

SOP Title	Process for Reconsideration or Appeal of Decisions of the REB
Number	REB SOP 212
Version Date	November 28, 2019
Approval Date	December 11, 2019
Approved By	REB

PURPOSE

1. The purpose of these procedures is to describe the reconsideration and appeal process of the University of Ontario Institute of Technology (Ontario Tech) for unfavourable decisions rendered by the Research Ethics Board (REB) on proposals involving human participants or human biological material. This procedure has been set out in accordance with the Tri-Council Statement: Ethical Conduct for Research Involving Humans (TCPS 2018).

DEFINITIONS

2. For the purposes of these procedures the following definitions apply:

“Appeal” is a process that allows a researcher to request a review of a research ethics board (REB) decision when, after reconsideration, the REB has refused ethics approval of the research.

“Ethics Approval” refers to the research ethics approval granted by the University REB in accordance with the UOIT Research Ethics Policy.

“Human Biological Materials” refers to any human tissues, organs, blood, plasma, serum, DNA, RNA, proteins, cells, skin, hair, nail clippings, urine, saliva and other body fluids, embryos, fetuses, fetal tissues, reproductive materials, and stem cells collected from participants for research purposes.

“Human Participants” describes individuals whose data or responses to interventions, stimuli or questions by a researcher are gathered or utilized for the purposes of a research project.

“Principal Investigator (PI)” is the head of the research team who has overall responsibility for the ethical conduct of the study and for the actions of any member(s) of the research team. The PI is responsible for communicating any changes to the study, material incidental findings, new information, and/or unanticipated events to their own REB as well as to local site researchers for multi-site studies, who must then inform their respective local REBs.

“Proposal” refers to the REB application, study protocol, and/or supporting documents for research involving human participants or human biological materials.

“REB” refers to the Research Ethics Board authorized by the University.

“REB Administration” includes the Research Ethics Officer and/or REB delegate who provides operational support to the University research ethics framework and REB.

“Research” is defined as the systematic investigation to establish and communicate facts, principles, understandings, or generalizable knowledge. Research involving human participants may include, but is not limited to, projects where data are derived through:

- a. the collection of information through any interaction or intervention with a living individual;

- b. the secondary use of data previously collected from human participants;
- c. identifiable private information about an individual; and/or
- d. human remains, cadavers, human organs, tissues and biological fluids, embryos, or fetuses.

“Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans (TCPS2 2018)” is the joint policy of Canada’s three federal research agencies – the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC). This policy outlines ethical norms relevant to the conduct of research involving humans.

“University” means the University of Ontario Institute of Technology (Ontario Tech).

“University Member” means any individual who is:

- a. employed by the University;
- b. registered as a student, in accordance with the academic regulations of the University;
- c. holding an appointment with the University, including paid, unpaid, and/or honorific appointments; and/or
- d. otherwise, subject to University policies by virtue of the requirements of a specific Policy and/or the terms of an agreement or contract.

SCOPE AND AUTHORITY

3. 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.
4. The REB Chair, REB Vice-chair, REB administration and/or REB delegate are responsible for executing, overseeing the implementation, administration and interpretation of these procedures.

PROCEDURES

5. The REB encourages on-going collegial and collaborative discussions with the Principal Investigator (PI), through the REB Chair/Vice-Chair and/or REB administration relating to the submission of research proposals. In the event of a disagreement between the PI and REB over a decision regarding a research proposal that cannot be resolved through discussions, the PI is entitled to a 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 to these procedures (Article 6.19, TCPS2 2018).

6. Reconsideration of REB Decisions

- 6.1. The PI and REB must make every effort to resolve disagreements with the ethics review feedback or decision through deliberation, consultation or advice through a reconsidering process.
- 6.2. Reconsideration requests must be submitted to the REB Chair/Vice-Chair and/or REB administration in writing **no later than 30 days after the REB has rendered the written decision letter**. Written requests must include justification for the grounds on which the PI requests for a reconsideration by the REB. In addition, requests must explicitly indicate any

alleged breaches to research ethics review, or any elements of the REB decision that are not supported by the TCPS2 2018 (Article 6.18)

