

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 Research Ethics Boards (REB) 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 determining if research is eligible for delegated review. In some circumstances, the REB Chair or designee may delegate this task to qualified REB Support Staff; however, the responsibility for oversight remains with the REB Chair or designee.¹

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.² In all cases, proportionate review implies a consideration of foreseeable risks, potential benefits, and ethical implications of the research in question.³

In practice, the proportionate review implies different levels of REB review for different research projects. The two levels 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.⁴

Approval is effective as of the date of REB approval (final or initial, according to local REB procedure).⁵ It is effective for at most one year from this date. The letter of approval, however, is not issued until all the conditions for approval have been met.

¹ 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.

² TCPS2, art.2.9 and 6.12.

³ TCPS2, art. 2.9 and 6.12.

⁴ 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.*

⁵ *Modèle, s. 11; TCPS2, art. 6.12.*

If the research cannot be approved by delegated review, a Full Board Review will be done.

5.1 Determination of Qualification for Delegated Review

5.1.1 Full Board review is the default option⁶;

5.1.2 New research projects that fall under Article 21 of the *Civil Code of Québec*⁷ cannot be evaluated by delegated review at the time of initial REB review⁸;

5.1.3 Submissions that meet the following criteria are eligible for delegated review:

- Research projects that involve no more than minimal risk,⁹
- Research projects that do not interfere with the integrity¹⁰ of a minor or of a person of full age incapable of giving consent,¹¹
- Changes to approved research that have no impact on the risk/benefit ratio,¹²
- Annual renewal of ethics approval, when authorized in accordance with applicable rules and regulations,¹³ for the following:
 - approved minimal risk research,¹⁴
 - research that is more than minimal risk for which enrolment is closed permanently and all research-related interventions for all participants are complete,¹⁵
 - 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, 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 response by the Researcher to REB requests for modifications and/or clarifications, unless otherwise stated by the REB,

⁶ TCPS2, art. 6.12.

⁷ Civil Code of Québec, c. CCQ-1991, art. 21.

⁸ *Modèle*, s. 10.2.

⁹ TCPS2, art. 6.12.

¹⁰ *Modèle*, s. 10.2.

¹¹ Civil Code of Québec, c. CCQ-1991, art. 21.

¹² 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.

¹³ TCPS2, art. 6.12.

¹⁴ TCPS2, art. 6.12.

¹⁵ TCPS2, art. 6.12.

- 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;

5.1.4 Reportable events, including adverse events and drug safety updates, are reviewed according to the SOP on activities related to ongoing REB review;

5.1.5 The REB Chair or designee may use delegated review procedures for the review of other types of minor changes¹⁶ including, but not limited to, the following:

- Participant materials such as: recruitment posters or scripts, diaries, validated questionnaires, clinical trial identification/wallet cards,
- Address changes;

5.1.6 The REB Chair or designee may review miscellaneous items such as changes to meeting minutes that previously received approval with conditions at a Full Board meeting;

5.1.7 When determining if initial review of research or modifications to previously approved research are eligible for delegated review, the REB Chair or designee will 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 The REB Chair or designee or qualified REB Support Staff will determine whether the submission meets the criteria for delegated review¹⁷;

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 designee¹⁸;

5.2.3 The authority of REB members conducting a delegated review is similar to that of the REB, but without the power to disapprove a research project¹⁹;

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 research²⁰;

¹⁶ ICH GCP, s. 3.3.5.

¹⁷ TDR, s. 6.3; TCPS2, art. 6.12.

¹⁸ TCPS2, art. 6.12.

¹⁹ TCPS2, art. 6.12.

²⁰ TCPS2, art. 6.5; TDR, s. 4.6; ICH GCP, s. 3.2.6.

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.

5.3 Notification of the REB

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
REB-SOP 402.001	2020-03-20	Original version

8 APPENDICES