

Title	Annual Review – Renewal of REB Approval
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1 PURPOSE

This standard operating procedure (SOP) describes the procedures and criteria for the annual review and continued ethics approval of research that is overseen by the Research Ethics Board (REB).

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.

4 DEFINITIONS

See Glossary of Terms.

5 PROCEDURES

REBs must establish procedures for conducting the continuing review of approved research involving human participants.¹ Renewal of ethics approval takes place at appropriate intervals, but at least once a year.² Periodic review of research activities is necessary to determine whether approval should be continued or withdrawn.

5.1 Review of the Application for Annual Renewal

5.1.1 The level of REB review (Full Board meeting or delegated review) will be determined according to criteria set out in the REB SOP on Delegated Review;

5.1.2 The REB may determine that the research requires continuing review more often than once per year by considering the following³:

- The risks posed by the research,
- The vulnerability of the population under study,
- The belief by the REB that, for whatever other reason, more frequent review is required;

¹ *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique, Ministère de la Santé et des Services sociaux du Québec (PAM), 1998; Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization (WHO), 2000, hereafter "TDR", s. 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. 13; 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; Note de clarification relative au concept de suivi continu de l'éthique des projets, Note 2, Gouvernement du Québec, Direction générale adjointe de l'évaluation, de la recherche et des affaires extérieures, Ministère de la Santé et des Services sociaux, Unité de l'éthique, May 2007.*

² ICH Harmonised Tripartite Guideline – Guidelines for Good Clinical Practice E6(R1), Health Canada, 1997, hereafter "ICH GCP", s. 3.1.4; *Modèle*, s. 11; 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. 6.14; TDR, s. 2.

³ TCPS2, art. 6.14, p. 83.

- 5.1.3 At a minimum, the REB requires that an application for continuing review be submitted once per year until the end of the research (see REB SOP on Research Completion)⁴;
- 5.1.4 The Researcher is required to submit an application for continuing review of research, at a frequency to be determined by the REB and which will be defined at the time of initial approval of the research, or as otherwise revised⁵;
- 5.1.5 If the Researcher receives instructions from the Sponsor to report events or submit documents not required by the REB according to the SOP on activities related to current review, the Researcher may nonetheless submit them to the REB at the time of the annual review for renewal of ethics approval;
- 5.1.6 Continuing review applications are due at least 4 weeks prior to the deadline for ethics approval, regardless of the type of review;
- 5.1.7 To assist the Researchers in submitting on time, courtesy reminder(s) prior to the expiry date may be generated;
- 5.1.8 The designated REB Support Staff reviews the application for completeness. Incomplete applications may be returned to the Researcher;
- 5.1.9 The designated REB Support Staff will add the application to the agenda of the next REB meeting, if the research meets the criteria for Full Board review according to the related SOP;
- 5.1.10 The REB Support Staff will forward the application to the appropriate REB reviewer(s). The REB Support Staff may also process the application if this is specifically provided for in the REB delegation log;
- 5.1.11 The REB may request additional information or clarification, as necessary, and will make a decision regarding the annual renewal of ethics approval for continued conduct of the research;
- 5.1.12 Decisions of delegated reviews of annual ethics approval renewals will be added to the agenda of the next REB Full Board meeting.

5.2 Criteria for REB Determinations

- 5.2.1 To grant annual renewal of the ethics approval of the research, the REB must determine that:
- Any and all material changes have been reported to the REB,
 - Any new information that has emerged that might affect the safety or the well-being of research participants has been reported to the REB;

⁴ ICH GCP, s. 3.1.4; *Modèle*, s. 11; TCPS2, art. 6.14; TDR, s. 2.

⁵ TCPS2, art. 6.14; *Avis*, p. 1040; *Modèle*, s. 13; TDR, s. 9; ICH GCP, s. 3.3.4.

5.2.2 The REB may also:

- Request changes to documents related to the study,
- Request changes to the interval for renewal of ethics approval,
- Impose special precautions,
- Suspend or terminate REB approval.

5.3 Continuing Review Applications not Received by the Expiry Date

5.3.1 If an application for continuing review is not submitted by the expiry date, a warning, suspension notice, or notice of closure could be issued to the Researcher;

5.3.2 At the expiry of ethics approval, the Researcher must suspend all research activities associated with the research project, as long as the termination does not endanger the safety of the participants. The Researcher is responsible for notifying the REB if there is a need to continue research-related medical treatment of current participants for their safety and well-being;

5.3.3 The Researcher must document the reasons for the lapse and identify the steps taken to prevent future lapses;

5.3.4 Renewal granted by the REB is not retroactive; i.e. there will be no ethics approval for the period covering the lapse.

6 REFERENCES

See footnotes.

7 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
REB-SOP 406.001	2020-03-20	Original version (MUHC Board of Directors acknowledged 2020-03-20; approved 2021-03-22)

8 APPENDICES