

Document Title	PRC Policy on Appeal of CHIPER Decisions
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Approving Body	Provincial RITHIM Committee (PRC)
Responsible Officer	Director, RITHIM

# **1** INTRODUCTION

The Tri-council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) provides for the appeal of a decision taken by a research ethics board. Accordingly, this policy sets out the procedures for the appeal of CHIPER decisions.

# 2 APPEAL OF CHIPER DECISIONS

- 2.1 Researchers must have exhausted the reconsideration process before submitting an appeal. Every effort will be made to resolve disagreements between a researcher and CHIPER through deliberation, consultation, and advice without the need for a formal appeal.
- 2.2 The appeal process is not intended simply to provide the means for a "second opinion." Rather, the request for an appeal must indicate the reasons for the appeal, which may include a negative decision but may not be based on any conditions imposed by CHIPER.
- 2.3 If, after reconsideration by CHIPER, a researcher wishes to appeal a CHIPER negative decision, a formal request for appeal of the CHIPER decision may be made within ten (10) business days following receipt of the CHIPER decision to uphold its decision.
- 2.4 The researcher must submit a letter of appeal to the Director of RITHIM, who has delegated authority from the Provincial RITHIM Committee, and who serves as an *ex officio* member and is the Chair of the Standing Committee on Appeals.
- 2.5 It is the responsibility of the researcher to indicate the alleged breaches in CHIPER's review process (procedural grounds), including any breaches of the procedures supported by the Tricouncil Policy Statement: Research Involving Human Subjects (TCPS2). If the reason for the appeal is based on the substance of the project about which the researcher and CHIPER did not agree, this must be fully documented.
- 2.6 <u>THE APPEAL APPLICATION</u>: A researcher's appeal must include the following:



- The original application submitted, along with any amendments made during the reconsideration process;
- The correspondence from the CHIPER Chair in which the committee's original decision (and reasons) were communicated;
- The correspondence from the CHIPER Chair in which the committee's decision (and reasons) following reconsideration were communicated; and
- The grounds of the appeal (procedural and/or substantive).
- 2.7 The Director of RITHIM will send a letter acknowledging receipt of the appeal.
- 2.8 The Director of RITHIM will convene the Provincial RITHIM Committee's Standing Committee on Appeals expeditiously following receipt of the appeal, normally within ten (10) business days.

### 2.9 <u>MEMBERSHIP OF THE STANDING COMMITTEE ON APPEALS</u>:

- 2.9.1 The Standing Committee on Appeals includes the following individuals:
  - The Director of RITHIM, ex officio (who serves as the chair);
  - The Chair of the CHIPER research ethics board who was not involved in the original review (i.e., the Biomedical Research Ethics Board (BREB) Chair for Health Research Ethics Board (HREB) reviews and the HREB Chair for BREB reviews), ex officio. If either the BREB or HREB Chair is in conflict, the Vice-Chair may serve in their place;
  - The CHIPER Program Officer, ex officio;
  - Two CHIPER members with broad experience in the methods or in the area covered by the research approval that is being appealed, who were not involved in the original review;
  - Two members of the Provincial RITHIM Committee, representing different institutional affiliations and disciplines, at least one of which has expertise in law and/or ethics and/or privacy; and
  - One CHIPER member who is a public (community) member, and who was not involved in the original review.

In keeping with RITHIM's commitment to equity, diversity, and inclusion, the membership of the Standing Committee on Appeals will include individuals from diverse backgrounds.

The Director of RITHIM shall ensure that the members of the Standing Committee on Appeals are free of any conflicts of interest with respect to the appeal application.

## 2.10 ELIGIBILITY FOR APPEAL:

Upon receipt of a request for appeal, the Director of RITHIM; the Chair of the CHIPER research ethics board who was not involved in the original review; and the CHIPER Program Officer shall determine whether the requested appeal relates to an appealable matter as outlined in section 2.5.



### 2.11 <u>APPEAL PROCESS:</u>

The Director of RITHIM shall determine the process of the appeal, in a manner consistent with the principles of natural justice, including:

- Date and place;
- Any expert assistance required;
- Any witnesses who may be called;
- Any disclosure requirements;
- Any deadlines; and
- Any other procedural matters.

#### 2.12 DECISIONS AND COMMUNICATION OF THE STANDING COMMITTEE ON APPEALS:

- 2.12.1 The Standing Committee on Appeals is empowered to review decisions of CHIPER that have been appealed. The Standing Committee on Appeals may approve, disapprove or request modifications to the research project. The decision of the Standing Committee on Appeals is final and binding.
- 2.12.2 The decision of the Standing Committee on Appeals will be communicated to the researcher by the Standing Committee on Appeals Chair within five (5) business days following its meeting.
- 2.12.3 The Chair of the Standing Committee on Appeals will provide a report to the Chair of the Provincial RITHIM Committee summarizing its deliberations (i.e., a summary of the issues, factual evidence, conclusions, and the reasons for its decision).
- 2.12.4 The report of the Chair of the Standing Committee on Appeals will be retained by the RITHIM office, in accordance with its procedures for document management (N2/CAREB SOP 303).