Western Research

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Guidance Document	REB Continuing Ethics Review (CER) – Initial Approval Date & CER Date Determination
Effective Review	Delegated & Full Board
Version Date	May1st 2025

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) Full Board and Delegated streams are determined. This document also describes how Continued Ethics Review (CER) dates are determined.

SUMMARY DEADLINES

Table 1: Dates related to expiration date

Action	Earliest CER submission	Earliest CER review	Expiration	Sent to full board for board voted closure
Days	45 days before review	30 before review	1 day after expiration date	14 days after expiration

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. **Tabled (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

Full Board: When the REB conducts the initial review of a study at a convened meeting and approves the research study without requiring either (a) changes to the protocol or consent document(s), or (b) clarification or additional documents, the effective date of the initial approval will be set as the meeting date.

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

REB Review Decision: Pending/Deferred

Full Board: When the REB conducts the initial review of a study and requires modifications to the submission (either by a pending decision or tabled decision), the effective date of the initial

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approval is the date on which the REB Chair, or designee, has reviewed and accepted all changes to the protocol and supplementary documents, required by the REB from the PI.

Delegated: When the REB conducts the initial review of a study and requires modifications to the submission (by a pending decision), the effective date of the initial approval is the date on which the REB Chair, or designee, has reviewed and accepted all changes to the protocol and consent document(s), or any other responsive materials, required by the REB from the PI.

Table 2: REB Approval Dates

Review Level	**Review Decision**		
	Approved	**Pending**	**Tabled**
Full Board Review	FB Meeting Date	Chair or designee Sign-off Date	FB Meeting Date
Delegated Review	Chair or designee Sign-off Date	Chair or designee Sign-off Date	N/A

CONTINUING ETHICS REVIEW (CER) FREQUENCY

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

For studies lasting **less than one year** a Study Closure application must be submitted before the study expiry date.

It is the PI's responsibility to submit the CER form on time. To assist PI's, the Office of Human Research Ethics (OHRE) will send a courtesy reminder at different time points prior to the expiry date. Should an PI fail to submit the CER form despite the reminder/follow-up notifications, a notice that REB approval has expired will be issued and the study will be suspended. If the CER form is still not submitted within 2 weeks of the study expiry date the REB may close the file, and PIs will be required to submit a new study. If the CER form is submitted after the expiry date but before file closure this will result in a lapse in REB approval. The OHRE may also elect to pursue investigations for 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 may be Closed

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CER DUE DATES & SUBMISSION TIMELINES

The date by which continuing review must occur will be 1 year from the initial approval date (e.g., if the approval date is Feb 1, 2024, the date by which a continuing review must occur is no later than Feb 1, 2025).

To ensure adequate time for the OHRE to process the CER, each completed CER form must be received **no more than 45 days before the CER is due and no later than 14 days prior to the REB expiry date.** It is the responsibility of the PI to submit a CER to the OHRE within these timelines.

Note: While CER applications will be accepted up to 45 days before their expiration date, they will not be reviewed until within 30 days of the expiry date. This policy is consistent with the U.S. Office for Human Research Protections (OHRP), which outlines that for REBs that maintain an anniversary date, a continuing review of a study must be conducted within 30 days of the expiry date (HHS.gov, 2010). Western's REB applies this rule to all CERs to ensure consistency and to prevent accidentally missing a U.S.-supported study that has this requirement.

Once received, the REB will review the CER form for completeness and may request clarifications from the PI. Once the CER form is reviewed and there are no outstanding issues an REB approval notification will be issued.

FDA REGULATED STUDY TIMELINES

FDA regulated studies: ALL FDA regulated studies will be reviewed at a convened REB meeting unless it meets the requirements for a delegated review (see 45 CFR 46.110(F)(8) and 45 CFR 46.110(F)(9)). In order to comply with U.S regulations, the REB MUST perform a continuing review and issue re-approval of the research within 30 days before the REB approval period expires. Therefore, PIs are required to check when the REB full board meetings will occur and submit the CER form no later than 14 days before the meeting date.

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**. If a study is closed by the full board 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 STUDY EXPIRES

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

If REB approval expires but the PI wishes to continue the study, it is their responsibility to promptly notify the OHRE if there are safety related needs that require study participants to continue to receive study related treatments/procedures. The REB Chair or designee will review the request as quickly as possible and discuss the proposed continued activities with the PI;

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The PI must document the reasons the study expired and identify the steps taken to prevent this from happening again. These activities will be documented and filed.

If REB approval expires and the PI wants to continue with the research, the PI must submit the CER form, and the REB will complete the review as soon as possible and the PI may resume study related activities once re-approval of the research has been issued. The lapse in approval will be documented.

If a CER form or Study Closure form has not been 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 board voted closure. If a study is closed by the full board 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 the outstanding CER is submitted, and the REB has granted re-approval OR (2) a Study Closure form is submitted.

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-eptc2_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);