

Procedures: Human Research Ethics**SOP 409: Reconsideration of REB Decisions and Appeal Process**

Associated Policy	Human Research Ethics Policy AR-03
Procedure Holder	Associate Vice President Research (AVPR)
Executive Lead	Research Services
Approval Authority	President
Original Date	Replaces AR-03 procedures (May 2009, Oct. 2014)
Effective Date	July 2022

1.0 PURPOSE

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

2.0 SCOPE AND AUTHORITY

These procedures apply to all research proposals involving human participants or human biological materials where the researcher does not receive ethics approval or conditional approval based on the ethical acceptability of the research proposal.

3.0 RESPONSIBILITIES

The AVPR, REB Co-Chairs, REB Coordinator and/or REB delegate are responsible for executing, overseeing the implementation, administration and interpretation of these procedures.

4.0 DEFINITIONS

See the Glossary of Terms

5.0 PROCEDURES

The YukonU REB is guided by the principles of natural justice in their decision-making. In fulfilling their mandate, the YukonU REB shall function impartially, provide a fair hearing to the researchers involved, and provide reasoned and appropriately documented opinions and decisions. The REB encourages on-going collegial and collaborative discussions with the Researcher/PI, through the REB Co-Chairs and/or REB Coordinator relating to the submission of research proposals. In the

event of a disagreement between the PI and REB over a decision regarding research proposal that cannot be resolved through discussion, the PI is entitled to reconsideration by the REB (Article 6.18 TCPS2 2018). If the reconsideration does not resolve the disagreement, the PI may appeal the REB decision in accordance with these procedures (Article 6.19, TCPS2 2018).

5.1 Reconsideration

- 5.1.1 A Researcher/Principal Investigator (PI) may request, and the REB has an obligation to provide, prompt reconsideration of the REB's decision. Initial reconsideration may be by way of informal discussions between the Researcher and the Co-Chairs of the REB;
- 5.1.2 If the matter is resolved through this informal process, the resolution will be documented by the Research Ethics Office and will also be reflected in the ethics application and study materials as appropriate;
- 5.1.3 If informal discussions do not result in a resolution of the issues, the Researcher may request formal reconsideration. In order to receive formal reconsideration, the Researcher shall submit a written request to the REB;
- 5.1.4 Reconsideration will take place at the next regularly scheduled Full REB meeting;
- 5.1.5 The onus is on researchers to justify the grounds on which they request reconsideration by the REB and to indicate any alleged breaches to the established research ethics review process, or any elements of the REB decision that are not supported by TCPS2 or University Policy;
- 5.1.6 The Researcher may provide additional information for the Board's consideration, and may also attend the Full Board Meeting in person; however, the Researcher shall not be present during the REB's deliberation;
- 5.1.7 The Researcher shall submit any additional information for consideration on or before the application deadline for the next available Full REB meeting;
- 5.1.8 The Researcher and the REB must have fully exhausted the formal reconsideration process and the REB must have issued its final decision before the Researcher may initiate an appeals.

5.2 Notice of Appeal

- 5.2.1 If, after the completion of the relevant REB's reconsideration, a Researcher is still not satisfied with the decision made by a REB, the Researcher may seek an appeal of

that decision by sending a written Notice of Appeal to the Research Ethics Coordinator who has been delegated authority by the Associate Vice President Research (AVPR) to receive and manage appeals as outlined in this SOP;

- 5.2.2 The written Notice of Appeal must be filed with the Research Ethics Coordinator within thirty (30) working days of the final decision being received by the Researcher;
- 5.2.3 The appeal process is NOT a forum to merely seek a second opinion of the REBs decision. Instead, the Notice of Appeal must clearly state the grounds on which the appeal is being made and should be accompanied by supporting documentation. Such supporting documentation may include (but is not limited to):
 - 5.2.3.1 The original ethics application,
 - 5.2.3.2 The original REB decision,
 - 5.2.3.3 All subsequent written communications between the REB and the Researcher,
 - 5.2.3.4 Documents and records, including a copy of the funding proposal (if appropriate),
 - 5.2.3.5 Relevant references or copies of pertinent guidelines, internal and external policies, and legislation;
- 5.2.4 An appeal may be based on:
 - 5.2.4.1 procedural grounds (e.g., alleged noncompliance with the REB's terms of reference or procedures). A procedural error that materially and adversely influenced the decision of the originating REB, including real or reasonably apprehended bias, or undeclared conflict of interest on the part of one or more members of the REB, or
 - 5.2.4.2 substantive grounds (e.g., alleged noncompliance with a specific article of the TCPS2 or a relevant regulation or guideline);
- 5.2.5 The Research Ethics Coordinator will acknowledge receipt of the Notice of Appeal in writing and forward a copy of the written Notice of Appeal to the Vice-President Research and the Co-Chairs of the REB;
- 5.2.6 The Chair of the REB will within fifteen (15) working days from the date the REB Coordinator received the Notice of Appeal provide written acknowledgement of the Notice of Appeal and, if the Co-Chairs of the REB deems it necessary, a response and documentation clarifying the REB's decision;

