

Institutional Review Board

Expired Institutional Review Board (IRB) Approval Policy

Scope

Applies to personnel at Mayo Clinic Human Research Protection Program when involved in Human Subjects Research for which Mayo Clinic IRB is the IRB of Record.

Purpose

To describe the responsibilities of the Principal Investigator (PI) and IRB upon expiration of IRB approval for Human Subjects Research requiring IRB Continuing Review (CR).

Policy

Principal Investigator Responsibilities

- All research activities must cease upon expiration and must not resume until and unless the IRB grants approval.
- If cessation of all the research activities **will not jeopardize the health or safety** of any currently enrolled subject, the PI:
 - Ceases all research activities, including enrollment of new subjects, study interventions, data collection, and data analysis.
 - Reports any research activity that occurred after the expiration date to the IRB.
 - For studies that have expired without submission of a CR report and where the PI wishes to continue the research activities, a new study application must be submitted to the IRB.
 - For studies that have expired after a CR report was submitted, but where the CR is incomplete or is not submitted within a reasonable time frame to allow the IRB perform its review, the IRB may require a new study application.
- If cessation of all or some of the research **activities would jeopardize the health or safety** of a currently enrolled subject, the PI:
 - Consults with the IRB Medical Director or the on-call IRB Chair. If the Medical Director or Chair agrees that it is in the best interests of individual subjects to continue participating in all or some of the research interventions or interactions, the PI may be allowed to continue those interventions or interactions with currently enrolled subjects.
 - Ceases all other research activities, including data collection, data analysis and enrollment of new subjects.
 - Submits a Continuing Review report using the IRB electronic system within 5 calendar days.

IRB Medical Director or Chair Responsibilities

The on-call Medical Director or Chair determines whether cessation would jeopardize the health or safety of currently enrolled subjects.

- If cessation of all research activities **will not jeopardize** the health or safety of a currently enrolled subject, the Medical Director or Chair will instruct the PI to cease all research activities, including enrollment of new subjects, study interventions, data collection, and data analysis. IRB approval of a new application will be required before resuming any human subjects research activity.
- If cessation of all research activities **will jeopardize** the health or safety of a currently enrolled subject, the Medical Director or Chair will:
 - Advise the PI to continue study interventions for currently enrolled subjects but stop enrollment of new subjects.
 - Advise the PI to submit a CR report to the IRB within 5 calendar days.
 - Notify IRB staff of the research project status including details, IRB application number and the PI's name. This information may be communicated by calling (507) 266-4000 (Internal (77) 6-4000).

IRB Staff Responsibilities

- Upon receiving notification from the Medical Director or Chair that a PI may continue study interventions on currently enrolled subjects, IRB Staff will record the notice from the Medical Director or Chair using the "Already Enrolled Subjects May Continue Treatment" activity within the CR workspace.
- If a CR report has been submitted:
 - The Specialist reviews the CR report for completeness and schedules it to the next available meeting agenda as applicable.
- If a CR report is in a "Pre-submission state", the Specialist will review the report once it has been submitted to IRB.
- If no CR report has been created or submitted, an IRB Site Administrator may initiate a CR report on behalf of the PI.
 - The Specialist will:
 - Send a notification to the PI that includes a link to the CR report and a reminder to complete and submit the report within the stipulated timeframe.
- For those research projects where the Medical Director or Chair allowed the study interventions to continue with currently enrolled subjects, a CR report must be submitted within 5 calendar days.
 - If the CR has not been submitted in 5 calendar days the IRB will escalate the matter to the Medical Director for decision.

Continuing Review Report Submitted After Expiration of IRB Approval.

Upon receipt of a CR report for an expired study, the Specialist checks whether the IRB record reflects the Medical Director's or Chair's allowance for the research activity on currently enrolled subjects to continue.

- If yes, the Specialist proceeds to process the CR report.
- If no, the Specialist advises the PI to comply in accordance with the Principal Investigator Responsibilities section of this document, and sends a request to an IRB Site Administrator to administratively close the study.

IRB Responsibilities

The IRB reviews Continuing Review reports in accordance with the approved IRB procedure, [Continuing Review of Research Policy](#).

IRB Electronic (IRBe) Notifications

- On the day of expiration of IRB approval, the IRB electronic system issues an Expiration Notice to the PI and automatically changes the status of the IRB application to "Expired".
- For an expired research project where a CR report was not submitted to the IRB, the IRB electronic system will automatically change the status of the IRB application to "Completed", on the sixth calendar day following the expiration date.

Policy Notes

NA

Related Procedure

N/A

Related Documents

[Continuing Review of Research Policy](#)

Definitions

Expired Study: When continuing review of the research does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically. The study expires on the date specified on the approval letter and the consent document. No activities can occur after the expiration date.

References

[OHRP \(Office for Human Research Protections - Guidance on IRB Continuing Review \(November 10, 2010\)\)](#)

Owner

[Tammy S. Neseth, M.A.](#) on behalf of the Office for Human Research Protections

Contact

[Michelle K. Daiss](#), [Heidi M. Hanf](#)

Revision History

Date	Synopsis of Change
12/21/2020	Scheduled review. Minor edits by Policy office.
12/16/2019	Minor edit to update name of Continuing Review Policy. Contact

	updated Contact from Angela Patterson to Heidi Hanf.
01/21/2019	Clarified Scope to apply only to Human Subjects Research requiring IRB continuing review. Changed Owner to T. Neseth.
02/16/2019	Approved by Mayo Clinic Human Research Protection Program Oversight Committee
12/28/2017	Scheduled Review. These changes are administrative/editorial only. Under IRBe notifications - expiration on the day of expiration of IRB approval, the IRB electronic system issues an Expiration Notice to the PI and automatically changes the status of the IRB application to "Expired".
10/06/2017	Removal of expiration notification text as this detail is not needed in the policy.
11/08/2016	Scheduled review - updating to new template. Clarification that a new application is required when cessation of research activities will not jeopardize health or safety of subjects; Site Administrators will administratively close studies with a CR submitted after expiration; administrative edits.
02/18/2016	Scheduled review. Removed reference to Vice Chair role and editorial revisions for clarity.
08/28/2014	Scheduled review.
07/01/2012	Scheduled review.
09/17/2011	Scheduled review.
04/18/2011	Scheduled review.
04/28/2010	Approval for need to establish document: Mayo Clinic Human Research Protection Program Oversight Committee

[Content Information](#)

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Site(s): Rochester, Arizona, Florida

Workflow Reviewer Name(s): Shanthi L. Siva Shanmuga
Sundaram, M.A., M.Phil; Hanf, Heidi M.; Michelle K. Daiss

Workflow Approver Name(s): Neseth, Tammy S., M.A.

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