Title	4.05 Continuing Review (Renewals)
Version	1.0
Effective Date	June 1, 2025

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.

Scope

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

Responsibilities

REB members, Office of Human Research Ethics (OHRE) Personnel, and Researchers are responsible for ensuring that the requirements of this SOP are met.

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

Procedure

REBs must conduct the continuing review of approved research involving human participants to determine whether approval should be continued or withdrawn. Such review is required at intervals appropriate to the degree of risk, but not less than once a year, and any time a Researcher seeks to amend the approved protocol.

Continuing Review: General

- The Researcher is required to submit an application for continuing review of research in the prescribed form 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.
- 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 REB may determine that the research requires continuing review more frequently than once per year. Consideration 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.

- 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.
- To assist Researchers in submitting on time, courtesy email reminder(s) are generated prior to the expiry date.
- OHRE Personnel will review the continuing review application for completeness, including verification of the currently approved informed consent form(s), and request any clarifications, missing documents or other information from the Researcher as applicable.
- Studies are not considered renewed until a Renewal Approval Letter is received by the Researcher. **Submission of a renewal request must not be construed as approval to continue the study.**
- The study expiry date is found in the Renewal Approval Letter.
- Where circumstances merit (e.g. longitudinal studies that have continued for some time, new phases of data collection, recruitment not yet started after a significant period of time has elapsed since approval, insufficient data management plans, outdated consent forms, changes to TCPS2), an REB Chair may, at their discretion, require the Researcher to submit a new protocol in the approved format.

Continuing Review: Delegated Review Procedures

- When the research receives initial approval via delegated review it may undergo delegated review at the time of continuing review.
- 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 necessary conditions for a delegated review are met.
- OHRE Personnel will forward the application to the REB Chair or designee responsible for reviewing the application.
- 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.
- 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.

Continuing Review: Full Board Review Procedures

- OHRE Personnel will assign the application to the agenda of the next REB meeting if the research meets the criteria for Full Board review.
- A summary report of the continuing review applications assigned to the REB meeting may be attached to the REB meeting agenda.
- 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.

REB Determinations

- To grant a continuation of the approval of the research the REB must determine that Criteria for REB Approval, as described in SOP 4.03 (Initial Criteria for REB Approval) are still met.
- The REB may also make additional determinations, as per SOP 4.02 (REB Review Decisions).

Continuing Review Applications not Received by Expiry Date

- If an application for continuing review is not submitted by the expiry date, a notice will be issued to the Researcher indicating that the Protocol has expired. When expired, the Researcher must suspend all research activities with participants as specified by the REB.
- If the REB approval lapses and the Researcher wants to continue with the research, the REB may allow the Researcher to submit an application for continuing review within 7 days of the expiry notice. 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.
- If the Continuing Review application is not submitted within 7 days, the research project is considered terminated.
- Terminated Protocols can only be re-opened at the discretion of the REB Chair where there are extenuating circumstances that prevent the Researcher from submitting an application for continuing review (e.g. illness, unforeseen circumstances affecting the Researcher).
- Terminated Protocols that cannot be re-opened and where continued participant engagement is required, must undergo REB review through the submission of a new application in the prescribed form.
- No contact with participants is permitted when a research project is expired or terminated.
- All expired/terminated projects must be closed in the prescribed manner. Failure to close a project will result in non-compliance with the TCPS2 and is a breach of the University's Responsible Conduct of Research Policy and Procedure.

Revision History

Version	Effective Date	Summary of Changes