal the REB decision to the Research Ethics Appeal Committee.

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 RESPONSIBILITIES

HREB members, Research Ethics Office (REO) Personnel, and members of Appeal boards are responsible for ensuring that the requirements of this SOP are met.

4.0 PROCEDURE

In fulfilling its mandate, the HREB shall function impartially, provide a fair hearing to the researchers involved, and provide reasoned and appropriately documented opinions and decisions.

4.1 Reconsideration

- 4.1.1 A Researcher may request a reconsideration of a decision of the HREB and the Board shall conduct a review on receipt of the request.
- 4.1.2 In order to receive formal reconsideration, the Researcher shall submit a written request for consideration to the Ethics Director, who will direct the request to the HREB.

- 4.1.3** Reconsideration will take place at the next regularly applicable Full Board meeting.
- 4.1.5** Researchers will justify the grounds on which they request reconsideration by the HREB and indicate any alleged breaches to the established research ethics review process, as well as any elements of the HREB decision that are not supported by TCPS2 or other relevant legislation, regulation or guidance.
- 4.1.6** The Researcher may provide additional information for the HREB's consideration, and may also attend the Full Board meeting in person. At an appearance before the HREB, the Researcher may be represented by a person of his or her choice; however, the Researcher and/or representative shall not be present during the HREB's deliberations.
- 4.1.7** The Researcher shall submit any additional information for consideration on or before the application deadline for the next available Full Board meeting.

4.2 Notice of Appeal

- 4.2.1** A Researcher who wishes to appeal a decision of the HREB, including a decision on a reconsideration by it, shall apply to the Chairperson of the Appeal Panel by sending a written Notice of Appeal to the Ethics Director, who has been delegated authority by the HREA Board of Directors to receive and manage appeals as outlined in this SOP.
- 4.2.2** The Notice of Appeal will clearly state the grounds on which the appeal is being made and should be accompanied by supporting documentation. Such supporting documentation will include (but is not limited to):
 - the original ethics application;
 - the original HREB decision;
 - all subsequent written communications between the HREB and the Researcher; and
 - reference to any alleged breaches in the established research ethics review process, or to any elements of the HREB decision that are not supported by TCPS2 or other relevant legislation, regulation or guidance.
- 4.2.5** The Ethics Director will acknowledge receipt of the Notice of Appeal in writing and forward a copy of the written Notice of Appeal to the Chair of the HREA Board of Directors, the Chairperson of the Appeal Panel and the Chairperson of the HREB.
- 4.2.6** The Chairperson of the HREB will provide written acknowledgement of the Notice of Appeal and, if the Chairperson of the HREB deems it necessary, will also provide information related to the HREB decision.
- 4.2.7** The Chairperson of the HREB will send the response and information to the Ethics Director, who will forward a copy to the Chair of the HREA Board of Directors, the Chairperson of the Appeal Panel, and the Researcher.

4.3 Composition of the Appeal Panel and Appeal Boards

- 4.3.1** The HREA Board of Directors, following consultation with the Minister of Health and Community Services, the President of the Memorial University of Newfoundland and the Chief Executive Officer of the Eastern Regional Health Authority, shall appoint an Appeal Panel of persons to act as members of Appeal Boards.
- 4.3.2** One of the persons appointed to the Appeal Panel shall be appointed by the HREA Board of Directors as Chairperson of the Appeal Panel.
- 4.3.3** Persons appointed to the Appeal Panel shall not be members of the HREA Board of Directors, the HREB or a research ethics body approved by the HREA Board of Directors.
- 4.3.4** Members of the Appeal Panel shall be appointed for a 3-year term and are eligible for reappointment.
- 4.3.5** Upon receipt of a Notice of Appeal, the Chairperson of the Appeal Panel shall appoint an Appeal Board consisting of 5 members of the Panel for the purpose of hearing the appeal.
- 4.3.6** In appointing an Appeal Board the Chairperson of the Appeal Panel shall have regard to the subject matter of the appeal and the need for a range of expertise and knowledge similar to that of the HREB and which meets the procedural requirements of the Tri-Council Policy Statement (TCPS2).
- 4.3.7** The Appeal Board will appoint ad hoc experts as required.
- 4.3.8** Members of the Appeal Board must all be free of conflicts of interest in relation to the study under appeal. In addition, no member of the Appeal Board may be a member of the HREB whose decision is under appeal, or may have been a member of the HREB when the decision under appeal was originally made.
- 4.3.9** The Appeal Board will be appointed on an ad hoc basis.
- 4.3.10** The Appeal Board will appoint one of its members to serve as Chairperson for the conduct of the appeal.

4.4 The Appeal

- 4.4.1** The Appeal Board shall have the authority to review decisions made by the HREB. In so doing, it may uphold the appeal and substitute the decision it considers appropriate or it may dismiss the appeal. Its decision shall be binding on the Researcher and the HREB.
- 4.4.2** The Ethics Director will assemble and distribute the Notice of Appeal and supporting

documentation (including the HREB minutes pertaining to the submission) to the Appeal Board for review, as well as a copy to both the Chairperson of the HREB whose decision is under review and the Researcher.

- 4.4.3** A meeting of the Appeal Board, with provision for presentations by both the Researcher and the HREB Chairperson (or other representatives of the HREB as delegated by the Chairperson), will be organized by the REO. Both parties may be accompanied by a colleague of their choice who will not participate in the meeting.
- 4.4.4** Both the Researcher and the HREB representative have the right to speak to issues raised in the Notice of Appeal and supporting documentation, and the Appeal Board may ask questions throughout the process. Neither party shall be present when the Appeal Board deliberates and makes a decision.
- 4.4.5** The majority decision of the Appeal Board will be binding.
- 4.4.6** The Chairperson of the Appeal Board will communicate the decision of the Appeal Board in writing, including a summary of the issues, factual findings, conclusions and reasons for the decision to the Researcher, the Chairperson of the HREB, the Ethics Director and the Chair of the HREA Board of Directors.
- 4.4.7** The Chairperson of the HREB will be responsible for any implementation and follow up required through the HREB.
- 4.4.8** A Researcher who wishes to appeal from a decision of the Appeal Board shall apply to the Trial Division in accordance with section 18 of the HREA Act.

5.0 REFERENCES

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 6: [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 \(2022\) \(ethics.gc.ca\)](https://www.ethics.gc.ca)

Health Research Ethics Authority (HREA) Act, Section 13-18: [SNL2006 CHAPTER H-1.2 - HEALTH RESEARCH ETHICS AUTHORITY ACT \(assembly.nl.ca\)](https://www.assembly.nl.ca)