EXPIRATION OF IRB APPROVAL

SUSPENSION AND TERMINATION OF IRB APPROVAL

1. PURPOSE

This SOP establishes the procedures to be followed when a research study approved by the Minneapolis VA Institutional Review Board (IRB) fails to obtain continuing review approval prior to expiration of the current IRB approval (i.e., at continuing review), and when actions require suspension or termination of approval.

2. POLICY

The investigator must provide documents for continuing review by the date required by the IRB. If the investigator fails to provide the requested materials to the IRB with sufficient time to allow IRB review, all research must stop on the date IRB approval expires. Any continuation of human subject activity after the expiration will only be approved if the IRB finds it is in the best interest of individual subjects to continue participation in research interventions or interactions.

3. DEFINITION

Expiration of approval period: The maximum continuing review approval period is 365 days. If continuing review and approval do not occur within one year for a project approved for this period, the approval period expires on day 366.

Suspension of IRB approval: A temporary interruption in selected research activities (e.g., new enrollments or specific interventions) due to concerns about the safety, rights, or welfare of human subjects, research personnel, or others, regardless of whether the action to suspend was taken by an investigator, facility official, research review committee, or external entity. Suspension does not refer to interruptions for other reasons, including the expiration of project approval periods.

Termination of IRB approval: A permanent halt in all research activities due to concerns about the safety, rights, or welfare of human subjects, research personnel, or others, regardless of whether the action to terminate was taken by an investigator, facility official, research review committee, or external entity. Termination does not refer to interruptions for other reasons, including the expiration of project approval periods.

4. RESPONSIBILITIES

a. **Investigators:** The investigator holds the ultimate responsibility for tracking approval periods and ensuring that IRB approval does not expire. Failure to receive or notice IRB reminders does not absolve investigators of this responsibility, nor does it change the consequence of an expired approval.

b. **IRB Administrator and IRB Staff:** It is the responsibility of the IRB Staff to notify the investigator when the documents necessary for the continuation of the study are due. Dates identified by the IRB are determined to allow for timely review of submitted materials as required for approval.

5. PROCEDURES

A. EXPIRATION OF IRB APPROVAL

1) Reminders. The IRB will send two messages to investigators requesting the materials required for continuing review including a link to the materials. Each reminder will include a due date. The reminders will generally be sent during the 3-month period preceding the expiration of the current approval period.

2) If the investigator does not wish to continue the study past the expiration date, he or she should submit closure documents to the IRB by the same date that continuing review documents are due. Choosing to close a study rather than pursue a continuing review does not extend the due date for submission of required materials.

3) Submission of the continuing review documents prior to expiration of IRB approval but later than the date required does not allow sufficient time for IRB review and may result in an expiration of IRB approval.

4) **If an IRB approval expires, all research activities involving human subjects must stop,** except those that meet very specific and limited criteria. "All" includes, but is not limited to, subject contact, data collection, and data analysis. The IRB will notify the investigator of these requirements in writing upon expiration of approval.

   - Even if the continuing review materials have been submitted to the IRB, all activities must stop until IRB re-approval is granted for the study.
   - There is no "grace period" extending research activities beyond the expiration of IRB approval, even if the continuing review documents have been submitted.
   - Activities that occur without a current IRB approval are considered non-compliance, with appropriate consequences. For example, data collected following an expiration of IRB approval cannot be described (e.g., in a publication) as being part of an IRB-approved study.
   - Retroactive approval for work done after the expiration date will not be granted.
   - An expiration of IRB approval is not considered a suspension or termination.

5) The only research activities that are permitted following an expiration of IRB approval are those:

   - necessary to eliminate apparent immediate hazards to the subjects;
   - interventions that may be of direct benefit to individual subjects; or

- where withholding or stopping the research intervention may increase risks to subjects.

6) In the event of an expiration of IRB approval, the investigator must immediately submit to the IRB Chair a list of research subjects who could be harmed by stopping specified study interventions or interactions. Within two business days, the IRB Chair, with appropriate consultation with the facility Chief of Staff, will determine if subjects on the list may continue participating in the research interventions or interactions. The determination may be made for all enrolled subjects as a group, or for specific individual subjects. If it is determined that previously enrolled subjects should continue to receive study intervention, data collection (especially safety information) should continue for such subjects while the study is being systematically closed. IRB approval cannot be reestablished. If the investigator wishes to obtain IRB approval, a new project must be submitted for IRB review.

7) The determinations noted above will be made on a case-by-case basis as to whether activities meet the criteria for continuing research activities when IRB approval has expired.

ADMINISTRATIVE CLOSURE OF THE STUDY

a. On the day of IRB approval expiration, the administrative staff of the IRB will initiate the process of documenting the closure of the study..

   i. The IRB will send a letter to the investigator notifying them that following expiration of IRB approval, their project status has been updated to "closed." The letter will inform the investigator that the closure, precipitated by the expiration of IRB approval, will be reported to the IRB Chairs and the R&D Committee at the next convened meeting.

   ii. The investigator will be instructed to submit all study records to the Research Office within 30 days. All data from the closed study will be sequestered by the Research Office. The investigator will no longer have access to the data.

B. SUSPENSIONS/TERMINATIONS

Internal: (Suspensions/Terminations initiated internally, e.g., by IRB).

IRB Administrator will report the action to the Medical Center Director (MCD), Associate Chief of Staff/R&D (ACOS/R&D), and Research Compliance Officer (RCO) within 5 business days of the action. MCD will report to VA Office of Research Oversight (ORO) within 5 business days of receiving the internal notification.

External: (Suspensions/Terminations initiated externally, e.g., by FDA).

The IRB must be notified within 5 business days after becoming aware of any suspension or termination of VA research by, or at the direction of, any entity external to the facility.

The convened IRB must review the report within 30 business days to determine whether it:

(a) Resulted from a local adverse event(s), local noncompliance, or other local issue(s); or

(b) Requires local action (in addition to the suspension/termination) to ensure the safety, rights, or welfare of local human research subjects, personnel, or others or the effectiveness of the local HRPP.

If either(a) or (b) applies, IRB Administrator will report the determination of the committee to the Medical Center Director (MCD), Associate Chief of Staff/R&D (ACOS/R&D), and Research Compliance Officer (RCO) within 5 business days. MCD will report to VA Office of Research Oversight (ORO) within 5 business days of receiving the internal notification.

7. REFERENCES

VHA Handbook 1058.01 (06/15/2015)

VHA Directive 1200.05 (01/07/2019)

VA Record Control Schedule 10-1 (03/2017)