



# Research Ethics Board

## Standard Operating Procedure

<b>SOP File #</b>	<b>REB.SOP.412</b>
<b>Title</b>	Reconsiderations and Appeals
<b>Effective Date</b>	March 2022
<b>Next Review</b>	2027
<b>Next Administrative Review</b>	2025

### 1. Purpose

This standard operating procedure (SOP) describes the procedures to be undertaken in formally requesting a reconsideration or appeal of a decision made by the Research Ethics Board's (REB).

### 2. Definitions

See the MSVU **REB Glossary of Terms (REB.INFO.001)**

### 3. Scope

This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

Where researchers do not receive ethics approval or receive approval conditional on revisions that they find compromise the feasibility or integrity of the proposed research, they are entitled to reconsideration by the REB. If that is not successful, they may appeal using the established appeal mechanism in accordance with the institution's procedures.

An appeal can be launched for procedural or substantive reasons. 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 the [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans](#) (TCPS) (TCPS Article 6.20).

### 4. Responsibilities

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

Researchers have the right to request, and REBs have an obligation to provide, prompt reconsideration of decisions affecting a research project (TCPS Article 6.18).

In all cases of reconsideration or appeals regarding a graduate or undergraduate research project, the request must be activated by the faculty supervisor responsible for the project.

## 5. Procedures and/or Specific Policies

### 5.1. Reconsideration

Researchers and REBs will make every effort to resolve outstanding issues. If a resolution cannot be reached and a negative decision is made the researcher shall have the option of appealing the REB decisions through the established appeal process (Article 5.2 below).

### 5.2. Appeals

5.2.1. It should be noted that the appeal process is neither a substitute for the REBs and researchers working closely together to ensure high-quality ethical research, nor is it a forum merely to seek a second opinion.

5.2.2. The Appeals Committee will function impartially and will provide a fair hearing to those involved. Both the researcher and a representative of the REB shall be granted the opportunity to address the Appeals Committee, but neither shall be present when the Appeals Committee deliberates and makes a decision.

5.2.3. Appeals Committee decisions shall be final and will be communicated in writing (in print or by electronic means) to researchers and to the REB whose decision was appealed.

5.2.4. Recourse to judicial review may be available to the researcher.

### 5.3. Committees Designated for Appeals

The Appeals 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 shall be final (TCPS Article 6.20). In all cases, members of an appeals committee must immediately disclose to the Chair any conflict of interest with the file and/or the researcher(s).

**NOTE:** If a conflict of interest is declared, the member will be removed from the review and another member or an ad hoc member will be appointed by the REB Chair in consultation with the REB membership.

5.3.1. For researchers who have received a negative decision from a MSVU

#### **Departmental Research Ethics Board (DREB):**

5.3.1.1. The MSVU appeals committee will be drawn from members of the UREB for proposals that have received a negative decision at the DREB level and that have not previously been reviewed by the UREB. When acting as an Appeals Committee, the committee members of the UREB must ensure that they have no conflict of interest, and that the committee has the membership configuration consistent with the TCPS2, including the community member (TCPS Article 6.19).

- 5.3.1.2. If a conflict of interest is declared, the member will be removed from the review and another member or an ad hoc member will be appointed by the Chair of the MSVU REB.
- 5.3.2. For MSVU researchers appealing a negative decision by the University **Research Ethics Board (UREB):**
  - 5.3.2.1. Through a signed Memorandum of Understanding (MOU), the Research Ethics Board at Saint Mary's University (SMU REB) will act as the Appeals Committee for faculty, student and other proposals that have been reviewed by the UREB and declined. Members of the SMU REB assigned to the Appeals Committee will ensure that they have no conflict of interest, and that the committee has the membership configuration consistent with the TCPS2, including the community member (TCPS Article 6.19).
  - 5.3.2.2. If a conflict of interest is declared, the member will be removed from the review and another member or an ad hoc member will be appointed by the Chair of the SMU REB.
- 5.3.3. For researchers appealing negative decisions from the **SMU REB:**
  - 5.3.3.1. The MSVU UREB will act as the Appeals Committee for proposals that have received a negative decision from the SMU REB. When acting as an Appeals Committee, the committee members drawn from the UREB must ensure that they have no conflict of interest, and that the committee has the membership configuration consistent with the TCPS2, including the community member (TCPS Article 6.19).
  - 5.3.3.2. If a conflict of interest is declared, the member will be removed from the review and another member or an ad hoc member will be appointed by the Chair of MSVU REB.

