

Title	Delegated Review
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## 1 PURPOSE

This standard operating procedure (SOP) describes the processes for determining when research meets the criteria for delegated ethics review and the associated delegated review procedures.

## 2 SCOPE

This SOP pertains to ~~the MUHC~~ Research Ethics ~~Board~~Boards (REB) that ~~reviews~~review human participant research in compliance with applicable regulations and guidelines. ~~The term "Chair" in this SOP includes MUHC 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 determining if research is eligible for delegated review. In some circumstances, the REB Chair or designee may delegate this task to qualified REB ~~Office Personnel~~Support Staff; however, the responsibility for oversight remains with the REB Chair or designee.<sup>1</sup>

~~The REB Chair or designee or qualified REB member(s) is responsible for conducting the delegated review.~~

## 4 DEFINITIONS

See Glossary of Terms.

## 5 PROCEDURES

REBs should adopt a proportionate approach to ethics assessment based on the general principle that the more invasive or harmful the proposed and ongoing research, the greater should be the care in assessing the research. ~~While<sup>2</sup> In all research must be reviewed adequately, requirements for cases, proportionate review allow the REB to provide implies a higher level consideration of scrutiny foreseeable risks, potential benefits, and correspondingly more protection, for ethical implications of the most ethically challenging research in question.<sup>3</sup>~~

In practice, the proportionate review implies different levels of REB review for different research projects. The two levels ~~typically~~typical used by REBs are Full Board review or delegated review by one or more experienced REB members, as determined by the REB Chair or designee. ~~The REB Chair or designee may authorize delegated review based primarily on the level of risk entailed in the research.<sup>4</sup>~~

~~When the research qualifies for delegated review, the reviewer(s) has the authority to approve the application, to require modifications to any aspect Approval is effective as of the application, or to~~

<sup>1</sup> 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. 6.12.

<sup>2</sup> TCPS2, art. 2.9 and 6.12.

<sup>3</sup> TCPS2, art. 2.9 and 6.12.

<sup>4</sup> TCPS2, art. 2.9 and 6.12; *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. 10.2; Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization (WHO), 2000, hereafter "TDR", s. 6.3.

~~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.~~

~~The approval is the date of the REB approval (final approval letter. The expiry date of the initial, according to local REB approval procedure).<sup>5</sup> It is calculated effective for at most one year from the REB final approval this date. The approval letter shall be of approval, however, is not issued once until all of the conditions for approval have been met.~~

If the research cannot be approved ~~through the~~ by delegated review ~~mechanism, it must be reviewed at~~, a Full Board ~~meeting~~ Review will be done.

## 5.1 Determination of Qualification for Delegated Review

5.1.1 Full Board review is the default ~~for most new~~ option<sup>6</sup>;

~~5.1.15.1.2~~ 5.1.2 New research projects ~~submitted to that fall under Article 21 of the REB; however, some research may Civil Code of Québec<sup>7</sup> cannot be eligible for~~ evaluated by delegated review at the time of initial REB review<sup>8</sup>;

~~5.1.25.1.3~~ 5.1.3 Submissions that meet the following criteria ~~may be~~ are eligible for delegated review:

- Research projects that involve no more than minimal risk,<sup>9</sup>
- ~~For research involving minors or other persons incapable of giving consent, review may be delegated if there is no possibility that the research could~~ Research projects that do not interfere with the integrity<sup>10</sup> of his a minor or of a person: of full age incapable of giving consent,<sup>11</sup>
- ~~Minor or minimal risk changes~~ Changes to approved research, ~~that have no impact on the risk/benefit ratio,~~<sup>12</sup>
- ~~Continuing review of~~ Annual renewal of ethics approval, when authorized in accordance with applicable rules and regulations,<sup>13</sup> for the following:
  - approved minimal risk research,<sup>14</sup>
  - ~~Continuing review of~~ research that is more than minimal risk for which enrolment is closed permanently and all research-related interventions for all participants are

<sup>5</sup> Modèle, s. 11; TCPS2, art. 6.12.

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

<sup>7</sup> Civil Code of Québec, c. CCQ-1991, art. 21.

<sup>8</sup> Modèle, s. 10.2.

<sup>9</sup> TCPS2, art. 6.12.

<sup>10</sup> Modèle, s. 10.2.

<sup>11</sup> Civil Code of Québec, c. CCQ-1991, art. 21.

<sup>12</sup> ICH Harmonised Tripartite Guideline – Guidelines for Good Clinical Practice E6(R1), Health Canada, 1997, hereafter “ICH GCP”, s. 3.3.5; TCPS2, art. 6.12.

<sup>13</sup> TCPS2, art. 6.12.

<sup>14</sup> TCPS2, art. 6.12.

