***TITLE: Administrative Hold***

***SOP*** RM XX.XX

***Author(s):***

***Developed by Date***

***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***Approval:***

***Approved by Date***

***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***Annual review of current version Review date Comment***

***\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

|  |
| --- |
| **Instructions for modifying this template:**   1. This is a template and should be used as such. Please use this in the manner most appropriate for your research unit. 2. Anything in this template can and may be modified as appropriate for your area while accounting for your interpretation of the most current FDA Guidance. 3. After you have modified this SOP template, do not forget to remove the “**Instructions for modifying this template**” table. 4. Number the SOP using you own guidelines for numbering. |

**I. SCOPE/PURPOSE**

The purpose of this SOP is to provide guidance on the policies and procedures of the UAB Office of the Institutional Review Board related to administrative holds, suspensions, or terminations of research studies.

**II. ALLOWABLE EXCEPTIONS**

This SOP is meant to be followed without deviation. However, it is an allowable exception to follow procedures specified in a protocol or by the sponsor. If a deviation from this SOP occurs, a description of this event will be written and filed with this list of SOPs and the protocol.

**III. RELEVANT REGULATIONS/GCP**

FDA (Food and Drug Administration) and IRB Requirements

45 CFR 46

UAB Office of the IRB Guidebook

**IV. DEFINITIONS/ACRONYMS**

**Administrative Hold:** A voluntary action by a PI to temporarily stop some or all approved research activities. An administrative hold is not a suspension or termination. Studies on administrative hold are not closed with the IRB and require continuing review by the IRB. Additionally, requirements for reporting non-compliance and unanticipated problems involving risks to participants or others remain.

**Suspension:** An action by the convened IRB, IRB Chair or designee to temporarily stop some or all previously approved research activities, or to permanently stop some previously approved research activities. Suspended protocols are not closed with the IRB and require continuing review by the IRB.

**Termination:** An action by the convened IRB or IRB Chair to permanently stop all activities of a previously approved research protocol. Terminated protocols are closed protocols, and they no longer require continuing

**P.I.:** Principal Investigator

**V. RESPONSIBLE PERSONNEL**

This SOP applies to the following – Investigators, Key Research Personnel, Data Management, Regulatory Affairs, and sponsors.

**VI. DETAILS**

The P.I. may decide to place a research study on administrative hold for a variety of reasons. For example, a P.I. may determine additional training of key personnel is necessary or time is required to analyze interim results. The IRB may consult with the P.I. to determine:

1. Whether any additional procedures are needed to protect the rights and welfare of currently enrolled research participants, and
2. Whether participants will be notified of the administrative hold
3. The P.I. must submit an amendment to notify the IRB in writing of:
   1. Voluntarily placing a study on administrative hold
   2. Reason the study was placed on administrative hold
   3. Plan for addressing reason study was placed on administrative hold
   4. A description of the research activities that will be stopped
   5. The actions to be taken to protect currently enrolled participants
   6. The actions to be taken prior to IRB approval of the proposed changes (if applicable) in order to eliminate apparent immediate harm to research participants.

Upon receipt of amendment to place a study on administrative hold, the IRB will review at their next convened meeting. Exceptions may apply.

Before an administrative hold is put into effect, the convened IRB or the IRB Chair considers whether any additional procedures are needed to protect the rights and welfare of currently enrolled participants. Such procedures may include:

a. Notification of current participants

b. Making arrangements for clinical care outside of the research study

c. Allowing continuation of some research activities under the supervision of an independent monitor.

d. Transferring the study to another PI

e. Notification of participants who are considered complete (if applicable)

**Resuming Research Activities after:** documentation of all items relating to the hold have been addressed. Assure that there has been documentation of hold being released.

**VII. QA**

N/A

**VIII. APPENDICES / RESOURCES**

N/A

**IX. RELATED SOPS**

N/A