

Guidance Document	REB Continuing Ethics Review (CER) – Initial Approval Date & CER Date Determination
Effective Review	Delegated & Full Board
Version Date	March 21 st , 2016

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 investigator and REB responsibilities. It outlines how 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.

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/Tabled

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 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 investigator.

NOTE: Prior to January 1st, 2014, submissions reviewed at a convened HSREB full board meeting where the board's decision was to approve the submission with modifications required the initial approval date was set as that meeting date.

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 investigator

Table 1: REB Approval Dates

Review Level	Review Decision		
	Approved	Pending	Tabled
Full Board Review	FB Meeting Date	Chair or designee Sign-off Date	Chair or designee Sign-off 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 Investigator 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** an End of Study (EOS) Report must be submitted before the study expiry date.

It is the Investigator's responsibility to submit the CER form on time. To assist Investigators, the Office of Human Research Ethics (OHRE) will send a courtesy reminder at different time points prior to the expiry date. Should an Investigator 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 file will be presented at a convened full REB meeting and the REB may close the file and Investigators 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 2: Study Status & CER Dates

Event	OHRE Reminder 1 (2 months)	OHRE Reminder 2 (1 month)	OHRE Reminder 3 (CER Due Date)	OHRE Reminder 4 (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			Suspended	Study may be Closed

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, 2015, the date by which continuing review must occur is no later than Feb 1, 2016).

In order to ensure adequate time for the OHRE to process the CER, each completed CER Form must be received NO MORE than 60 days before the CER is due and no later than 14 days prior to the REB expiry date to allow time for the REB to process the submission. It is the responsibility of the Principal Investigator (PI) to submit a CER to the OHRE within these timelines.

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

HSREB FDA REGULATED STUDY TIMELINES

FDA regulated studies: ALL FDA regulated studies will be reviewed at a convened REB meeting. In order to comply with FDA regulations, the REB MUST perform continuing review and re-approval (with or without conditions) of the research within 30 days before the REB approval period expires. Therefore, Investigators 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 3: How to Select the Correct FB Meeting Date for FDA CERs

Initial Approval Date	Feb 1, 2014	<u>Board Meeting Dates</u>
CER Reminder 1	Nov 30, 2014	Jan 6, 2015
CER Reminder 2	Dec 31, 2014	*Jan 20, 2015*
CER Due Date	Jan 31, 2015	Feb 3, 2015
REB Expiry Date	Feb 1, 2015	Feb 17, 2015
Study Suspension Date	Feb 2, 2015	Mar 3, 2015
Potential Study Closure Date	Feb 16, 2015	Mar 17, 2015

Send in CER 2 weeks before this date

LATE CERs

If the CER Form is not submitted to the OHRE within the timelines mentioned above, the REB Chair will determine the appropriate action to take (may include suspension of study related activities, including enrollment or termination of REB approval) and any post-approval event submissions and new submissions will not be reviewed by the OHRE.

CER NOT RECEIVED BY THE REB EXPIRY DATE

If the CER form is not submitted by the expiry date, a warning or suspension notice will be issued to the Investigator. When suspended, the Investigator must suspend all study related activities as specified by the REB. **NOTE:** Participants already enrolled in the study may be able to continue receiving study related procedures to ensure their safety and well-being. Investigators must promptly notify the OHRE if there is 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 Investigator;

In the event of a lapse in approval, the Investigator must document the reasons for the lapse and identify the steps taken to prevent future lapses. These activities will be documented and filed;

If the REB approval lapses and the Investigator wants to continue with the research, the REB will complete the review of the research as soon as possible and the Investigator may resume the suspended activities once approval of the research has been issued. The lapse in approval will be documented.

REFERENCES

1. TCPS2-2nd edition of Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 6.14
2. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2); Article 2.8 and 6.12;
3. The International Conference on Harmonization Good Clinical Practices, Sections 3, 4.4, 4.5, 4.10, 4.11, 4.12;
4. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.109, 46.111, 46.113, 46.115;
5. OHRP Guidance on Continuing Review;
6. US Food and Drug Administration (FDA) CFR Title 21 Part 56.102, 56.108, 56.109, 56.110, 56.111, 56.115;
7. FDA Information Sheets: FAQ Section IV.