MacEwan UNIVERSITY | RESEARCH ETHICS BOARD

SOP 407.01

Title	Continuing Review
SOP Code	407.01
Effective Date	February 6, 2023

Site Approvals

Name and Title (typed or printed)	Signature	Date
Dr. Craig Kuziemsky Associate Vice-President, Research	*Original signed.*	October 2020
Dr. Craig Kuziemsky, AVPR	*Original signed*	February 2023

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 REBs that review human participant research in compliance with applicable policies and guidelines.

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/or REB members are responsible for reviewing continuing review submissions and respective materials as appropriate for Full Board or delegated review.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

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 Periodic review of research activities is necessary to determine whether approval should be continued or withdrawn.

5.1 Continuing Review by the Full Board

5.1.1 The Researcher is required to submit, in ROMEO, 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 approval 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 reviews 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 approval 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 approval 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;

5.2.3 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;

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

5.2.5 The reviewer may request additional information or clarification, as necessary, and will make a decision regarding the continued approval 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 approval of the research the REB must determine that:

- There have been no material changes to the research or to the informed consent form that have not been previously submitted and approved,
- There is no new conflict of interest or new information that has emerged that might adversely affect the safety or the well-being of research participants,
- Risks to research participants are minimized and reasonable in relation to the anticipated benefits,
- Selection of research participants is equitable,
- Informed consent processes continue to be appropriate and documented,
- Adequate provisions are in place for data protection to ensure the safety and privacy of participants and confidentiality.

5.3.2 The REB may also make additional determinations, including:

- Request changes to the informed consent form(s),
- Request changes for the continuing review interval (based on risks),

- Require modifications to the research,
- Suspend or terminate REB approval.

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, suspension notice will be issued to the Researcher. At this time, all research activities must cease, per MacEwan policy, 'The Responsible Conduct of Research and Creative Activity';

5.4.2 If a renewal is submitted within thirty days past the original expiry date, the Researcher may resume the suspended activities once the approval of the research has been issued. The lapse in approval will be documented;

5.4.3 If the study remains expired thirty days past the original expiry date, the study will be discontinued in the system by the Chair or the designee. Once the study is discontinued, a new application for ethics review must be submitted.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
407.00	October 8 2020	Original version
407.01	February 6 2023	Updates to management of expired studies in 5.4