

Guidance Document	REB Continuing Ethics Review (CER) – Initial Approval Date & CER Date Determination
Effective Review	Delegated & Full Board
Version Date	March 3, 2026

OVERVIEW

Regulatory requirements mandate Research Ethics Boards (REBs) to conduct continuing review of human participant research that is within the jurisdiction of the REB. This guidance outlines the criteria for continuing review, and Principal Investigator (PI) and REB responsibilities. It outlines how the initial approval dates for studies reviewed by Western University’s Health Sciences/Non-Medical Research Ethics Board (HSREB/NMREB) are determined. This document also describes how Continued Ethics Review (CER) dates are determined.

SUMMARY DEADLINES

Table 1: Dates related to expiry date

Action	Earliest CER submission	Earliest CER review	REB approval end date	Sent to full board for board voted closure
Days	60 days before review	30 days before expiry	12:01am on the REB approval end date	14 days after expiry

REVIEW DECISIONS

All studies reviewed by the REB’s Delegated and Full Board streams will receive one of the following review decisions:

1. **Approved** - No Changes Required
2. **Pending** – Modifications Required to Proposed Study
3. **Deferred** – The REB has deferred its decision to a subsequent meeting as the research proposal does not have sufficient information for the REB to arrive at a determination.

DETERMINING THE EFFECTIVE DATE OF INITIAL REB APPROVAL

REB Review Decision: Approved

When the REB conducts the initial review of a study and approves the research study without requiring either (a) changes to the protocol and/or supplementary document(s), or (b) clarification or additional documents, the effective date of the initial approval will be set on the date the review was completed.

REB Review Decision: Pending

When the REB conducts the initial review of a study and requires modifications to the submission (either by a pending decision or deferred decision), the effective date of the initial approval is the date on which the Full Board (for deferrals), REB Chair, or designee, has reviewed and accepted all changes to the protocol and supplementary documents, required by the REB from the PI.

REB Review Decision: Deferred

When the REB defers a study, the submission requires substantive modifications, clarification, or additional information that cannot be addressed outside a convened Full Board meeting.

Deferred studies must return to a future Full Board meeting for further review. A new REB determination will be issued at that time. Because a deferral does not constitute an approval, no approval date is assigned. If the study is subsequently approved at a later meeting, the effective date of approval will be the date of that later Board review. If the study is instead approved pending modifications, the effective approval date will be the date on which the REB Chair or designee reviews and accepts all required changes.

CONTINUING ETHICS REVIEW (CER) FREQUENCY

Annual Review Requirements

For multiyear studies, the REB must review progress reports once per year for the duration of the study. These reports must be submitted by the PI using the Continuing Ethics Review (CER) Form, unless the REB advises otherwise.

Studies Less Than One Year

For studies that will be completed in under one year, a Study Closure application must be submitted before the approval end date.

PI Responsibilities

It is the PI's responsibility to ensure the CER form is submitted on time.

To support timely compliance, the Office of Human Research Ethics (OHRE) will send courtesy reminders at set intervals leading up to the expiry date. If the PI does not submit the CER form despite the reminder and follow-up notices, a notice will be issued indicating that REB approval has expired.

Failure to Submit the CER Form

If the CER form is still not submitted within two weeks of the study expiry date, the expired study will be reviewed at the next convened full board meeting. At that meeting, the REB may vote to close the file (known as a Board Voted Closure (BVC)).

Late Submission

If the CER form is submitted after the expiry date but before a BVC decision - and the study is re-approved - there will be a documented lapse in REB approval, which will appear on the re-approval letter.

The OHRE may also decide to investigate concerns related to serious or continuing non-compliance.

Table 3: Study Status & CER Dates

Event	OHRE Reminder 1 (45 days before expiry date)	OHRE Reminder 2 (30 days before expiry date)	OHRE Reminder 3 (7 days before expiry date)	OHRE Reminder 4 (1 day after expiry date)	OHRE Reminder 5 (2 weeks after expiry date)
Result	CER Due Date Reminder	CER Due Date Reminder	CER Due Date Reminder	Overdue CER and expired study	File reviewed at full board meeting
Study Status	Active			Expired	Study will be Closed

CER DUE DATES & SUBMISSION TIMELINES

The date by which continuing ethics review must occur is one year from the initial approval date

Example: If the approval date is Feb 1, 2024, the date by which a continuing ethics review must occur is no later than Feb 1, 2025).

