Title	REB Review Decisions
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~~**Approvals**~~

Status	~~Name and~~ Title	Date
~~Authored~~Author of Harmonized Template	~~CAE, Manager~~SOPs, Institutional REBs	~~2017-02-20~~2019-04-01
Approved	~~Director, MUHC Centre for Applied Ethics~~MUHC REB Full Board Meeting	~~2017~~2020-02-~~20~~13
Acknowledge ~~of~~ receipt	MUHC Board of Directors	2020-03-20

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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 designated REB ~~Office Personnel~~staff 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, and that the decision is clearly communicated to the ~~researcher~~Researcher and documented in the REB minutes.

4 DEFINITIONS

See Glossary of Terms.

5 PROCEDURES

The REB has the authority to approve, approve with modifications~~/clarifications~~, or disapprove the submitted research. ~~If~~[1] The determination should be made within a reasonable timeframe.[2] Nonetheless, 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[3] at which there is a quorum.[4] Full Board review is the default option for most initial submissions received by the REB.[5]

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1 ICH Harmonised Tripartite Guideline – Guidelines for Good Clinical Practice E6(R1), Health Canada, 1997, hereafter "ICH GCP", s. 3.1.2 and 3.3.9; *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche*, *Ministère de la Santé et des Services sociaux*, DGAERA, 2004, hereafter "*Modèle*", s. 4.2.

2 ICH GCP, s. 3.1.2; Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization (WHO), 2000, hereafter "TDR", s. 6 and 8; *Modèle*, s. 11.4.1.

3 TDR, s. 7.6; Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2014 (TCPS2), art. 6.13.

4 *Modèle*, s. 10.6 and 11; TCPS2, art. 6.9; ICH GCP, s. 3.2.3; TDR, s. 4.5.2 and 7.3.

5 TCPS2, art. 6.12.

Some research submissions may be eligible for delegated review, in accordance with the SOP on that topic. REB members assigned to the delegated review may approve the research or ask for modifications or further information, but they do not have the power to disapprove. Only Full Board reviews may disapprove research.[6]

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),~~[7] in accordance with ~~N2 SOP Conflicts of Interest REB Members, including MUHC REB Addendum (Forthcoming), and the organization's~~the institution's conflict of interest policies and the SOPs on conflicts of interest.

~~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.[8]

5.1 REB Decisions

5.1.1 REB decisions are made either by consensus or a majority vote of the REB members present at a Full Board meeting,[9] with the exception of those who have recused themselves in accordance with the conflict of interest policies. ~~In the event that~~If consensus ~~is not~~cannot be reached, the decision will proceed to a vote ~~may be held.~~[10]

An REB member who disagrees with ~~approval or approval with modifications/clarifications~~a decision may express ~~his~~ dissent or abstention~~. This dissent or abstention~~; this will be ~~documented~~recorded in the minutes.[11]

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[12]:

[6] TCPS2, art. 6.12.
[7] *Avis sur les conditions d'exercice des comités d'éthique de la recherche désignés ou institués par le ministre de la Santé et des Services sociaux en vertu de l'article 21 du Code civil, Gazette officielle du Québec*, Part I, vol. 35, 1998, hereafter "*Avis*", p. 1040; TCPS2, art. 7.3; TDR, s. 7.1.
[8] TCPS2, art. 6.19 and 6.20.
[9] TDR, s. 7.6; TCPS2, art. 6.13.
[10] TDR, s. 7.6.
[11] TCPS2, art. 6.13.
[12] ICH GCP, s. 3.1.2; *Modèle*, s. 4.2; TCPS2, art. 6.3.

- **Approval** (approve the application as submitted, including the consent form):
  - When ~~an acceptable risk/benefit ratio exists~~the research meets the ethical standards and the regulatory criteria required for approval~~ are satisfied, the research~~, it may be approved as submitted,
  - The approval ~~date~~ is ~~defined according to the date~~effective as of the date of REB final approval.
  - ~~The expiry date of the REB approval~~ It is ~~calculated~~effective for at most one year from this date.[13]
- **Approval with Modifications~~/Clarifications~~:**
  - ~~When an acceptable risk/benefit ratio exists,~~Even if the research meets the ethical standards and satisfies the regulatory criteria required for approval~~ are satisfied, but~~, the REB members may require modification ~~to any aspect of the application or clarification~~ or further information ~~to secure approval,~~ before granting final approval. Such decisions may include clarifications on how to review the ~~REB may recommend Approval with Modifications/Clarifications.~~changes,[14]
  - ~~When the~~ Except where otherwise indicated by the REB~~ recommends Approval with Modifications/Clarifications~~, the REB Chair or designee ~~should ensure that~~has the responsibilities for additional ~~information,~~ review and approval decision following the modifications~~,~~ or clarifications ~~required are identified at the REB meeting and noted in~~brought by 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.~~Researcher. This responsibility may be delegated to one of the following:
    - One or more named REB members ~~that~~who were present at the REB meeting or who submitted written comments on the application,
    - A ~~sub-group~~subgroup 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).~~

[13] *Modèle*, s. 11; TCPS2, art. 6.14.
[14] *Modèle*, s. 11.

- The ~~researcher is granted a 6~~ Researcher has 3 months ~~delay~~ to respond to ~~any request from the REB~~the REB, after which date the file will be closed and the research would have to be resubmitted,
- 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~~'Deferral' process below),
- The approval is effective ("effective date ~~is the date~~") as of the date of REB final approval ~~letter.~~. It is effective for at most one year.[15] The expiry date ~~of the REB approval~~ is calculated from the ~~REB final approval~~effective date~~. The~~; however, the final approval letter ~~shall be~~is not issued ~~once~~until all of the conditions for approval have been met~~.~~,

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

- 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 next REB meeting and included in the minutes.