- 5.2.7 The Co-Chairs of the REB will send the response and documentation to the Research Ethics Coordinator, who in turn will forward a copy to the AVPR, the Coordinator of Research Ethics, and the Researcher.

5.3 Composition of the Research Ethics Appeal Committee

- 5.3.1 Upon receipt of a Notice of Appeal, the Research Ethics Coordinator will contact the Aurora College Research Ethics Manager to request the review by their Research Ethics Committee who have agreed to serve as the Research Ethics Appeal Committee for the purpose of reviewing the appeal;
- 5.3.2 The composition of the Appeal Committee is that of the Aurora College Research Ethics Committee (REC) and reflects the required range of expertise and knowledge for an REB whose decision is being appealed, and must also meet the procedural requirements of the Tri-Council Policy Statement (TCPS2) and Yukon University policy;
- 5.3.3 Specifically, the Appeal Committee shall consist of at least five (5) members, of whom:
- a) at least 2 members shall have broad expertise in the methods or in the areas of research that are covered by the relevant REB,
 - b) at least one member shall be knowledgeable in ethics, and
 - c) at least one member shall have no affiliation with the Institution, but shall be recruited from the community served by the institution;
- 5.3.4 The Appeal Committee may appoint ad hoc experts as required;
- 5.3.5 Members of the Appeal Committee must all be free of conflicts of interest in relation to the study under appeal. In addition, no member of the Appeal Committee may be a member of the REB whose decision is under appeal, or can have been a member of the REB when the decision being appealed was made;

5.4 The Appeal

- 5.4.1 The onus is on the Researcher who filed the Notice of Appeal to justify the grounds of the appeal and to indicate any breaches to the research ethics review process or any elements of the REB decision that are not supported by the TCPS2, relevant regulations or guidelines, or YukonU policy;
- 5.4.2 The Appeal Committee shall have the authority to review negative decisions made by an REB. In so doing, it may approve, reject or request modifications to the research proposal. Its decision on behalf of the institution shall be final;

- 5.4.3 The Research Ethics Coordinator will assemble and distribute the Notice of Appeal and supporting documentation (including the REB minutes pertaining to the submission) to the appeal Committee for review, with a copy to the REB Co-Chairs whose decision is under review and the Researcher;
- 5.4.4 A meeting of the Appeal Committee, with provision for presentations by both the Researcher and the REB Co-Chairs (or other representative of the REB as delegated by the Co-Chair), will be organized by the Office of Research Ethics and held within **sixty (60) days** of receipt of the Notice of Appeal by the Research Ethics Coordinator. Both parties may be accompanied by a colleague of their choice who will not participate in the meeting; Attendance of the YukonU REB Co-Chairs and Researcher will be done via remote methods.
- 5.4.5 Meetings of the Appeal Committee will be conducted in accordance with the principles of natural justice. Both the Researcher and the REB representative have the right to speak to issues raised in the Notice of Appeal and supporting documentation and the Appeal Committee may ask questions throughout the process. Neither party shall be present when the Appeal Committee deliberates and makes a decision;
- 5.4.6 The majority decision of the Appeal Committee will be final and binding and will normally be communicated within thirty (30) days of the meeting;
- 5.4.7 The Chair of the Appeal Committee will communicate the decision of the Appeal Committee in writing, including a summary of the issues, factual findings, conclusions and reasons for the decision to the Researcher, the Co-Chairs of the REB, the AVPR and Research Ethics Coordinator;
- 5.4.8 The Co-Chairs of the REB will be responsible for any implementation and follow up required through the REB.

6.0 REFERENCES

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 6.13, 6.18, 6.19, 6.20

7.0 REFERENCES

See References.

8.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 409	July 2022	YukonU version adapted from University of British Columbia (UBC) SOP 409 and Ontario Tech University REB SOP 212