To ensure adequate processing time, each completed CER form must be received **no earlier than 45 days before** the CER due date and **no later than 14 days before** the REB expiry date. It is the PIs responsibility to submit a CER form within these timelines.

Note: CER applications will be accepted up to 45 days before their expiry date; however, they will **not** be reviewed until they fall within 30 days of the expiry date. This approach aligns with the U.S. Office for Human Research Protections (OHRP), which specifies that when an REB maintain an anniversary date, continuing review must be conducted **within 30 days** of the expiry date (HHS.gov, 2010). Western’s REB applies this rule uniformly to ensure consistency and to avoid inadvertently missing requirements for U.S.-supported studies.

Once received, the REB will review the CER form for completeness. The PI may be contacted for clarifications or revisions. When the review is complete and no outstanding issues remain, an REB approval notification will be issued.

FDA REGULATED STUDY TIMELINES

FDA regulated studies: all CERs will be reviewed at a convened REB meeting unless the study qualifies delegated review (see 45 CFR 46.110(F)(8) and 45 CFR 46.110(F)(9)).

To comply with U.S regulations, the REB must complete the continuing ethics review and issue re-approval within 30 days before the REB expiry date. Therefore, PIs must verify upcoming full board meeting date and submit the CER form no later than 14 days before the scheduled meeting.

Table 4: How to Select the Correct FB Meeting Date for FDA CERs

Initial Approval Date	Feb 1, 2024	Board Meeting Dates
CER Reminder 1	Dec 18, 2024	*Jan 14, 2025*
CER Reminder 2	Jan 2, 2025	*Jan 28, 2025*
CER Reminder 3	Jan 25, 2025	Feb 11, 2025
REB Expiry Date	Feb 1, 2025	**Feb 25, 2025**
CER Reminder 4	Feb 2, 2025	
Potential Study Closure Date	Feb 15, 2025	

Example: Expiry date is Feb 1, 2025

Send in CER 2 weeks before this date in order to be reviewed at this full board meeting **Note:** Please check the [Board Deadlines & Timelines page](#) for a list of full board meeting dates.

If no CER is submitted within 2 weeks of the expiry date (e.g., Feb 1, 2025), ****Study may be sent to this meeting for board voted study closure****. When a study expires, the PI will be placed on a holds list (cannot submit a new study or amendment to an existing study) until either (1) the outstanding CER is submitted and the REB has granted re-approval OR (2) a Study Closure form is submitted.

CER OR STUDY CLOSURE FORM NOT SUBMITTED AND REB APPROVAL EXPIRES

1. Immediate Effect of Lapsed Approval

If REB approval expires, **all study related activities must stop immediately**.

If required follow-up actions (submission of a CER or Study Closure Form) are not completed, the PI may be placed on a **holds list** (unable to submit new studies or amendments) until either:

- 1) The outstanding CER is submitted, and re-approval is granted OR
- 2) A Study Closure form is submitted.

2. If the PI Wishes to Continue the Study

If REB approval expires but the PI wishes to continue the study, the PI must:

- Promptly notify the OHRE if participants require continued study-related treatments or procedures for safety reasons.
- The REB Chair or designee will review the request as quickly as possible and discuss the proposed continued activities with the PI;

3. Required Documentation

The PI must document:

- The reasons the study expired and
- The steps taken to prevent this from happening again.

These activities will be documented and filed.

4. Submitting a Late CER

If the PI submits the CER Form after REB approval expires:

- The REB will complete the review as soon as possible.
- Study-related activities may only resume once re-approval has been issued.
- The lapse in approval will be formally documented in the re-approval letter.
- Once re-approval is granted, the PI will be removed from the **holds list**

5. No CER or Closure Form Submitted Within 14 Days

If neither a CER form nor a Study Closure form is received by the OHRE within 14 days after REB approval expires:

- The study will be sent to the next convened REB full board meeting for BVC.

REFERENCES

1. Ethics.gc.ca. TCPS2-2nd edition of Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2), Article 6.14, and 6.15. https://ethics.gc.ca/eng/policy-politique_tcps2-epic2_2022.html
2. The International Conference on Harmonization Good Clinical Practices, Sections 4.10 and 5.21;
3. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.109(e), 46.110(F)(8), 46.110(F)(9) and 46.115(a)(3);
4. HHS.gov. (2010). U.S. Department of Health and Human Services. Guidance on continuing review. Retrieved from <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-continuing-review-2010/index.html#section-f>;
5. US Food and Drug Administration (FDA) CFR Title 21 Part 56.109(f) and 56.115(a)(2);