- **Deferral:**
  - 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~~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~~has 3 months to respond to ~~any request from~~ the REB requests, The research ~~and the Researcher's response materials~~ shall be reviewed at a ~~future~~subsequent 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).~~

[15] *Modèle*, s. 11; TCPS2, art. 6.14.

- **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 clearly identified and communicated to the Researcher.[16] The Researcher will be given an opportunity to respond in person or in writing, to request reconsideration of the decision, and ~~finally, may undertake~~to file an appeal ~~process~~.[17]

Delegated Reviews:

- Delegated reviews ~~must comply~~may be performed in accordance with ~~MUHC REB~~the SOP ~~402.001~~ on that topic.

5.2 Reconsideration and Appeal of REB Decisions

5.2.1 A Researcher may ~~request a reconsideration~~ask that the decision of the REB ~~decision be~~ reconsidered if ~~they~~the Researcher can justify the grounds ~~on which the reconsideration of the decision is requested.~~for the request.[18] The ~~researcher~~Researcher/applicant shall have the right to be heard at a Full Board meeting ~~of~~at which he/she presents the ~~original panel to present their~~ arguments ~~relevant to~~in favour of the ~~reconsideration.~~case[19];

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~~REB will hand down its verdict. If the REB maintains its decision to disapprove the research, the REB may offer the ~~study reconsidered by~~Researcher another ~~panel~~ hearing, in front of a quorum distinct from the REB. The decision of ~~the MUHC REB.~~ that second quorum is final;

If ~~they agree, it is with~~ the ~~understanding that the decision of the reconsidering panel shall be final.~~

[16] *Modèle*, s. 11; TDR, s. 7.9 and 8.13.
[17] *Modèle*, s. 11.
[18] TCPS2, art. 6.18.
[19] TCPS2, art. 6.13; *Modèle*, s. 11.

5.2.25.2.3 ~~If the researcher~~Researcher does not ~~agree to~~accept a ~~second reconsideration,~~ hearing in front of a quorum distinct from the REB, an appeal may be launched for procedural or substantive reasons[20];

5.2.35.2.4 The ~~organization at which the~~ appeal will take place ~~will~~ at one of the REBs of the Quebec Health and Social Services Network (*Réseau de la santé et des services sociaux du Québec*), to be determined ~~on a case-by- case basis from those within~~ jointly between the REB and the ~~RSSS by the REB in consultation with the~~ Researcher;

5.2.45.2.5 The ~~appeal~~appeals committee ~~shall have the authority to~~ will review ~~negative decisions made by the REB and in~~ the research proposal. In so doing, it may approve, disapprove or request modifications ~~to the research proposal. Its~~.[21] The decision of the appeals committee must be justified and shall be final. The decision shall be ~~final and shall be~~ communicated to the Researcher and the REB in writing.[22]

5.3 Documenting REB Decisions

5.3.1 ~~5.3.1.~~ The REB ~~meetings~~meeting minutes will ~~document:~~contain the following: membership attendance, ~~projects and~~ research proposals, documents examined, review types, items reviewed ~~and the type of review, the issues raised and the~~(see Appendix), requests for modification and clarification, decisions ~~made,~~taken, and abstentions and dissents along with their respective 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~~[23];

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~~[24];

5.3.3 If the REB defers its decision or asks for modifications, the letter to the Researcher should include the issues of concern and ~~what further~~the additional information ~~is~~ required[25];

[20] TCPS2, art. 6.19.
[21] TCPS2, art. 6.20.
[22] TCPS2, art. 6.19.
[23] *Modèle*, s. 8.5.2; TCPS2, art. 6.17.
[24] TDR, s. 8; TCPS2, art. 6.13.
[25] *Modèle*, s. 11.4.2.

5.3.4 The final approval letter should include standard conditions of approval to which the Researcher must adhere, such as the duration of approval and the need to obtain authorization from the person formally mandated before starting the research[26];

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~~given by electronic means (e.g. Nagano), the notification or correspondence to the Researcher ~~may~~ be issued by the REB ~~Office Personnel~~Support Staff.

5.4 ~~Cancelling~~ Cancellation of REB Review ~~Process~~

The REB may ~~choose to cease review functions and withdraw a particular project~~terminate the review process or cancel the initial approval of a research proposal if the ~~researcher~~Researcher has not ~~communicated~~ responded and/or ~~provided REB~~ submitted the requested documents to the REB within ~~6~~ 3 months ~~of the REB's last communication.~~
~~Should the researcher not respond within the 6 months delay~~since the last REB ~~shall, at its discretion, cancel its review process and close the submission.~~

5.4.1 ~~Prior~~correspondence 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.~~Researcher (except for reminders).

6 REFERENCES

See footnotes.

[26] *Modèle*, s. 11.4.2.

7 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
~~MUHC-~~REB-SOP-~~-~~401.001	~~2017-02-~~ ~~24~~N.A.	Original ~~Version~~version
~~MUHC-~~REB-SOP-~~-~~401.001~~—~~1	~~2017-07-~~ ~~07~~2020-03-20	~~5.0. Reference to MUHC-REB Addendum (Forthcoming) added;~~ ~~5.0. Minor changes to references to other SOPs.~~5.4.1: exclusion for reminders
~~MUHC-REB-SOP-401.001_2~~	~~2018-11-20~~	~~5.3.1 Clarification of how meeting minutes can be approved~~

~~6~~8 APPENDICES