

Ethics proposals may go through a detailed consultation process with the REB to finalize the research plan. In the case of a final negative result where the Principal Investigator's research proposal is not approved by the Research Ethics Board (REB) or relevant Faculty, Department or School ethics review body, the Principal Investigator may appeal that decision to the Trent Research Ethics Appeal Board (EAB). The decision of EAB is final and binding on the agreements.

(A) Terms of Reference

See Senate Committees and Sub-committees: Terms of Reference and Composition (May 2019)

(B) Grounds for Appeal

The appeal process is NOT a forum to seek a second opinion of an REB decision. Instead, an 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):

- The original ethics application;
- The original REB decision;
- All subsequent written communications between the REB or Ethics Review Board and the Principal Investigator;
- Documents and records, including a copy of the funding proposal (if appropriate);
- Relevant references or copies of pertinent guidelines, internal and external policies, and legislation

An appeal may be based on procedural grounds (e.g., alleged noncompliance with Trent's Policy for Research Involving Human Participants) or substantive grounds (e.g., alleged noncompliance with a specific article of the TCPS2, 2018, or a relevant regulation or guideline).

(C) Procedures for an Appeal

- I. A Principal Investigator may file a formal appeal of a decision of the REB or Ethics Review Body normally within 30 days of receipt of the decision in writing.
- II. Appeals applications must contain the text of the REB or ethics review body's decision, the specific ground on which the appeal is made, and evidence in support of these grounds.
- III. The EAB has the right to all documents that were considered by the Research Ethics Board or Ethics Review Body. The Certifications and Compliance Officer is responsible for the provision of these documents to the EAB.

(D) The Appeal

- I. The onus is on the Principal Investigator who filed the Appeal to justify the grounds of the appeal (Section C), and to indicate any breaches to the research ethics review

process or any elements of the REB or Ethics Review Body decision that are not supported by the TCPS2 or Trent's Policy for Research Involving Human Participants.

- II. The EAB shall have the authority to review negative decisions made by the REB or Ethics Review Body. In so doing, it may "approve", "approve with required modifications", or "reject" the research proposal.
- III. The Certification and Compliance Officer shall assemble and distribute the supporting documentation (including the REB or Ethics Review Body or Ethics Review Board minutes pertaining to the submission) to the EAB for review, with a copy to the Chair of the REB whose decision is under review, and the Principal Investigator.
- IV. A meeting of the EAB, with provision for presentations by the Principal Investigator and the Chair of the REB or Ethics Review Board (or other representative of the REB or Ethics Review Board as delegated by the Chair), will be organized by the Office of Research and Innovation and held normally within 30 days of receipt of the Appeal.
- V. Meetings of the EAB will be conducted in accordance with the principles of the Tri-Council Ethics Policy (TCPS2). Both the Principal Investigator and the REB or Ethics Review Board representative have the right to speak to issues raised in the Appeal and supporting documentation. The EAB may ask questions throughout the process. Neither party shall be present when the EAB deliberates and makes a decision.
- VI. The decision of the EAB will be final and binding.
- VII. The Chair of the EAB will communicate the decision of the EAB in writing, including a summary of the issues, factual findings, conclusions and reasons for the decision to the Principal Investigator, the Chair of the REB or Ethics Review Board, and the Vice President, Research and Innovation;
- VIII. The Chair of the REB or Ethics Review Board will be responsible for any implementation and follow up required through the REB or EAB.
- IX. The EAB will report annually to Senate on appeals heard and the disposition of those appeals, including a summary of the reasons given for its decision