

Title	Continuing Review
SOP Code	405.002
Effective Date	2023-NOV-03

Site Approvals

Name and Title	Signature	Date (yyyy.mm.dd)
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1.0 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 approval.

2.0 SCOPE

This SOP pertains to the Human Research Ethics Board (HREB), Mount Royal University.

3.0 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 ethics clearance renewal submissions (continuing review) and respective materials as appropriate for Full Board or delegated review.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

The HREB is responsible for establishing procedures for conducting renewal reviews of ethically cleared 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 Periodic review of research activities is necessary to determine whether ethics clearance should be continued or withdrawn.

5.1 Continuing Review by the Full Board

5.1.1 The Researcher (Principal Investigator) is required to submit an application for ethics clearance renewal (via Romeo Progress Report) at a frequency to be determined by the REB and which will be defined at the time of the initial approval of the research, or as otherwise revised;

5.1.2 At a minimum, the REB requires that an application for ethics clearance renewal (Romeo Progress Report) 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 ethics clearance renewal 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 Ethics clearance renewal Romeo Progress Reports must be submitted within Romeo two weeks in advance of the date of ethics clearance 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 will be noted in the “my Reminders” section on ROMEO.;

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

5.1.7 The REB Chair or designate will review the study’s Progress Report. The report may be sent for a delegated review or full board review based on the level of risk to participants.

- 5.1.8 A summary report of the ethics clearance renewal (Romeo Progress Report) 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 where the Board will make a decision regarding the renewal of ethics approval for the study, 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 approval via delegated review, it may undergo delegated review at the time of ethics clearance renewal (Progress Report) submission;
- 5.2.2 Research that was previously reviewed by the Full Board may also be reviewed at the time of ethics clearance renewal using delegated review procedures if REB Office personnel determine that:
 - 5.2.2.1 No material changes to the research or the informed consent have been requested in the Progress Report compared to what was submitted and ethically cleared in the original application;
 - 5.2.2.2 No new information has emerged that might adversely affect the safety or well-being of research participants;
- 5.2.3 REB Office Personnel will review the ethics clearance renewal application (Romeo Progress Report) 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 The ethics clearance renewal application will be delegated for review to the Research Compliance Officer (RCO);
- 5.2.5 Additional information or clarification, as necessary, may be requested from the Researcher and a decision regarding the ethics clearance renewal and the continued conduct of the research will be determined;
- 5.2.6 Should the RCO determine that risks are now greater than minimal after reviewing the ethics clearance renewal application originally approved through delegated review, the RCO will refer the ethics clearance renewal application (Romeo Progress Report) for review by the Full Board.

5.3 REB Determinations

- 5.3.1 To grant ethics clearance renewal of the research the REB must determine that Criteria for REB Approval, 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 Renewal of Applications not Received by the Expiry Date

- 5.4.1 HREB Ethics clearance expires at 11:59 pm on the date the renewal is due. If an application for ethics clearance renewal is not submitted by the expiry date, the Researcher must suspend all research activities as specified by the REB.
- 5.4.2 A suspension ethics letter will be issued to the Researcher by the HREB Chair advising the Researcher that their study's research ethics clearance has expired, and that all research activity must be suspended. This letter will be copied to all research team members listed on ROMEO.
- 5.4.3 Once suspended, and the Researcher wants to continue with the research, the REB may allow the Researcher to submit a letter explaining the reasons for the ethics lapse and identify the steps taken to prevent future lapses. 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 and recorded on the renewal letter issued by HREB. A Full Board Review may be required to lift the suspension.
- 5.4.4 If the research study has been completed or terminated by the Researcher, then it is the responsibility of the Researcher to inform HREB through a Completion Report on the ROMEO system.
- 5.4.5 HREB will not review new research ethics applications until lapses in ethics clearance have been resolved for any ongoing research projects.
- 5.4.6 In the event that the ethics clearance renewal (Progress Report) submission is not submitted within ten business days from the date of the Suspension of Ethics Letter, a Termination of Ethics Clearance Letter will be issued to the Researcher notifying them that ethics clearance is terminated and they must cease all research activities associated with the lapsed ethics clearance. This letter will be copied to:
 - the Research Team as listed on the ROMEO system,
 - the Researcher's Dean or Director as applicable.

- 5.4.7 The RCO will follow up with the Researcher and the Research Team, as listed on the ROMEO system, to ensure that all research activities have ceased.
- 5.4.8 If ethics clearance has been terminated and the PI would like to have ethics clearance reinstated, HREB may allow the Researcher to submit a letter explaining the reasons for the ethics lapse and identify the steps taken to prevent future lapses. HREB will complete the review of the research as soon as possible and the Researcher may resume the suspended activities should approval of the research be issued. A Full Board Review may be required to lift the suspension;
- 5.4.9 If HREB makes the decision not to reinstate ethics clearance, the Researcher must complete and submit a new ethics application on ROMEO and receive approval to resume research activities.
- 5.4.10 The REB may define a reasonable length of time for which a Researcher may submit ethics clearance renewal applications, beyond which the research is closed and a renewal application will not be accepted. A new submission will be required.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 405.001	2023.06.02	Original version
SOP 405.002	2023.11.03	Updating notification of ethics termination