



SOP Number and Title	1.5 Reconsideration and Appeal of CHIPER Decisions
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Approving Body	Provincial RITHIM Committee
Responsible Officer	Director, RITHIM

## 1 INTRODUCTION

The Tri-council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) (2018) provides for the reconsideration and appeal of a decision taken by a research ethics board. Accordingly, this policy sets out the procedures for the reconsideration and appeal of CHIPER decisions.

## 2 RECONSIDERATION OF CHIPER DECISIONS

- 2.1 In the event that a research protocol is not approved by a CHIPER Board, the researcher may request that the CHIPER Board reconsider its decision. Requests for reconsideration must be submitted in writing within five (5) business days after the CHIPER Board's decision is communicated to the researcher. The researcher's request for reconsideration must be submitted to RITHIM's Research Ethics and Privacy Officer, and will include the reasons for the request for reconsideration (i.e., procedural or substantive grounds).
- 2.2 All efforts should be made by the CHIPER Board (through its Chair or designate) and the researcher to achieve a mutually agreed upon protocol that is both scientifically and ethically acceptable (including matters related to privacy), and acceptable at the institution(s) where the research is proposed to be conducted.
- 2.3 If the CHIPER Chair and researcher are unable to reach agreement, the CHIPER Chair will reconvene the CHIPER Board to review the protocol (or bring the reconsideration to the CHIPER Board at its next full board meeting). The researcher will be given five (5) business days' notice of the CHIPER Board meeting, and the researcher will have an opportunity to provide additional information to, and answer questions from, the CHIPER Board.
- 2.3 If agreement is not reached and the protocol is still deemed to be unsatisfactory, the CHIPER Board (through its Chair or designate) shall uphold its decision to disapprove the application, and



communicate this in writing to the researcher. Such communication shall be sent within five (5) business days of the Board's reconsideration meeting.

### 3 APPEAL OF CHIPER DECISIONS

3.1 Researchers must have exhausted the reconsideration process before submitting an appeal. 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.

3.2 If, after reconsideration by the CHIPER Board, a researcher wishes to appeal the rejection of a protocol, a formal request for appeal of the CHIPER decision may be made within ten (10) business days following receipt of correspondence from the CHIPER Chair.

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.

The onus is on the researcher to indicate the alleged breaches in the CHIPER Board's review process (procedural grounds), including any breaches of the procedures supported by the Tri-council Policy Statement: Research Involving Human Subjects (TCPS2) (2018). If the reason for the appeal is based on the substance of the protocol about which the researcher and the CHIPER Board did not agree, this must be fully documented.

3.2 THE APPEAL APPLICATION: 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).

3.4 The Director of RITHIM will send a letter acknowledging receipt of the appeal.

3.5 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.

3.6 MEMBERSHIP OF THE STANDING COMMITTEE ON APPEALS:

3.6.1 The Standing Committee on Appeals includes the following individuals:

- The Manager of RITHIM, *ex officio* (who serves as the chair);
- The Chairs of the CHIPER Biomedical Board and the CHIPER Health Board, *ex officio*;
- The Research and Privacy Officer, RITHIM, *ex officio*;



- Two members of the CHIPER Roster with broad experience in the methods or in the area covered by the research approval that is being appealed, and 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 member of the Provincial RITHIM Committee who is a public (community) member

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 the appeal application.

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

- 3.8.1 The Standing Committee on Appeals is empowered to review decisions of the CHIPER Board that have been appealed. The Standing Committee on Appeals may approve, disapprove or request modifications to the research protocol. The decision of the Standing Committee on Appeals is final and binding.
- 3.8.2 The decision of the Standing Committee on Appeals will be communicated to the researcher within five (5) business days following its meeting.
- 3.8.3 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).
- 3.8.4 The report of the Chair of the Standing Committee on Appeals will be retained in RITHIM's office, in accordance with its procedures for document management (N2/CAREB SOP 303.003).