



## Expired IRB Approval

### Scope

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 upon expiration of IRB approval.

### Policy

#### 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. 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 prior to 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 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. This information may be relayed 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 continuing report workspace.
- If a Continuing Review report has been submitted:
  - The Specialist reviews the continuing review report for completeness and schedules it to the next available meeting agenda as applicable.
- If a Continuing Review report is in a "Pre-submission state", the Specialist will review the report once it has been submitted to IRB.
- If no Continuing Review report has been created or submitted, an IRB Site Administrator may initiate a Continuing Review report on behalf of the PI.
  - The Specialist will:
    - Send a notification to the PI that 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 or Chair 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 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 Continuing Review report.
- If no, the Specialist advises the PI to comply with the Principal Investigator Responsibilities section of this document, and sends a request to an IRB Site Administrator to administratively close the study.

### **Convened IRB Responsibilities**

The convened IRB 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 electronic system 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 Chair-on-call. 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. 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-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.

## **Procedural Notes**

NA

## **Related Procedure**

[Continuing Review of Research Projects](#)

## **Related Documents**

NA

## **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 \(November 10, 2010\)\)](#)

## **Approved by**

Mayo Clinic Human Research Protection Program Oversight Committee 2/16/2016

## **Owner**

Pamela Kwon on behalf of the Office for Human Research Protections

## **Contact**

Angela Patterson La Baw, Michelle Daiss

## Revision History

Date	Synopsis of Change
11/8/2016	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.
2/18/2016	Scheduled review. Removed reference to Vice Chair role and editorial revisions for clarity.