Expired IRB Approval

Content Applies To

Mayo Clinic Human Research Protection Program
Research for which the Mayo Clinic IRB is the IRB of Record

Purpose

This procedure describes the responsibilities of the Investigator and IRB Staff upon expiration of IRB approval.

Principal Investigator Responsibilities

Expiration of IRB Approval

- 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 principal investigator (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 Continuing Review 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 Continuing Review (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 or Vice Chair. If the Medical Director, Chair or Vice 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, Chair and/or Vice Chair Responsibilities

The on-call Medical Director, Chair or Vice 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, Chair or Vice Chair will instruct the PI to cease all research activities, including enrollment of new subjects, study interventions, data collection, and data analysis.
- If cessation of all research activities **will jeopardize** the health or safety of a currently enrolled subject, the Medical Director, Chair or Vice Chair will:
    - Advise the PI to continue study interventions for currently enrolled subjects but cease enrollment of new subjects.
    - Advise the PI to submit a Continuing Review report to the IRB within 5 calendar days.
    - Notify IRB staff of the research project status including details, IRB application number and the Principal Investigator's name, by calling (507) 266-4000 (Internal (77) 6-4000).

IRB Staff Responsibilities

- Upon receiving a notification from the Medical Director/Chair/Vice Chair that a PI may continue study interventions on currently enrolled subjects, the Site Administrator/ IRB Staff will determine if a Continuing Review report has been submitted.
- If a Continuing Review report has been submitted, the Specialist will insert the Medical Director/Chair/Vice Chair's notice into the IRB record, using the "Already Enrolled Subjects May Continue Treatment" activity option in the IRB electronic system.
- The Specialist reviews the continuing review report for completeness and schedules it to the next available meeting agenda.
- If a Continuing Review report is in a "Pre-submission state", the Specialist will insert the Medical Director /Chair/Vice Chair's notice using the "Already Enrolled Subjects May Continue Treatment" activity in the report workspace within the IRB electronic system.
- If no Continuing Review report has been created or submitted, an IRB Site Administrator initiates a Continuing Review report on behalf of the PI. The notice from the Medical Director/Chair/Vice Chair is inserted using the "Already Enrolled Subjects May Continue Treatment" activity within the report workspace and a note is sent to the PI which includes a link to the Continuing Review report and a reminder to complete and submit the report within the stipulated timeframe.

- For those research projects where the Medical Director/Chair/Vice Chair has contacted the PI and allowed the study interventions to continue with currently enrolled subjects, a Continuing Review 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 Continuing Review report for an expired study, the Specialist checks whether the Medical Director/Chair/Vice Chair has given notice to the IRB regarding his/her agreement that research activity on currently enrolled subjects be continued.

- If yes, the Specialist proceeds to process the Continuing Review report.
- If no, the Specialist advises the PI to comply with the Principal Investigator Responsibilities section of this document.

Convened IRB Responsibilities

The Committee reviews Continuing Review reports in accordance with the approved IRB procedure, *Continuing Review of Research Projects*.

IRBe Notifications

- On the day of expiration of IRB approval, the IRB issues an Expiration Notice to the PI. One of two Expiration Notices will be used:
    - A1. Notice of Expiration of IRB Approval on a Study that Expired Without a Continuing Review Report Submission
    - A2. Notice of Expiration of IRB Approval on a Study that Expired After the Continuing Review Report Had Been Submitted
- For an expired research project where a Continuing Review report was not submitted to the IRB, the IRB electronic system will automatically change the status of the research project to “Completed", on the sixth calendar day following the expiration date.

Types of Expiration Notifications

A.1: Notice of Expiration of IRB Approval on a Study that Expired Without a Continuing Review Report Submission

Subject: Notice of Expiration of IRB Approval

From: IRB

To: Principal Investigator/s

CC: (Co-Investigators and Study Coordinators)

Re: IRBe # & "title of study"

The IRB Approval for study entitled "___ “expired on mm/dd/yyyy (due to the lack of a Continuing Review report submission). In accordance with federal regulations, once IRB approval for a research study expires, all research activities on that study must cease.

- If cessation of all study activities would jeopardize the health or safety of a currently enrolled subject, the PI will advise and consult with the IRB Medical Director or Chair/Vice Chair-on-call. If the Medical Director/Chair/Vice Chair agrees that it is in the best interests of individual subjects to continue participating in the research interventions or interactions, the PI may continue those interventions or interactions with currently enrolled subjects. The PI must cease all other research activities, including data collection, data analysis and enrollment of new subjects. The PI will submit a Continuing Review report to the IRB within 5 calendar days.
- If cessation of all study activities will not jeopardize the health or safety of any currently enrolled subject, the PI will cease all research activities, including enrollment of new subjects, study interventions, data collection, and data analysis;
- The PI will report to the IRB if research activity occurs after the expiration date;
- If the PI wishes to continue the research activities, a new study application must be submitted;
- If the study is funded through federal funds, your Research Administrator should be contacted immediately to ensure compliance with federal financial compliance regulations.

A.2: Notice of Expiration of IRB Approval on a Study that Expired With a Continuing Review Report Submission

Subject: Notice of Expiration of IRB Approval

From: IRB

To: Principal Investigator/s

CC: (Co-Investigators and Study Coordinators)

Re: IRBe # & "title of study"

The IRB Approval for study entitled "___ “expired on mm/dd/yyyy. Although a Continuing Review report had been submitted prior to the expiration date, review on it has not yet been completed. In accordance with federal regulations, once IRB approval for a research study expires, all research activities on that study must cease.

- If cessation of all study activities would jeopardize the health or safety of a currently enrolled subject, the PI will advise and consult with the IRB Chair/Vice Chair-on-call and if the Chair agrees that it is in the best interests of individual subjects to continue participating in the research

interventions or interactions, the PI may continue those interventions or interactions with currently enrolled subjects. The PI must cease all other research activities, including data collection, data analysis and enrollment of new subjects.

- If cessation of all study activities will not jeopardize the health or safety of any currently enrolled subject, the PI will cease all research activities, including enrollment of new subjects, study interventions, data collection, and data analysis;
- The PI will report to the IRB if research activity occurs after the expiration date;
- The IRB will continue review of the submitted Continuing Review report and provide you with a minute excerpt as soon as possible. If the Continuing Review was incomplete or submitted without sufficient time to allow IRB review the IRB may require a new application submission. If the Continuing Review application is returned to the PI via "Request Changes" and the PI does not respond within 30 days, the study may be administratively closed and any subsequent continuation of the research will require a new application submission;
- If the study is funded through federal funds, your Research Administrator should be contacted immediately to ensure compliance with federal financial compliance regulations.

References

Continuing Review of Research Projects

OHRP (Office for Human Research Protections - *Guidance on IRB Continuing Review* (November 10, 2010)

Effective Date

August 22, 2014