

THE UNIVERSITY OF WINNIPEG

UW-UHREB 2.001	Reconsideration and Appeal of UHREB Decisions
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Approving Body	
Responsible Officer	Vice-President, Research and Innovation

1. PURPOSE

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, the procedures for the reconsideration and appeal of UHREB decisions is outlined in this document.

2. **RESPONSIBILITY**

This procedure applies to all UHREB members, including the Chair and Vice-Chair.

3. SPECIFIC POLICIES AND PROCEDURES

3A. RECONSIDERATION OF UHREB DECISIONS

- 3A.1 In the event that a research protocol is not approved by the UHREB, the researcher may request that the UHREB reconsider its decision. Requests for reconsideration must be submitted in writing within five (5) working days after the UHREB's decision is communicated to the researcher. The researcher's request for reconsideration must be submitted to the Ethics Officer, and will include the reasons for the request for reconsideration (i.e., procedural or substantive grounds).
- 3A.2 All efforts should be made by the UHREB (through its Chair or designate) and the researcher to achieve a mutually agreed upon protocol that is both scientifically and ethically acceptable.

- 3A.4 If the UHREB Chair and researcher are unable to reach agreement, the UHREB Chair will reconvene the UHREB to review the protocol (or bring the reconsideration to the UHREB at its next full board meeting). The researcher will be given five (5) working days' notice of the UHREB meeting, and the researcher will have an opportunity to provide additional information to, and answer questions from, the UHREB.
- 3A.5 If agreement is not reached and the protocol is still deemed to be unsatisfactory, the UHREB (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) working days of the Board's reconsideration meeting.

3B. APPEAL OF UHREB DECISIONS

- 3B.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.
- 3B.2 If, after reconsideration by the UHREB, a researcher wishes to appeal the rejection of a protocol, a formal request for appeal of the UHREB decision may be made within ten (10) working days following receipt of correspondence from the UHREB Chair.

The researcher must submit a letter of appeal to the Ethics Officer. The onus is on the researcher to indicate the alleged breaches in the UHREB'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 UHREB did not agree, this must be fully documented.

3B.3 <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 UHREB Chair in which the committee's original decision (and reasons) were communicated;
- The correspondence from the UHREB Chair in which the committee's decision (and reasons) following reconsideration were communicated; and
- The grounds of the appeal (procedural and/or substantive).
- 3B.4 The Ethics Officer will send a letter acknowledging receipt of the appeal.
- 3B.5 The appeal application will be forwarded to the Committee on Appeals, the Brandon University Research Ethics Committee (BUREC), for its review. Normally, the BUREC meeting will be convened within ten (10) working days following receipt of the appeal.
- 3B.6 DECISIONS AND COMMUNICATION OF COMMITTEE ON APPEALS:

- 3B.6.1 The Committee on Appeals (BUREC) is empowered to review decisions of the UHREB that have been appealed. The Committee on Appeals may approve, disapprove or request modifications to the research protocol. The decision of the Committee on Appeals is final and binding.
- 3B.6.2 The decision of the Committee on Appeals will be communicated to the researcher within five (5) working days following its meeting.
- 3B.6.3 The Chair of the Committee on Appeals will provide a report to the University of Winnipeg Ethics Officer summarizing its deliberations (i.e., a summary of the issues, factual evidence, conclusions, and the reasons for its decision).
- 3B.6.4 The report of the Chair of the Committee on Appeals will be retained in the Ethics Office, in accordance with its procedures for document management (N2/CAREB SOP 303.003).