SOP 904: ADMINISTRATIVE HOLD, SUSPENSION AND TERMINATION OF RESEARCH

DEFINITIONS

a)	**Administrative Hold**	An administrative hold is a voluntary action by an investigator to temporarily or permanently stop some or all approved research activities. Administrative holds are not suspensions or terminations. Protocols on administrative hold remain open and require continuing review.
b)	**Suspension**	A suspension of IRB approval is a directive of the convened IRB, or IRB designee either to stop temporarily some or all previously approved research activities, or to stop permanently some or all previously approved research activities. Suspended protocols remain open and require continuing review.
c)	**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 to suspend or terminate approval of research that is not being conducted in accordance with the IRB policies, is not in compliance with Federal Regulations or that has been associated with unexpected serious harm to participants. Suspensions and terminations will be reported to OHRP, FDA and appropriate institutional officials when applicable as listed in SOP 905 (Reporting Procedures).

An investigator may also place a voluntary administrative hold on previously approved research when in the judgment of the investigator an administrative hold is appropriate to protect the rights or welfare of participants.

In this policy, an IRB designee refers to the following: The IRB Chair, IRB Vice-Chair, IRB Director, Institutional Official, or a person designated in writing to temporarily assume the role of one of these persons.

PROCEDURES

1. Procedures for Administrative Holds

1.1. An investigator may place a research study on administrative hold. Some or all research activities may be placed on administrative hold until additional information can be obtained in order to determine if a change in the risk/benefit assessment of the research has occurred, or if potential areas of non-compliance exist in a currently approved research protocol.
1.2. The IRB or IRB designee in consultation with the investigator determines whether any additional procedures need to be followed to protect the rights and welfare of current participants as described in SOP 906 (Protection of Research Participants).
1.3. The IRB or IRB designee in consultation with the investigators determine how and when currently enrolled participants will be notified of the administrative hold.

1.4. Investigators must:

- Notify the IRB in writing that the investigator is voluntarily placing a study on administrative hold.
- Provide a description of the research activities that will be stopped. Research activities may include but are not limited to recruitment, screening/enrollment, research intervention/interaction, follow-up, or all research activities.
- Provide a list of all currently enrolled participants' status within the study, and the proposed actions to be taken (if needed) to protect the rights and welfare of current participants during the administrative hold action according to SOP 906 (Protection of Research Participants).
- Provide a written description of actions that will be taken prior to IRB approval of proposed changes in order to eliminate apparent immediate harm.

1.5. After written notification from the investigator has been received, the IRB staff is notified by the IRB Chair or designee of the study on administrative hold and actions to be taken.

1.6. An IRB administrator initiates an inquiry process and considers if the additional information gathered during the inquiry stage of an investigation determines that no change to the risk/benefit ratio has occurred, the rights or welfare of participants have not been compromised, and issues of non-compliance have been ruled out. The inquiry may necessitate a for-cause audit according to SOP 908 (Routine and For-Cause Audits) to obtain the needed information.

1.7. The IRB administrator writes a report of the findings. The IRB Chair or designee notifies the investigator in writing of these findings and what corrective actions are necessary, if any, and allows the study to return to active status. Determinations of unanticipated problems involving risks to participants or others or non-compliance that are a result of these findings will be made according to SOP 901 (Unanticipated Problems Involving Risks to Participants or Others) and SOP 903 (HRPP and Non-Compliance).

2. Procedures for Suspension or Termination of IRB Approved Research by the Convened IRB or IRB Designee for Cause

2.1. If research is not being conducted in accordance with the policies, requirements, and determinations of the IRB, or federal rules or regulations including the requirements of the VHA Directive 1200.5 governing human subject research, or has been associated with unexpected serious harm to participants, the convened IRB or designee may suspend or terminate some or all research activity to protect the rights or welfare of participants.

2.2. The IRB designee considers whether any actions need to be implemented to protect the rights and welfare of current participants as described in SOP 906 (Protection of Research Participants), and orders any actions that need to be taken during the investigation process.

2.3. The IRB designee notifies IRB staff of the suspension and actions ordered.

2.4. The IRB Chair or designee notifies the investigator of the suspension in writing that there are reasonable concerns that infractions have occurred and an investigation has been initiated. This letter is drafted following Procedures for Communication of Terminations and Suspensions below.

2.5. An IRB administrator initiates an investigation process and considers if the additional information gathered during the inquiry stage of an investigation determines that no change to the risk/benefit ratio has occurred, the rights or welfare of participants have not been compromised, and issues of non-compliance have been ruled out. The investigation may necessitate a for-cause audit according to SOP 908 (Routine and For-Cause Audits) to obtain the needed information.

2.6. The IRB administrator writes a written report detailing the findings of the investigation as well as appropriate corrective actions for any problems or deficiencies. The written report is sent to the convened IRB, IRB Chair, IRB Director, and other Institutional Officials and other units within the University or the covered entity as appropriate.

2.7. The convened IRB considers the written report and whether any actions need to be implemented to protect the rights and welfare of current participants as described in SOP 906 (Protection of Research Participants) and votes on the actions to be taken. Possible actions the convened IRB considers may include, but are not limited to the following:

- Continuing interventions that are being administered to currently enrolled participants under the research protocol, at least temporarily, when those interventions hold out the prospect of direct benefit to the subjects or when withholding those interventions poses increased risk to subjects.
- Transferring currently enrolled participants to another institution engaged in the research so that participation of the subjects may continue.
- Transitioning currently enrolled participants to medical management outside of the research context.

Determinations of unanticipated problems involving risks to participants or others or non-compliance that are a result of the findings will be made according to SOP 901 (Unanticipated Problems Involving Risks to Participants or Others) and SOP 903 (HRPP and Non-Compliance).

2.8. The convened IRB votes to lift the suspension, continue or modify the suspension, or terminate the study.

2.9. The IRB administrator and coordinator document in the IRB minutes the reasons for the suspension or termination and if applicable, any actions ordered to take place.

2.10. IRB staff communicates with the investigator following Procedures for Communication of Terminations and Suspensions below.

3. Procedures for Communication of Terminations and Suspensions to Investigators

3.1. The IRB staff drafts a letter to the investigator. The IRB Chair reviews and signs the letter. Copies are to be provided to the Institutional Official, IRB Director, IRB members, and the immediate supervisor or department chair of the Investigator. The letter includes:

- The activities to be stopped;
- Actions to be taken by the Investigator;
- An explanation of the reasons for the decision;
- A request to immediately notify the IRB Chair with a list of names of participants who might be harmed by stopping research procedures and a rationale as to why they might be harmed.

3.2. The investigator may appeal or respond to the convened IRB in writing.

3.3. IRB staff will follow the SOP 905 (Institutional Reporting Procedures) on reporting the suspension or termination of approved research by the IRB to appropriate organizational officials, sponsors, coordinating centers and regulatory agencies.