UNIVERSITY OF SOUTH ALABAMA

# IRB SOP 505
# Study Completion, Suspension or Termination

## Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the procedures for study completion, closure or termination.

## Scope

The SOP applies to all human research projects submitted to the IRB.

## Definitions

**Administrative Hold:** An administrative hold is a voluntary action by an investigator to temporarily or permanently stop some or all approved research activities and are not considered suspensions or terminations. Protocols on administrative hold remain open and require continuing review.

**Administrative Closure:** This is an administrative status whereby a previously approved protocol's expiration date has passed and an investigator has not submitted a renewal, or the investigator has submitted a study closure request. The IRB assumes that no human subject research activities are ongoing and, for administrative record keeping, the study record is closed.

**Suspension:** A suspension of IRB approval is directive of the convened IRB, or IRB designee either to stop temporarily some or all previously approved research activities, or to stop permanently some of all approved research activities. Suspended protocols remain open and require continuing review.

**Termination:** A termination of IRB approval is a directive of the convened IRB or IRB designee to stop permanently all activities in a previously approved research protocol. Terminated protocols are considered closed and no longer require continuing review.

## Policy

The IRB has the authority and responsibility to suspend or terminate approval of research that is not being conducted in accordance with the IRB policies and procedures, is not in compliance with Federal Regulations, or that has been associated with unexpected harm to participants or others. The IRB has the ability to temporarily or permanently suspend or terminate approval for some or all research activities. Depending on the circumstances surrounding the suspension or termination action, the investigator may be required to submit a report to the IRB, detailing any adverse events and/or study outcomes that were previously unreported to the IRB for consideration. Any letter of suspension or termination of approval to an investigator must include a statement of the reasons for the action by the IRB (45 CFR 46.113 and 21 CFR 56.113).

An investigator may also place a voluntary administrative hold on previously approved research when in the judgement of the investigator and administrative hold is appropriate to protect the welfare of subjects.

The IRB Chair, Vice-Chair, or the Vice President for Research is authorized to suspend or terminate the enrollment of subjects; and the ongoing involvement of subjects in research, as it deems necessary to protect the rights and welfare of participants. This also includes compelling and urgent instances when subject safety is of concern.

## Procedures

### 1.0 IRB Review

1.1 The IRB will review suspensions and terminations at a subsequent convened meeting.
1.2 A plan will be developed that takes into account the rights and welfare of currently enrolled subjects and those subjects who may need to be withdrawn from the study.
1.3 If the agreed upon plan of action involves withdrawal of enrolled participants, the IRB will take into account their rights and welfare (e.g., transfer to another researcher, and continuation in the research under independent monitoring).
1.4 If the IRB determines that a suspension or termination of the research will place subjects at risk of harm, the investigator will be requested to submit a proposed script or letter for participants for IRB review and approval.
1.5 The IRB determines the information that is to be provided to participants and the method of their notification e.g., in writing (certified mail return receipt) or by telephone. This includes appropriate participant follow-up and notification of the reasons for the action.

## 2.0 When can a project be submitted to the IRB for study closure

Research studies can be deemed complete for a number of reasons, each requiring a different degree of IRB involvement. More often, however, the investigator or sponsor will close the study and the IRBs role will be more passive, receiving study completion documents and archiving the records for the study. The IRB requires confirmation from the study sponsor regarding study site closure for clinical trials. A study closure should be completed and submitted via IRBNet. This form serves as notification to the IRB that continuing review of the study is no longer needed.

2.1 A project may be closed when the following apply:

- 2.1.1 All subject recruitment and enrollment is complete
- 2.1.2 All subject specimens, records, data have been obtained (no additional collection of data from or about living individuals)
- 2.1.3 No further contact with subjects is necessary
- 2.1.4 Analysis of subject identifiable data, records, specimens are complete

## 3.0 Study Closure by Investigator/Sponsor

By submitting a Final Closure report, the researcher confirms that the study is finished and that researchers have no further interaction with subjects or their data. Once the IRB receives and accepts the Final Closure report form, the researcher is no longer required to submit for continuing review for renewal.

