

Title	REB Review Decisions
SOP Code	403.01
Effective Date	September 2023

Site Approvals

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

1.0 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.

2.0 SCOPE

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

3.0 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.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

As a result of its review, an REB has the authority to approve, reject, or to require modifications to submitted research. If there are questions that must be addressed prior to a determination, the REB may defer its decision. 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.

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 institution's conflict of interest policies.

When the delegated review procedure is used, the REB Chair and/or REB member(s) who are assigned to the review can decide to approve the research or to request revisions to the research; the decision to reject the research must be made by the Full Board.

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 as submitted;
 - The approval date is defined according to local REB procedure;
 - The expiry date of the REB approval is calculated from this date.
- **Deferral with Request for Revisions:**
 - When REB members require revisions to any aspect of the application or clarification or further information to satisfy initial review criteria required for approval, the REB may defer their decision upon response to a "Request for Revisions";

- The REB must decide whether the researcher's response to the "Request for Revisions" should be reviewed by the Full Board, a subset of the board, an REB member (such as the lead reviewer), or the REB Chair or designee alone;
 - In deciding the review procedure to be followed, the REB should consider the significance of the requested revisions and clarifications;
 - Substantive revisions or clarifications may require review by the Full Board, lead reviewer(s) or relevant expert member(s);
 - Where the information or modifications are straightforward, it is acceptable to delegate the consideration of that material to the REB Chair or designee alone;
 - If the Researcher's response is deemed complete and satisfactory, approval can be issued;
 - If the Researcher's response is incomplete and does not fully address the matters raised, a request for further revisions or clarification should be sent to the Researcher;
 - The reviewers may decide upon reviewing the Researcher's response that the application and the Researcher's response materials should be reviewed at a subsequent Full Board meeting.
- **Rejection:**
 - The REB may reject 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;
 - Rejection cannot be decided through the delegated review mechanism. If the recommendation under delegated review is to reject 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 rejection are identified at the Full Board meeting for communication to the Researcher;
 - If the research is rejected, the reasons for rejection 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 approve the application, to require modifications to any aspect of the application, or to 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;
- When delegated review procedures are followed, approval is considered as the day the research is approved by the REB Chair or designee as well as all other designated reviewer(s), if applicable. The expiry date of the REB approval is calculated from this date; however, the approval letter is not issued until all of the conditions for approval have been met;
- If the research cannot be approved through the delegated review mechanism, it must be reviewed at a Full Board meeting.

5.2 Reconsideration and Appeal of REB Decisions

- 5.2.1 A Researcher may request that the REB reconsider its negative decision. The Researcher may choose to attend the Full Board meeting where the reconsideration takes place and may provide information to the REB in person or in writing. The Researcher may not be present during the following discussion or deliberations of the Board.
- 5.2.2 A Researcher may appeal the decision of the REB if the disagreement between the Researcher and the REB cannot be resolved through a reconsideration process at a Full Board meeting at which the Researcher shall have the right to be heard;
- 5.2.2 The Researcher must justify the grounds on which the appeal is requested. An appeal may be launched only for procedural or substantive reasons, and 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 institutional policy.
- 5.2.4 The appeal committee shall have the authority to review negative decisions made by the REB and in so doing it may approve, reject 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 requirements;
- 5.3.2 The REB shall notify the Researcher in writing of its decision to approve or

reject 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;
- 5.3.5 When the decision to approve a submission is recorded on behalf of the Full Board, or when a delegated reviewer electronically signs off on a decision (under delegated review procedures), the notification or correspondence to the Researcher may be issued by the REB Office Personnel.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
402.00	October 8 2020	Original version
402.01	September 2023	Reviewed, no revisions needed