Research Ethics Board

Standard Operating Procedure

SOP File #	**REB.SOP.408**
Title	Full Board Review
Effective Date	June 2022
Next Review	2027
Next Administrative Review	2024

1. Purpose

This standard operating procedure (SOP) describes the processes for determining when research meets the criteria for full board ethics review and the associated review procedures.

2. Definitions

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

3. Scope

This SOP pertains to Research Ethics Boards (REB) that review human participant research in compliance with applicable policies and guidelines.

Research ethics applications that exceed minimal risk may only be reviewed by the University Research Ethics Board (UREB)

4. Responsibilities

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

The REB Chair or designee may delegate this task to REB Office Personnel; however, the responsibility for oversight remains with the REB Chair or designee.

The REB Chair or designee or REB member(s) is responsible for conducting the delegated review.

5. Procedures and/or Specific Policies

REBs should adopt a proportionate approach to ethics assessment based on the general principle that the more invasive or harmful the research, the greater care in assessing the research by the REB. A REB Full Board review should be the default requirement for all research involving human participants unless the REB decides to authorize delegated review (see REB.SOP.401) based primarily on the harms that are expected to arise from the research. While all research must be reviewed adequately, requirements for proportionate review allow the REB to provide a higher level of scrutiny, and protection, for the most ethically challenging research.

In practice, the proportionate review implies different levels of REB review depending on the research project. These levels include Full Board review or delegated review by one or more experienced REB members, as determined by the REB Chair or designee. This document focuses on the Full Board Review.

5.1. Determination of Qualification for Full Board Review

5.1.1. Full Board review is the default for most new research projects submitted to the REB; however, some research may be eligible for delegated review;

5.1.2. Submissions that meet the following criteria shall be required to undergo a full board ethics review:

- Research projects that involve more than minimal risk,
- Research projects where it is uncertain whether or not participation will exceed minimal risk, necessitating a full committee review,
- Modifications to approved protocol that increase risk,
- Continuing review of approved research that exceeds minimal risk,
- Continuing review of research that is more than minimal risk when there has been little or no modification of the research; and when there has been no increase in risk to or other ethical implications for participants since the initial review by the full REB, and where the REB Chair has determined that delegated review is appropriate.

5.1.3. When determining if initial review of research or modifications to previously approved research require full board review, the REB Chair or designee will take into consideration the methods used to conduct the research, recruitment practices, participant population, confidentiality of data, and all ethics guidance and requirements as applicable.

5.2. Full Board Review Initial Process

5.2.1. REB Office Personnel will perform an initial screening of the submission. The REB Chair or designee will make the determination of whether the submission meets the criteria for full board review;

5.2.2. The REB Chair, designee and REB member(s) reviewing research under full board review must not have a Conflict of Interest in the research;

5.2.3. In reviewing the research under full board review procedures, the REB Chair, REB member(s) or designee may exercise all of the authorities of the REB, except that they may not disapprove the research; the research may be disapproved only after it has been reviewed by the REB at a Full Board meeting;

5.2.4. The REB Chair or designee may request the expertise of an ad-hoc advisor, if applicable. Ad hoc advisors may not participate in the final decision regarding approval of the research;

5.2.5. The decision regarding the designation of the research (i.e., either requiring Full Board or delegated review) and the outcome of the review will be recorded. The REB Office Personnel may issue the review or decision letter.

5.3. Review Process for Full Board Reviews

The full committee review proceeds as follows:

5.3.1. Applications that exceed minimal risk will be sent to all members of the board, however primary reviewers will be the Chair (or vice-chair), two faculty reviewers and one community reviewer.

5.3.2. In the event that an application that requires a full board review is made by a member of the UREB, as principal or co-investigator, they will not be privy to documents and/or discussion.

5.3.3. If the researcher is also a member of the UREB, they shall be advised in writing the results of the discussion as per the normal procedures.

5.3.4. The fact that a researcher is also a UREB member shall not preclude their ability to request a face-to-face meeting with the UREB to discuss the file, as is allowed with any researcher.

5.3.5. The four primary reviewers will respond with written comments to be compiled and distributed to other board members prior to the meeting. The file will be discussed at a face-to-face meeting.

5.3.6. All board members will be invited to provide feedback at the meeting.

5.3.7. A decision will be made as outlined in REB.SOP.403 – REB Review Decisions.

5.3.7.1. Every effort will be made to achieve consensus on the decision. In the event that consensus is not attainable, a vote shall be taken and majority vote shall guide the decision.

5.3.7.2. No final decision (modification/clarification, approval or decline) shall be made without quorum.

5.3.8. If revisions and/or clarifications are required, board members will determine if the required revisions and/or clarifications require full board re-review or if the re-review can be delegated to the Chair (or their designee). This is normally dependent on the nature of revisions/clarifications (minor – to Chair, major – to full board)

5.3.9. Within two working days of the meeting, the Chair will circulate to the board, an electronic draft of the letter to the researcher to ensure that the correspondence has correctly captured the Committee's response. Committee members will normally have two working days to review and respond with substantive comments. The Chair will revise the letter if necessary.

5.3.10. The Chair will send the letter electronically to the researcher on behalf of the committee, that the file has been approved, declined or requires additional modification/clarification.

5.3.11. Revisions and clarifications will be received and processed as per Article 5.3.8 above.

5.4. Documentation

5.4.1. The type of REB review conducted (i.e., Full Board or delegated) will be documented in the REB records and noted in the decision letter issued to the Researcher, where appropriate;

5.4.2. The REB meeting agendas and minutes will include a list of submissions that were reviewed and approved using full board review procedures.

6. References

See References listed (if applicable)

7. Acknowledgements

The development of this document has benefited directly from similar documents made public by the Tri-Council, as well as several Canadian universities. In some instances, specific formulations drawn from these sources have been incorporated into this document. Specific iterations were drawn from the following:

- Standard Operating Procedures for Observational Health and Non-Clinical Trial Research Ethics Boards - N2/CAREB-ACCER REB SOPs – Canadian Association of Research Ethics Boards (retrieved April 2022)
- N2/CAREB-ACCER REB SOPs - N2 Network of Networks - Resources - N2 Canada (retrieved April 2022)

8. SOP History

SOP Number	Key Changes	Effective Date
REB.SOP.408	New SOP #, extensively revised to align with REB.SOP.401, current practices, and TCPS requirements	June 2022
REB.SOP.144	Original – 2013	March 2013