Research Ethics Board

Standard Operating Procedure

Document Number	**REB.SOP.405**
Title	Continuing Review
Effective Date	September 23, 2021
Next Review	2026
Next Administrative Review	2023

1. **Purpose**
   This standard operating procedure (SOP) describes the procedures for the continuing review of research that is overseen by the Research Ethics Board (REB), and the criteria for continued REB clearance.

2. **Definitions**
   See the MSVU **REB Glossary of Terms (REB.INFO.001)**

3. **Scope**
   This SOP pertains to REBs that review human participant research in compliance with applicable policies and guidelines.

4. **Responsibilities**
   All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

   The REB Chair or designee and the REB members are responsible for reviewing continuing review submissions and respective materials as appropriate for Full Board or delegated review.

5. **Procedures and/or Specific Policies**
   REBs must establish procedures for conducting the continuing review of approved research involving human participants at intervals appropriate to the degree of risk, but not less than once a year. Periodic review of research activities is necessary to determine whether clearance should be continued or withdrawn.

   5.1. Continuing Review by the Full Board

   5.1.1. 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 the initial clearance of the research, or as otherwise revised;

   5.1.2. 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;

5.1.3. The REB may determine that the research requires continuing review more frequently than once per year. Considerations may include:
- The nature of any risks posed by the research,
- The degree of uncertainty regarding the risks involved,
- The vulnerability of the participant population;

5.1.4. Continuing review applications must be submitted with sufficient time to be reviewed and approved prior to the date of expiry, regardless of the type of review they may undergo;

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

5.1.6. REB Office Personnel will review the application for completeness, and requests any clarifications, missing documents or other information from the Researcher, as applicable;

5.1.7. REB Office Personnel will assign the application to the agenda of the next REB meeting if the research meets the criteria for Full Board review;

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

5.1.9. 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 clearance of the research, as well as any other additional determinations regarding the conduct of the research, as applicable.

5.2. Continuing Review by Delegated Review Procedures

5.2.1. When the research received initial clearance via delegated review it may undergo delegated review at the time of continuing review;

5.2.2. 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 (see SOP 401);

5.2.3. REB Office Personnel will review the continuing review application for completeness, including verification of which, if any, documents have been changed, and request any clarifications, missing documents or other information as applicable;

5.2.4. REB Office Personnel will forward the application to the appropriate REB reviewer;

5.2.5. The reviewer may request additional information or clarification, as necessary, and will make a decision regarding the continued clearance of the research and the continued conduct of the research;

5.2.6. Upon reviewing an application that was sent for delegated review, if the reviewer determines that the risks are now greater than minimal, the reviewer will refer the application for review by the Full Board.

5.3. REB Determinations

5.3.1. To grant a continuation of the clearance of the research the REB must determine that Criteria for REB Clearance, as described in SOP 403, are still met.

5.3.2. The REB may also make additional determinations, as per SOP 402, REB Review Decisions.

5.4. Continuing Review Applications Not Received by the Expiry Date

5.4.1. If an application for continuing review is not submitted by the expiry date, a warning or suspension notice will be issued to the Researcher(s). When suspended, the Researcher must suspend all research activities as specified by the REB.

5.4.2. If the REB clearance lapses and the Researcher wants to continue with the research, the REB may, in some special circumstances, allow the Researcher to submit an application for continuing review after the expiry date. The REB will complete the review of the research as soon as possible and the Researcher may resume the suspended activities once clearance of the research has been issued. The lapse in clearance will be documented.

5.4.3. The REB may define a reasonable length of time for which a Researcher may submit an application for continuing review, beyond which the research is closed, and a renewal application will not be accepted. A new submission will be required.

6. References

See References listed (if applicable)

7. Acknowledgements

The development of this document has benefited directly from similar documents made public by the Tri-Council, as well as several Canadian universities. In some instances, specific formulations drawn from these sources have been incorporated into this document. Specific iterations were drawn from the following:

- Standard Operating Procedures for Observational Health and Non-Clinical Trial Research Ethics Boards - N2/CAREB-ACCER REB SOPs – Canadian Association of Research Ethics Boards (retrieved July 2021)
- N2/CAREB-ACCER REB SOPs - N2 Network of Networks - Resources - N2 Canada (retrieved July 2021)

8. SOP History

SOP Number	Key Changes	Effective Date
REB.SOP.405	Original Version	September 2021

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