Title	~~Continuing~~Annual Review – ~~Annual~~ Renewal of REB Approval
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~~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
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1 PURPOSE

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

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.

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 ~~intervals~~ appropriate ~~to the degree of risk~~intervals, but ~~not less than~~at least once a year.[2] Periodic review of research activities is necessary to determine whether approval should be continued or withdrawn.

5.1 ~~Continuing~~ Review ~~by~~of the Application for Annual Renewal

~~1.1.~~ THE LEVEL OF REB REVIEW (Full Board

5.1.1 ~~The Researcher is required to submit an application for continuing review of research at a frequency to be~~ meeting or delegated review) will be determined ~~by~~according to criteria set out in the REB ~~and which will be defined at~~SOP on Delegated Review;

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[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.

5.1.2 The REB may determine that the ~~time of~~ research requires continuing review more often than once per year by considering the ~~initial approval of~~following[3]:

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

~~5.1.1~~5.1.3 At a minimum, the REB requires that an application for continuing review be submitted once per year until ~~all of the data has been collected, all contact with research participants has concluded and the closure of the research has been acknowledged by the REB~~the end of the research (see REB SOP on Research Completion)[4];

5.1.4 ~~Should the researcher have~~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 revised[5];

5.1.5

If the Researcher receives instructions from the ~~sponsor~~Sponsor to report~~/submit~~ events~~/~~ or submit documents ~~that are~~ not required by the REB ~~as per~~ according to the SOP ~~404, the researcher~~on activities related to current review, the Researcher may nonetheless submit them to the REB at the time ~~of annual or continuing review.~~

~~The REB may determine that the research requires continuing review more frequently than once per year by considering the following:~~

- ~~The nature of any risks posed by the research,~~
- ~~The degree of uncertainty regarding the risks involved,~~
- ~~The vulnerability~~ of the ~~participant population,~~
- ~~The projected rate of enrolment and estimated research closure date,~~
- ~~Whether the research involves novel interventions,~~

~~5.1.2~~5.1.6 ~~The REB believes that more frequent~~ annual review ~~is required~~for renewal of ethics approval;

~~5.1.3~~5.1.7 Continuing review applications are due at least ~~2~~4 weeks prior to the ~~REB meeting that pre-dates the expiry (i.e., the expiry date must be on or after the REB meeting date and prior to the date of~~

[3] TCPS2, art. 6.14, p. 83.
[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.

~~the subsequent REB meeting),~~deadline for ethics approval, regardless of the type of review ~~they may undergo~~;

~~5.1.4~~5.1.8 To assist the Researchers in submitting on time, ~~a~~ courtesy reminder(s) prior to the expiry date may be generated;

~~5.1.5~~5.1.9 The ~~responsible~~designated REB ~~Office Personnel~~Support Staff reviews the application for completeness~~, and requests any clarifications, missing documents or other information from the Researcher, as applicable~~. Incomplete applications may be returned to the Researcher;

~~5.1.6~~

~~The REB may request verification from sources other than the investigator that no material changes have occurred since previous REB review. For example:~~

- ~~Based on the results of a previous audit or inspection (internal or external),~~
- ~~In cases of suspected non-compliance,~~
- ~~For studies involving vulnerable populations,~~
- ~~For studies involving a potentially high risk to participants,~~
- ~~In cases of suspected or reported protocol deviations,~~
- ~~In cases of participant or Research Staff complaints,~~
- ~~Any other situation that the REB deems appropriate;~~

~~5.1.7~~5.1.10 ~~The responsible REB Office Personnel will assign~~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~~. (see~~ according to the related SOP ~~401);~~;

~~1.1.10. A summary report of the continuing review applications assigned to the REB meeting may be attached to the REB meeting agenda;~~

~~1.1.11. For research that meets the criteria for Full Board review, the REB will discuss the research at a Full Board meeting and will make a decision regarding the continued approval of the research, as well as any other additional determinations regarding the conduct of the research, as applicable.~~

~~**2.**~~

~~**3.** Continuing Review by Delegated Review~~ The REB Support Staff

~~**4.** When the research received initial approval via delegated review it may undergo delegated review at the time of continuing review;~~

~~**5.** Research that was previously reviewed by the Full Board may also be reviewed at the time of continuing review using delegated review procedures if the conditions are met as per SOP 401;~~

~~6. The responsible REB Office Personnel reviews the continuing review application for completeness, including verification of the currently approved informed consent form(s), and requests any clarifications, missing documents or other information as applicable;~~

~~5.1.8~~5.1.11 ~~The responsible REB Office Personnel~~ will forward the application to the appropriate ~~reviewer~~REB reviewer(s). The REB Support Staff may also process the application if this is specifically provided for in the REB delegation log;

~~5.1.9~~5.1.12 The ~~reviewer~~REB may request additional information or clarification, as necessary, and will make a decision regarding the ~~continued~~annual renewal of ethics approval ~~of the research and the~~for continued conduct of the research;

~~5.1.10~~5.1.13 ~~Upon reviewing an application that was sent for~~ Decisions of delegated ~~review, if~~ reviews of annual ethics approval renewals will be added to the ~~reviewer determines that~~agenda of the ~~risks are now greater than minimal, the reviewer will refer the application for review by the~~next REB Full Board meeting.

5.2 Criteria for REB Determinations

5.2.1 To grant ~~a continuation~~annual renewal of the ethics approval of the research, the REB must determine that:

- ~~There have been no~~Any and all material changes have been reported to the ~~research or to the informed consent form that have not been previously submitted and approved~~REB,
- ~~No new conflict of interest or~~Any new information that has emerged that might ~~adversely~~ affect the safety or the well-being of research participants has been reported to the REB~~,~~;

5.2.2 The REB may also:

~~Any new risks to research participants are minimized and reasonable in relation to the anticipated benefits,~~

~~make additional determinations, inclu~~

- Request changes to documents related to the study,
- Request changes to the ~~informed consent form(s),~~
  - ~~Request changes for the continuing review~~ interval ~~(based on risks),~~for renewal of ethics approval,
- Impose special precautions ~~(e.g., frequency of monitoring, the requirement for interim reports or duration of approval period),~~
  - ~~Require modifications to the research~~,
  - 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 ~~or a~~, suspension notice ~~will~~, or notice of closure could be issued to the Researcher~~. When suspended,~~;

At the expiry of ethics approval, the Researcher must suspend all research activities ~~as specified by the REB. The responsible REB Office Personnel will follow-up~~associated with the ~~Researcher to ensure that~~ research project, as long as the ~~application for continuing review is submitted as soon as possible;~~

~~5.3.1~~5.3.2 ~~In~~termination does not endanger the ~~event~~safety of ~~a lapse in approval,~~ the participants. The Researcher is responsible for notifying the REB if there is a need to continue research-related medical treatment of current ~~research~~ participants for their safety and well-being~~. The Researcher should provide as much detail as possible about the proposed continued activities. The REB Chair or designee will review the request as quickly as possible and discuss the proposed continued activities with the Researcher;~~;

~~5.3.2~~5.3.3 The Researcher must document the reasons for the lapse and identify the steps taken to prevent future lapses;

~~5.3.3 If the REB approval lapses and the Researcher wants to continue with the research, the REB will complete the review of the research as soon as possible and the Researcher may resume the suspended activities once approval of the research has been issued. The lapse in approval will be documented.~~

~~A lapse in approval of more than 30 days may result in termination of the study's ethics approval.~~

5.3.4 ~~See~~ 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
~~MUHC-~~REB-SOP~~-~~ 406.001	~~2017-02-24~~2020-03-20	Original ~~Version~~version

8 APPENDICES