

Title	Reconsiderations and Appeals
SOP Code	410.01
Effective Date	September 2023

Site Approvals

Name and Title (typed or printed)	Signature	Date
Dr. Craig Kuziemsky Associate Vice-President, Research	<i>Original signed</i>	October 2020
Dr. Craig Kuziemsky, AVPR	<i>Original signed</i>	September 2023

1.0 PURPOSE

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

2.0 SCOPE

This SOP pertains to all research submitted to MacEwan University's REB, and provides researchers with the opportunity to seek reconsideration of a REB decision. Such decisions can include rejection of a study, proposed modification or renewal, termination of an approved study, or determined non-compliance with the approved protocol, REB policies and procedures, or the TCPS2 or other relevant guideline or policy.

3.0 RESPONSIBILITIES

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

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

MacEwan's REB is guided by the principles of respect for persons, concern for welfare, and justice in their decision-making. In fulfilling its mandate, the REB functions impartially, provides a fair hearing to the researchers involved, and provide reasoned and appropriately

documented opinions and decisions.

5.1 Reconsideration

- 5.1.1 A Researcher 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 Chair of the REB;
- 5.1.2 If the matter is resolved through this informal process, the resolution will be documented in ROMEO and will also be reflected in revisions to 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 Board 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, MacEwan Policy, '*Ethical Review of Research with Human Participants*' or REB standard operating procedures;
- 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 deliberations;
- 5.1.7 The Researcher shall submit any additional information for consideration on or before the application deadline for the next available Full Board 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 appeal.

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 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 Associate Vice-President, Research within ten (10) 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):

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

5.2.4 An appeal may be based on procedural grounds (e.g., alleged noncompliance with the REB's terms of reference or procedures, deviation from originally approved protocol) or substantive grounds (e.g., alleged noncompliance with a specific article of the TCPS2 or a relevant regulation or guideline);

5.2.5 The AVPR will acknowledge receipt of the Notice of Appeal in writing and forward a copy of the written Notice of Appeal to the Research Ethics Officer, and the Chair of the REB;

5.2.6 Within ten (10) working days of receiving the Notice of Appeal, The Chair of the REB will provide written acknowledgement of the Notice of Appeal and, if the Chair of the REB deems it necessary, a response and documentation clarifying the REB's decision;

5.2.7 The Chair of the REB will send the response and documentation to the Research Ethics Officer who in turn will forward a copy to the AVPR and the Researcher.

5.3 Composition of the Research Ethics Appeal Board

5.3.1 Upon receipt of a Notice of Appeal, the AVPR shall appoint members to the Research Ethics Appeal Board ("REAB") for the purpose of hearing the appeal;

5.3.2 The composition of the REAB must reflect the range of expertise and knowledge similar to that of the REB whose decision is being appealed, and must also meet the procedural requirements of the Tri-Council Policy Statement (TCPS2);

5.3.3 Specifically, the REAB shall consist of at least five (5) members:
(a) are selected from faculty and professional staff, internal or external to MacEwan,
(b) at least one of whom is a student, in cases where the project has student participants,
(c) at least two of whom have broad experience in research methods,

(d) at least one of whom has extensive knowledge in ethics or previous experience in evaluating the ethical treatment of human research participants.

5.3.4 The REAB may appoint ad hoc experts as required;

5.3.5 Members of the REAB must all be free of conflicts of interest in relation to the study under appeal. Membership shall exclude:

- any member of the REB whose decision is under appeal, or individuals who were a member of the REB when the decision being appealed was made;
- any individual who may have a conflict of interest, whether real or perceived, with the Researcher who submitted the appeal.

5.3.6 The REAB will be appointed on an ad hoc basis and will appoint one of its members to serve as Board Chair. All members will sign confidentiality and conflict of interest agreements prior to their formal appointment to the REAB.

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 MacEwan Policy, *'Ethical Review of Research with Human Participants'*;

5.4.2 The REAB 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 Officer will assemble and distribute the Notice of Appeal and supporting documentation (including the REB minutes pertaining to the submission) to the REAB for review, with a copy to the Chair of the REB whose decision is under review and the Researcher;

5.4.4 A meeting of the REAB, with provision for presentations by both the Researcher and the REB Chair (or other representative of the REB as delegated by the Chair), will be organized by the Office of Research Services and held within thirty (30) days of receipt of the Notice of Appeal.

5.4.5 Meetings of the REAB 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 REAB may ask questions throughout the process. Neither party shall be present when the REAB deliberates and makes a decision;

5.4.6 The majority decision of the REAB will be final and binding and will normally be communicated within ten (10) days of the meeting;

- 5.4.7 The Chair of the REAB will communicate the decision of the REAB in writing, including a summary of the issues, factual findings, conclusions and reasons for the decision to the Researcher, the Chair of the REB, the AVPR and the Research Ethics Officer;
- 5.4.8 The Chair of the REB will be responsible for any implementation and follow up required through the REB.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
410.00	October 8 2020	Original version
410.01	September 2023	Reviewed, no revisions required