- 6.3. The REB Chair/Vice-Chair or REB administration shall acknowledge the reconsideration request in writing, no later than 7 days following the written reconsideration request and will outline the reconsideration process and requirements.
- 6.4. The REB members will receive the reconsideration request, along with any supporting documents for immediate discussion and review the next available REB meeting.
- 6.5. The REB will accommodate reasonable requests from the PI to participate in discussions of their research proposal(s) at the REB meeting. However, the PI shall not be present during the deliberation and ultimate decision-making of the reconsideration.
- 6.6. The REB may extend a meeting invite to the PI to discuss the reconsideration and provide more information, if required.
- 6.7. At the meeting, the REB will decide if the initial ruling will be overturned or to uphold the initial decision. The REB will communicate its decision in writing promptly after the REB meeting. If the initial ruling is overturned, the REB and PI will collaboratively work to reach a resolution. The PI may request an appeal of the decision when the initial REB decision is upheld. The REB must have issued a final decision before the PI initiates an appeal.

7. Appeal of REB Decision

- 7.1. Appeal requests are reserved for instances when a resolution has not been reached despite extensive discussions and reasonable attempts to find an agreement through a reconsideration process. In this case, the PI shall have the option of appealing the REB decisions (Article 6.19).
- 7.2. Appeal requests must be submitted to the REB Chair/Vice-Chair and/or REB administration in writing **no later than 30 days after the REB has rendered the written decision letter from the reconsideration process.** Written requests must include justification for the grounds on which the PI requests for an appeal. In addition, requests must explicitly indicate any alleged breaches to research ethics review, or any elements of the REB decision that are not supported by the TCPS2 2018 (Article 6.18)
- 7.3. The REB Chair/Vice-Chair or delegate shall acknowledge the appeal request in writing no later than 7 days following receipt of the appeal request and will outline the appeal process and requirements. The PI's Dean will receive a copy of the appeal request and other related correspondence.
- 7.4. Through institutional alliances, the REB shall seek an external REB with requisite knowledge, expertise and that meets the procedural requirements of the TCPS2 2018 as an ad-hoc appeal board to ensure arm's length of the review. The University research administration shall arrange for a formal letter of agreement between the institutions.

- 7.5. Project team members whose decision is under appeal shall not serve on that appeal committee. Members of the appeal board shall declare a Conflict of Interest (COI) when the member is part of the research team for the application under appeal.
- 7.6. The appeal process shall not be used as a substitute for the University REB, nor shall it be used to seek a second opinion from another REB (Article 6.19).
- 7.7. The appeal board will follow their institutional policies, procedures and work flow for conduct of appeals hearings and shall have the authority to review previous decisions made by the University REB.
- 7.8. The appeal board shall have the authority to approve, reject or request modifications to the research proposal and will render a decision on the appeals on behalf of the University (Article 6.20).
- 7.9. The PI will receive a formal appeal decision letter from the appeal board. The PI shall satisfactorily address all the conditions and concerns raised by the appeal board to receive ethics approval.
- 7.10. The decision of the appeals board shall be final and no further appeals will be granted (Article 6.20).

8. Access to Documents

- 8.1. The Appeal Committee shall receive the following documentation for review of the appeal:
 - a. The complete research proposal and supporting documents, all documents available at the REB meeting(s) related to the appeal, REB decisions letters.
 - b. All minutes of the REB meeting(s) related to the appeal.
 - c. PI's appeal letter and supporting documents.
- 8.2 The appeal committee may request additional material from either the PI or the REB Chair/Vice-Chair, and/or may seek advice from an expert(s) and/or may have a resource person(s) attend any or all portion of its meeting.
- 8.3 REB minutes and supporting review documents related to the reconsideration and/or appeals request are internal documents. These documents shall only be accessible to the REB Chair, REB Vice-Chair, REB members, REB administration, the President, compliance auditors and regulatory authorities. The PI will not gain access to the REB minutes and supporting review documents and will only have access to the documents available in the electronic system as listed in section 4.1.2 of REB SOP 102 Documentation and Document Management.

MONITORING AND REVIEW

9. These procedures will be reviewed as necessary and at least every three years. The REB Chair, REB Vice-Chair and REB administration are responsible to monitor and review these Procedures.

RELATED POLICIES, PROCEDURES & DOCUMENTS

10. REB SOP 102 Documentation and Document Management (Section 4.1.2).
11. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2 2018)
12. UOIT Research Ethics Policy (LCG 1124), 2013