#### 5.4. Procedures for Appeals

- 5.4.1. Appeals will be settled in a timely fashion, normally within thirty (30) working days of receipt of a complete and documented file.
- 5.4.2. Appeals must be made in writing and include all supporting documents. The appeal must be forwarded to the appropriate REB Chair within two (2) weeks of receipt of a negative decision by the REB that clearly outlines the reasons for the negative decision.
- 5.4.3. Upon receipt of the complete appeal file from the researcher, the Chair of the REB will determine the level of review within five (5) working days and will send the file to the appropriate reviewers on or before the fifth (5<sup>th</sup>) working day.
  - 5.4.3.1. The level of re-review will be proportionate to the level of risk involved in the research
    - 5.4.3.1.1. Minimal risk proposals will be reviewed by an Appeals Committee that consists of, at a minimum, the REB Chair, one Community Member and one member of the faculty component of the REB. Additional REB members

and/or *ad hoc* members may be utilized, if required, for their expertise. Members will be chosen based on their expertise in research by the Committee Chair.

- 5.4.3.1.2. Research ethics proposals exceeding minimum risk will be reviewed by an appeals committee that consists of the full complement of the REB. *Ad hoc* members may also be utilized, if required, to draw on their expertise.
- 5.4.4. For minimal risk files, the Appeals Committee will normally have fourteen (14) working days to thoroughly review the file and will convene a meeting on or before the final working day.
- 5.4.5. For a file that exceeds minimal risk, the Appeals Committee will normally have twenty (20) working days to thoroughly review the file and will convene a meeting on or before the final working day.
- 5.4.6. The meeting date will be announced one week prior and both the researcher as well as one member of the REB that issued the negative decision has the right to appear before the Committee adjudicating the appeal. Neither will be present during the deliberation and decision-making by the Appeals Committee.
- 5.4.7. A letter from the Appeals Committee Chair detailing the outcome of the deliberation will be sent electronically to the researcher with the original REB chair copied within two (2) working days of the meeting after a decision is reached. A hard copy will also be mailed to both parties. The letter will include a decision as follows:
  - 5.4.7.1. Approved as submitted, negative decision overturned
  - 5.4.7.2. Declined as submitted, negative decision upheld
  - 5.4.7.3. Modifications proposed, final decision pending
    - 5.4.7.3.1. In this case, the researcher will have ten (10) working days from the date the electronic copy of the letter is sent to make requested modifications and resubmit the application to the Appeals Committee for re-review. Upon receipt of modifications from the researcher, the Appeals Committee, with no change in membership.
    - 5.4.7.3.2. Should the researcher not respond to the Appeals Committee request for modifications within the ten (10) working day requirement, the file shall be declared declined as submitted, negative decision upheld.

## 6. References

See References listed (if applicable)

## 7. Acknowledgements

The development of this document has benefited directly from similar documents made public by the Panel on Research Ethics (PRE), as well as several Canadian universities.

- [C. Reconsideration and Appeals](#) (TCPS Chapter 6), retrieved February 2022

## 8. SOP History

SOP Number	Key Changes	Effective Date
REB.SOP.412	Minor revisions for clarity and to reflect process, new SOP and revised to fit new SOP template	March 2022
REB.SOP.111	Minor Revisions, pulled into unique SOP	September 2011
Section 9	Appeals - <i>Policies &amp; Procedures: Ethics Review of Research Involving Humans</i>	2000

This Page is intentionally left blank.