The IRB, in consultation with the investigator, may consider closing a study when active data analysis and publication pursuant to the approved study have ceased, even if the investigator retains records that may identify individual subjects. Additional research projects using data acquired in the approved study may constitute new human subjects research studies requiring to separate IRB review.

## 4.0 Administrative Withdrawal

The IRB Office will administratively withdraw project submissions to include:

- 4.1 No response from study site in 90 days after the project has been unlocked in IRBNet to address the requested IRB action items.
- 4.2 Duplication or submission error
- 4.3 Request by Investigator/study site

A decision letter will be sent via IRBNet to the PI and site personnel documenting the reason for the withdrawal. Administrative withdrawal will also be initiated if the Investigator has left the University and transfer of the study has not been pursued.

## 5.0 Administrative Hold

A decision by an investigator to voluntarily suspend or terminate some or all research activities being conducted under an IRB approved research protocol, which may be pending further review or investigation by the IRB or other entity within the institution, even if prompted by a verbal or written recommendation from the IRB Chair or another institutional official, is not considered a suspension or termination of IRB approval.

The investigators submit a plan indicating whether any additional procedures will be followed to protect the rights and welfare of current participants as described in "Protection of currently enrolled participants" below. The investigators should determine how and when currently enrolled participants will be notified of the administrative hold.

Investigators must notify the IRB in writing of the following:

- That they are voluntarily placing a study on administrative hold
- A description of the research activities that will be stopped
- Proposed actions to be taken to protect current participants
- Actions that will be taken prior to IRB approval of proposed changes in order to eliminate apparent immediate harm

Upon receipt of written notification from the investigator, the IRB Office places the research on the agenda for review. Investigators may request a modification of the administrative hold by submitting a request for a modification to previously approved research.

## 6.0 Termination of a Study by the IRB

In cases of serious adverse events or unanticipated problems, noncompliance, or protocol violations, the IRB may suspend a study to ensure subject safety. Upon investigation of the problem prompting suspension of the study, the convened IRB may decide that a study should be terminated. Following the vote of the IRB to terminate a study and the evaluation of any appeals made by the investigator, the study will be classified as closed. Though the chair may suspend a study, pending IRB review, only the convened IRB may vote to terminate a study.

## 7.0 Protection of currently enrolled participants

Before an administrative hold, termination, or suspension, is put into effect the convened IRB or IRB designee considers whether any additional procedures need to be followed to protect the rights and welfare of current participants. Such procedures might include:

- Transferring participants to another investigator
- Making arrangements for clinical care outside the research
- Allowing continuation of some research activities under the supervision of an independent monitor
- Requiring or permitting follow-up of participants for safety reasons
- Requiring unanticipated problems or outcomes to be reported to the IRB and the sponsor
- Notification of current participants
- Notification of former participants

## 8.0 Expiration of Approval Period

Once the approval period for a given study has expired prior to the renewal of approval by the IRB, it is considered a lapsed study and all research-related procedures must cease, except where doing so would jeopardize the welfare of the human subjects.

IRBNet generates a notice of expiration electronically to the investigator and all personnel with full access to the project, indicating that continuation of research studies is a violation of federal regulations, however if the subjects would be harmed by halting the activities permission must be obtained by the IRB to continue research study related activities.

If the Investigator fails to submit the materials for continuing review within two weeks following the expiration date, then the lapsed study will be classified as administratively expired. If the investigator submits the materials for continuing review within two weeks following the expiration date, the IRB will conduct continuing review (if applicable) and reactivate the protocol. This reactivation establishes a new approval period that is not retroactive to the prior date of expiration. If the investigator desires to continue a study that has lapsed for greater than two weeks, then the investigator must submit a new application for re-review by the IRB, and must receive IRB approval before resuming research under the protocol.

## 9.0 Reinstatement of a Project

To reinstate a project that has been suspended, the investigator must satisfactorily resolve any pending issues required by the IRB. To reinstate a project that has been terminated, the investigator must submit the project to the IRB as a new application and past issues must be resolved to the satisfaction of the IRB.

## Regulated Documentation

21 CFR 56.113; 45 CFR 46.113

## University Related Documents

IRB Study Closure Form (IRBNet Forms and Templates)

## HISTORY

Effective Date:
Revisions: October, 2018