



Title	REB Review Decisions
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Approvals

Status	Title	Date
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<i>Acknowledge of receipt</i>	MUHC Board of Directors	

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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. SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable regulations and guidelines. The term “Chair” in this SOP includes REB co-Chairs.

3. 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 communicated to the researcher and documented in the REB minutes.



4. DEFINITIONS

See Glossary of Terms.

5. PROCEDURE

The REB has the authority to approve, approve with modifications/clarifications, or disapprove 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 who are present at a Full Board meeting at which there is a quorum.

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 N2 SOP Conflicts of Interest REB Members, including MUHC-REB Addendum (Forthcoming), and the organization's conflict of interest policies.

Full Board review is the default for research projects submitted to the REB; however, some research may be eligible for delegated review in accordance with MUHC-REB SOP Delegated Review. A decision to disapprove 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 by consensus or a majority vote of the REB members present at a Full Board meeting, with the exception of those who have recused themselves in accordance with the conflict of interest policies. In the event that consensus is not reached, a vote may be held.

An REB member who disagrees with approval or approval with modifications/clarifications may express his dissent or abstention. This dissent or abstention will be documented in the minutes.

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:

a. Approval (approve the application as submitted, including the consent form):

- When an acceptable risk/benefit ratio exists and the regulatory criteria required for approval are satisfied, the research may be approved as submitted,
- The approval date is defined according to the date of the REB final approval.
- The expiry date of the REB approval is calculated from this date.

b. Approval with Modifications/Clarifications:

When an acceptable risk/benefit ratio exists, and the regulatory 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 and noted in the minutes.
- Unless otherwise specified by the board, the responsibility for additional review and the decision regarding approval conditions is delegated to the REB Chair. This responsibility may be delegated to one of the following:
 - ❖ 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 the regulations,
 - ❖ Where the additional information/modification is technical (e.g., statistical clarifications), the REB Chair or designee should review the information with consideration given to involving other REB members, such as the lead reviewer(s) or relevant expert member(s).
- The researcher is granted a 6 months delay to respond to any request from the REB,
- 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, 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),
- The approval date is the date of the REB final approval letter. The expiry date of the REB approval is calculated from the REB final approval date. The approval letter shall be issued once all of the conditions for approval have been met.
- c. 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 Researcher is granted a 6 month delay to respond to any request from the REB,



- The research and the Researcher's response materials shall be reviewed at a future 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).
- d. 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,
 - If the research is disapproved, the REB Chair or designee should ensure that the reasons for the disapproval are identified and communicated to the Researcher. The Researcher will be given an opportunity to respond in person or in writing, to request reconsideration and finally, may undertake an appeal process

5.1.3. Delegated Reviews:

Delegated reviews must comply with MUHC-REB SOP-402.001

5.2. Reconsideration and Appeal of REB Decisions

- 5.2.1. A Researcher may request a reconsideration of the REB decision if they can justify the grounds on which the reconsideration of the decision is requested. The researcher shall have the right to be heard at a Full Board meeting of the original panel to present their arguments relevant to the reconsideration.
- 5.2.2. After reconsideration, the decision must be issued by the panel. If the panel upholds its disapproval, the researcher will be offered the opportunity to have the study reconsidered by another panel of the MUHC REB. If they agree, it is with the understanding that the decision of the reconsidering panel shall be final.
- 5.2.3. If the researcher does not agree to a second reconsideration, an appeal may be launched for procedural or substantive reasons;
- 5.2.4. The organization at which the appeal will take place will be determined on a case-by-case basis from those within the RSSS by the REB in consultation with the Researcher;
- 5.2.5. The appeal committee shall have the authority to review negative 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 document: attendance, projects and documents reviewed and the type of review, the issues raised and the decisions made, abstentions and dissents with reasons. The REB meeting minutes can be approved at a subsequent meeting by two members who were in attendance at the meeting for which minutes are to be approved;
- 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;
- 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.

5.4. Cancelling REB Review Process

- 5.4.1. The REB may choose to cease review functions and withdraw a particular project if the researcher has not communicated or provided REB requested documents within 6 months of the REB's last communication.
- 5.4.2. Should the researcher not respond within the 6 months delay the REB shall, at its discretion, cancel its review process and close the submission.
- 5.4.3. Prior to the end of the 6 months delay, a researcher may submit a request to extend the response delay. This request must be justified to the satisfaction of the REB.

6. REFERENCES

Unité de l'éthique, Mesures correctives relatives au mode de fonctionnement des comités d'éthique de la recherche (2007)

7. REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
MUHC-REB-SOP-401.001	2017-02-24	Original Version
MUHC-REB-SOP-401.001_1	2017-07-07	5.0. Reference to MUHC-REB Addendum (Forthcoming) added; 5.0. Minor changes to references to other SOPs.
MUHC-REB-SOP-401.001_2	2018-11-20	5.3.1 Clarification of how meeting minutes can be approved