~~complete and the only remaining research activities are post-intervention activities or follow-up of participants; or, where the remaining research activities are limited to data analysis; or, where no participants have been enrolled and no additional risks have been identified,~~<sup>15</sup>

- ~~Continuing review of research that is more than minimal risk, where the remaining research activities are limited to data analysis,~~
- ~~research that is more than minimal risk, where no participants have been enrolled and no additional risks have been identified,~~
- ~~research that is more than minimal risk when there has been little or no modification of the research; and when there has been no increase in risk to, or other ethical implications for participants, since the initial review by the full REB; if permissible under all applicable governing Regulations,~~<sup>7</sup> or
- research that is more than minimal risk and when there has been no increase in risk to or other ethical implications for participants since the initial review by the full REB;
- The submission response by the Researcher ~~in response to the REB review as a condition of approval to~~ REB requests for modifications and/or clarifications, unless otherwise ~~specified~~stated by the ~~Board~~REB,
- Changes to consent documents that do not affect the rights and welfare of research participants or involve increased risk, or affect data integrity, or require significant changes in research procedures;<sup>12</sup>
  - ~~a. Changes to consent documents of a study that was initially approved through delegated review and that still meets the criteria for delegated review.~~

~~5.1.3~~5.1.4 Reportable events, including adverse events and Safety~~drug safety~~ updates ~~such as reports from the Data and Safety Monitoring Boards (DSMC);~~, are reviewed according to the SOP on activities related to ongoing REB review;

~~5.1.4~~5.1.5 The REB Chair or designee may use delegated review procedures for the review of other types of minor changes<sup>16</sup> including, but not limited to, the following:

- Participant materials such as: recruitment posters or scripts, diaries, validated questionnaires, clinical trial identification/wallet cards;<sup>14</sup>
- ~~Changes of address;~~
- Address changes;

~~5.1.5~~5.1.6 The REB Chair or designee may ~~be authorized by the full Board to use delegated review procedures for the review of~~ miscellaneous items such as changes to meeting minutes that previously received approval with conditions at a Full Board meeting;<sup>1</sup>

<sup>15</sup> TCPS2, art. 6.12.

<sup>16</sup> ICH GCP, s. 3.3.5.

5.1.65.1.7 When determining if initial review of research or modifications to previously approved research are eligible for delegated review, the REB Chair or designee will ~~consider the level of risk entailed in the research by taking~~take into consideration the methods used to conduct the research, recruitment practices, participant population, confidentiality of data, and all regulatory and ethics guidance requirements as applicable.

## 5.2 Delegated Review Process

5.2.1 ~~Qualified REB Office Personnel will perform an initial screening of the submission. Those submissions that meet a pre-defined set of criteria for delegated review as determined by the REB may be forwarded for delegated review. For all other submissions, the~~The REB Chair or designee ~~will make the determination of~~or qualified REB Support Staff will determine whether the submission meets the criteria for delegated review<sup>17</sup>;

5.2.2 For research that meets the criteria, delegated review may be conducted by the REB Chair, or by one or more qualified REB members as designated by the REB Chair or designee<sup>18</sup>;

The ~~authority of~~ REB ~~Chair or designee reviewing research under~~ members conducting a delegated review ~~must not have a conflict of interest in the research~~;

5.2.3 ~~In reviewing the research under delegated procedures, the REB Chair or designee may exercise all is similar to that of the authorities of the REB, except that he/she may not~~REB, but without the ~~power to~~ disapprove the research; the research may be disapproved only after it has been reviewed by the REB at a Full Board meetingresearch project<sup>19</sup>;

5.2.4 REB member(s) conducting a delegated review may request the expertise of an ad hoc advisor, if applicable. Ad hoc advisors may not participate in the final decision regarding approval of the research<sup>20</sup>;

5.2.5 If the REB Chair or designee subsequently determines that the level of risk for the submission is greater than minimal, the submission will be referred to a Full Board meeting for review<sup>2</sup>.

~~The REB Chair or designee will record the decision regarding the designation of the research (i.e., either requiring FB or delegated review) and the outcome of the review. The responsible REB Office Personnel may issue the review or decision letter.~~

## 5.3 Notification of the REB

<sup>17</sup> TDR, s. 6.3; TCPS2, art. 6.12.

<sup>18</sup> TCPS2, art. 6.12.

<sup>19</sup> TCPS2, art. 6.12.

<sup>20</sup> TCPS2, art. 6.5; TDR, s. 4.6; ICH GCP, s. 3.2.6.

5.3.1 At its next Full Board meeting the REB will be informed of any research that was reviewed and approved using delegated review procedures.

## 5.4 Documentation

5.4.1 The type of REB review conducted (i.e., Full Board or delegated) is documented in the REB records and noted in the decision letter issued to the Researcher, where appropriate;

5.4.2 The REB meeting agendas and minutes will include a list of submissions that were reviewed and approved using delegated review procedures from the time that the agenda for the previous REB meeting was issued.

## 6 REFERENCES

See footnotes.

## 7 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
<del>MUHC-REB-SOP-402.001</del>	<del>2017-02-24</del> <u>2020-03-20</u>	Original <del>Version</del> <u>version</u>
<del>MUHC-REB-SOP-402.001_1</del>	<del>2017-07-07</del>	<del>5.1.2.i. Addition of condition</del>

## 8 APPENDICES