Research Ethics Board

Standard Operating Procedure

Document Number	**REB.SOP.403**
Title	REB Review Decisions
Effective Date	September 23, 2021
Next Review	2026
Next Administrative Review	2023

1. **Purpose**
   This standard operating procedure (SOP) describes the decisions that the Research Ethics Board (REB) may make resulting from its review of proposed research for ethical acceptability.

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.

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 is responsible for ensuring that a decision is made for every submission that is reviewed by the REB, that the decision is clearly understood, and that the delegation of responsibility for considering any further information prior to issuing approval is clearly stated and agreed upon.

5. **Procedures and/or Specific Policies**
   As a result of its review, an REB has the authority to approve, disapprove, or to require modifications to submitted research. When the Full Board review procedure is used, decisions will be made by consensus or a majority vote of the REB members with voting rights who are present at a Full Board meeting at which there is a quorum. When a vote is used, dissenting opinions shall be documented (see SOP 302).

   REB members with a conflict of interest in the research under review must not participate in the deliberations or in the vote of the REB (if applicable), in accordance with the REB and organization's conflict of interest policies (see SOP 105A).

Researchers have the right to request reconsideration of the REB's decisions and to appeal the decision of the REB.

5.1. REB Decisions

5.1.1. REB decisions are made either by consensus or, if consensus cannot be reached, by a majority vote of REB members with voting rights who are present at a Full Board meeting, with the exception of those who have recused themselves in accordance with the conflict-of-interest policies.

5.1.2. The REB should reach one of the following decisions as a result of its review of research submitted for initial or for continuing review:

Approval

- When initial review criteria required for approval are satisfied, the research may be approved,
- The approval date is defined according to the REB's procedures,
- The expiry date of the REB approval is calculated from this date.

Approval with Modifications/Clarifications*

- When initial review criteria required for approval are satisfied, but the REB members require modification to any aspect of the application or clarification or further information to secure approval, the REB may recommend "Approval with Modifications/Clarifications",
- When the REB recommends "Approval with Modifications/Clarifications", the REB Chair or designee should ensure that the additional information, modifications, or clarifications required are identified (at the REB meeting for Full Board review or by designated reviewers for delegated review) and that the procedures for reviewing the additional information and issuing the approval are clear. The responsibilities for additional review and the decision regarding approval conditions should be delegated to one of the following:
  - The REB Chair or designee alone,
  - The REB Chair and one or more named REB members that were present at the REB meeting or who submitted written comments on the application,
  - A sub-group of the REB members designated by the REB Chair or designee or by the REB,
  - A designated REB member or members with sufficient knowledge and experience regarding the research and ethical requirements.
- In deciding the procedures to be followed, the REB should consider the significance of the requested additional information or modifications and the expertise necessary to assess it,
- Where the information or modifications are administrative, it is acceptable to delegate the consideration of that material to the REB Chair or designee alone,
- Where the additional information/modification is substantive (e.g., clarification on inclusion criteria), the REB Chair or designee should review the information with consideration given to involving other REB members, such as the assigned

reviewer(s) or relevant expert member(s),

- If the Researcher's response is deemed complete and satisfactory by the REB Chair, designee or REB (as determined above), approval can be issued,
- If the Researcher's response is incomplete and does not fully address the matters raised, requests for further information, modifications or clarification should be sent to the Researcher,
- The reviewers may decide upon reviewing the Researcher's response that the decision should be deferred and that the application and the Researcher's response materials should be reviewed at a subsequent Full Board meeting (see 'Deferral' process below),

*It is recognized that not all REBs utilize this category as a review decision.

Deferral

(defer decision-making on the application and continue the deliberation of the application at a future Full Board meeting):

- The REB will defer its decision to a subsequent Full Board meeting when significant questions are raised during its review of the research and/or when the criteria required for approval have not been met,
- The REB Chair or designee should ensure that all additional information, modifications or clarifications that are required are specifically identified at the Full Board meeting,
- The revised protocol and the Researcher's response materials shall be reviewed at a Full Board meeting,
- Upon consideration of the research along with the response from the Researcher, at the Full Board meeting, the REB should issue its final decision (approved, approved with modifications, deferral or disapproved),
- Researcher responses must be received and reviewed at a Full Board meeting. The approval date is defined according to local REB procedures. The expiry date of the REB approval is calculated from this date; however, the approval letter is not issued until all the conditions for approval have been met.

Disapproval

- The REB may disapprove the research when it fails to meet the ethical standards for approval and where revision is unlikely to enable the REB to reach a positive determination,
- Disapproval cannot be decided through the delegated review mechanism,
- If the recommendation under delegated review is to disapprove the research, a final decision must be made by the REB at a Full Board meeting,
- The REB Chair or designee should ensure that the reasons for the disapproval are identified at the Full Board meeting for communication to the Researcher,
- If the research is disapproved, the reasons for disapproval will be communicated to the Researcher and the Researcher will be given an opportunity to respond in person or in writing.

5.1.3. **Delegated Reviews**: When the research qualifies for delegated review, the reviewer(s) has the authority to make the final decision, i.e., approve the application, require modifications to any aspect of the application, or request clarification or further information before considering it eligible for ethics approval. The reviewer(s) may also refer the applications as submitted for a review at a Full Board meeting,

5.1.4. When delegated review procedures are followed, approval is considered as the day the research is approved by the REB Chair, designee or assigned reviewer(s), if applicable. The expiry date of the REB approval is calculated from this date. The approval letter is not issued until all the conditions for approval have been met,

5.2. Reconsideration and Appeal of REB Decisions

5.2.1. A Researcher may appeal the decision of the REB if the disagreement between the Researcher/applicant and the REB cannot be resolved through a reconsideration process at a Full Board meeting at which the Researcher/applicant shall have the right to be heard;

5.2.2. The Researcher must justify the grounds on which a reconsideration of the decision is requested. An appeal may be launched only for procedural or substantive reasons. A final decision after reconsideration must be issued by the REB prior to the initiation of an appeal process;

5.2.3. Appeals are conducted in accordance with the established organizational policy. The organization at which the appeal will take place will be determined on a case-by-case basis by the REB in consultation with the Researcher (and their affiliated organization);

5.2.4. The appeal committee shall have the authority to review the basis of the decisions made by the REB and in so doing it may approve, disapprove or request modifications to the research proposal. Its decision shall be final and shall be communicated to the Researcher and the REB in writing.

5.3. Documenting REB Decisions

5.3.1. The REB meetings minutes will satisfy the applicable policy/ies;

5.3.2. The REB shall notify the Researcher in writing of its decision to approve or disapprove the proposed research, or of modifications/clarifications required to secure approval of the research;

5.3.3. If the REB defers its decision, the letter to the Researcher should include the issues of concern and what further information is required;

5.3.4. The final approval letter should include standard conditions of approval to which the Researcher must adhere (e.g., requirement to submit amendments prior to implementing changes to the protocol);

5.3.5. Notification or correspondence to the Researcher may be issued by the REB Office Personnel.

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 July 2021)
- N2/CAREB-ACCER REB SOPs - N2 Network of Networks - Resources - N2 Canada (retrieved July 2021)

8. SOP History

SOP Number	Key Changes	Effective Date
REB.SOP.403	Original Version	September 2021

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