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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.

## 3 RESPONSIBILITIES

All REB members and designated REB 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 and documented in the REB minutes.

## 4 DEFINITIONS

See Glossary of Terms.

## 5 PROCEDURES

The REB has the authority to approve, approve with modifications, or disapprove the submitted research.<sup>1</sup> The determination should be made within a reasonable timeframe.<sup>2</sup> Nonetheless, if there are questions that must be addressed prior to 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<sup>3</sup> at which there is a quorum.<sup>4</sup> Full Board review is the default option for most initial submissions received by the REB.<sup>5</sup>

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.<sup>6</sup>

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> 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.

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

<sup>5</sup> TCPS2, art. 6.12.

<sup>6</sup> TCPS2, art. 6.12.

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,<sup>7</sup> in accordance with the institution's conflict of interest policies and the SOPs on conflicts of interest.

Researchers have the right to request reconsideration of the REB's decisions and to appeal the decision of the REB.<sup>8</sup>

## 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,<sup>9</sup> with the exception of those who have recused themselves in accordance with the conflict of interest policies. If consensus cannot be reached, the decision will proceed to a vote.<sup>10</sup>

An REB member who disagrees with a decision may express dissent or abstention; this will be recorded in the minutes.<sup>11</sup>

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<sup>12</sup>:

- **Approval** (approve the application as submitted, including the consent form):
  - When the research meets the ethical standards and the regulatory criteria required for approval, it may be approved as submitted,
  - The approval is effective as of the date of REB final approval. It is effective for at most one year from this date.<sup>13</sup>
- **Approval with Modifications:**
  - Even if the research meets the ethical standards and satisfies the regulatory criteria required for approval, the REB members may require modification or further information before granting final approval. Such decisions may include clarifications on how to review the changes,<sup>14</sup>
  - Except where otherwise indicated by the REB, the REB Chair or designee has the responsibilities for additional review and approval decision following the modifications

<sup>7</sup> *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.*

<sup>8</sup> TCPS2, art. 6.19 and 6.20.

<sup>9</sup> TDR, s. 7.6; TCPS2, art. 6.13.

<sup>10</sup> TDR, s. 7.6.

<sup>11</sup> TCPS2, art. 6.13.

<sup>12</sup> ICH GCP, s. 3.1.2; *Modèle*, s. 4.2; TCPS2, art. 6.3.

<sup>13</sup> *Modèle*, s. 11; TCPS2, art. 6.14.

<sup>14</sup> *Modèle*, s. 11.

or clarifications brought by the Researcher. This responsibility may be delegated to one of the following:

- One or more named REB members who were present at the REB meeting or who submitted written comments on the application,
- A 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;
- The Researcher has 3 months to respond to 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' process below),
- The approval is effective ("effective date") as of the date of REB final approval. It is effective for at most one year.<sup>15</sup> The expiry date is calculated from the effective date; however, the final approval letter is not issued until all of the conditions for approval have been met,
- 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 or designee should ensure that all additional information, modifications or clarifications that are required are specifically identified at the Full Board meeting,
  - The Researcher has 3 months to respond to the REB requests,
  - The research shall be reviewed at a subsequent Full Board meeting.

<sup>15</sup> *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.<sup>16</sup> The Researcher will be given an opportunity to respond in person or in writing, to request reconsideration of the decision, and to file an appeal.<sup>17</sup>

5.1.3 **Delegated Reviews:**

- Delegated reviews may be performed in accordance with the SOP on that topic.

5.2 **Reconsideration and Appeal of REB Decisions**

5.2.1 A Researcher may ask that the decision of the REB be reconsidered if the Researcher can justify the grounds for the request.<sup>18</sup> The Researcher/applicant shall have the right to be heard at a Full Board meeting at which he/she presents the arguments in favour of the case<sup>19</sup>;

5.2.2 After reconsideration, the REB will hand down its verdict. If the REB maintains its decision to disapprove the research, the REB may offer the Researcher another hearing, in front of a quorum distinct from the REB. The decision of that second quorum is final;

5.2.3 If the Researcher does not accept a hearing in front of a quorum distinct from the REB, an appeal may be launched for procedural or substantive reasons<sup>20</sup>;

5.2.4 The appeal will take place 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 jointly between the REB and the Researcher;

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<sup>16</sup> *Modèle*, s. 11; TDR, s. 7.9 and 8.13.

<sup>17</sup> *Modèle*, s. 11.

<sup>18</sup> TCPS2, art. 6.18.

<sup>19</sup> TCPS2, art. 6.13; *Modèle*, s. 11.

<sup>20</sup> TCPS2, art. 6.19.

5.2.5 The appeals committee will review the research proposal. In so doing, it may approve, disapprove or request modifications.<sup>21</sup> The decision of the appeals committee must be justified and shall be final. The decision shall be communicated to the Researcher and the REB in writing.<sup>22</sup>

### 5.3 Documenting REB Decisions

5.3.1 The REB meeting minutes will contain the following: membership attendance, research proposals, documents examined, review types, items reviewed (see Appendix), requests for modification and clarification, decisions taken, and abstentions and dissents along with their respective reasons<sup>23</sup>;

5.3.2 The REB shall notify the Researcher in writing of its decision<sup>24</sup>;

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 the additional information required<sup>25</sup>;

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<sup>26</sup>;

5.3.5 When the decision to approve a submission is given by electronic means (e.g. Nagano), the notification or correspondence to the Researcher may be issued by the REB Support Staff.

### 5.4 Cancellation of REB Review

5.4.1 The REB may terminate the review process or cancel the initial approval of a research proposal if the Researcher has not responded and/or submitted the requested documents to the REB within 3 months since the last REB correspondence to the Researcher (except for reminders).

## 6 REFERENCES

See footnotes.

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<sup>21</sup> TCPS2, art. 6.20.

<sup>22</sup> TCPS2, art. 6.19.

<sup>23</sup> *Modèle*, s. 8.5.2; TCPS2, art. 6.17.

<sup>24</sup> TDR, s. 8; TCPS2, art. 6.13.

<sup>25</sup> *Modèle*, s. 11.4.2.

<sup>26</sup> *Modèle*, s. 11.4.2.

## 7 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
REB-SOP 401.001	N.A.	Original version
REB-SOP 401.001-1	2020-03-20	5.4.1: exclusion for reminders (MUHC Board of Directors acknowledged 2020-03-20; approved 2021-03-22)

## 8 APPENDICES