

SOP: 904	ADMINISTRATIVE HOLD, SUSPENSION AND TERMINATION OF APPROVED RESEARCH
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AAHRPP Element II.4.D

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 in response to a request by the convened IRB or IRB designee to take such action. Administrative holds are not suspensions or terminations.
- 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 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. All such suspensions and or terminations will be reported to OHRP, FDA and appropriate institutional officials when applicable as listed in SOP 905 (Reporting Procedures).

The convened IRB or IRB designee may also request that an Investigator place a voluntary administrative hold on previously approved research when in the judgment of the IRB or IRB designee and in consultation with 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, Intuitional Official, or a person designated in writing to temporarily assume the role of one of those persons.

The Convened IRB will not approve any new or pending research proposals from an investigator whose research activities are on Administrative Hold, Suspension or Termination status.

PROCEDURES

1. Procedures for Administrative Holds

- 1.1. The convened IRB or IRB designee may request that an investigator 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 requesting the administrative hold in consultation with the investigators 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 requesting the administrative hold 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 in response to a request by the convened IRB or IRB designee.
 - 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 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.
- 1.7. The IRB administrator writes a brief report. 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. Otherwise the matter proceeds according to the SOP 908 (Audit for Cause).

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

- 2.1. If in the judgment of the convened IRB or IRB designee an investigator will not cooperate with an administrative hold, the convened IRB or IRB

designee may order a suspension or termination of some or all research activity pending the outcome of a formal investigation. Also, if research is not being conducted in accordance with the policies, requirements, and determinations of the IRB, or federal rules and regulations including the requirements of the VHA Handbook 1200.5 governing human subject research, or has been associated with unexpected serious harm to participants, the convened IRB may permanently 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 prior to review of the investigation report by the IRB Executive Committee, in order to eliminate apparent immediate hazards.
- 2.3. The IRB designee documents in the IRB Research Compliance record the reasons for the suspension and if applicable, any actions ordered to take place.
- 2.4. The IRB designee notifies IRB staff of the suspension or termination and actions ordered.
- 2.5. The IRB Chair or designee communicates with the investigator in writing that an investigation discloses reasonable concerns that infractions have occurred and a formal hearing process is initiated as described in SOP 908 (Audits for Cause). This letter includes an opportunity for the PI to respond to the Committee, and provide clarification of the issues.
- 2.6. If an investigation identifies evidence that requires a hearing an IRB administrator will schedule a meeting of the Executive Committee.
 - 2.6.1. The IRB staff distributes to all Executive Committee members a copy of the current protocol, the current consent documents, and any supporting information relevant to the suspension or termination.
 - 2.6.2. Whenever possible the IRB designee who ordered the suspension or termination attends the meeting. If the designee cannot attend the meeting, the designee must provide a written report.
 - 2.6.3. The IRB Executive Committee votes to continue, reverse or modify the suspension or termination. The Committee may request the development of an educational and corrective action plan. Studies may be reinstated for approval after corrective actions are completed to the Committee's satisfaction.
 - If the IRB Executive Committee votes to reverse the suspension or termination, the Committee may do so with or without additional sanctions. Additional sanctions may include but are not limited to mandating a data and safety monitoring report to the IRB at more frequent designated intervals or directed audits.
 - If the IRB Executive Committee votes to continue or modify the suspension or termination, the committee's report is brought before the convened IRB Board following the Procedures for the Suspension or Termination of IRB Approval by the Convened IRB.

3. Procedures for the Suspension or Termination of IRB approval by the convened IRB

- 3.1. The IRB Executive Committee's report regarding the suspension or termination of IRB approval is provided to all IRB members by the IRB staff.
- 3.2. The convened IRB 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 votes on the actions to be taken.
- 3.3. 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.
- 3.4. The convened IRB considers 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).
- 3.5. IRB staff communicates with the investigator following Procedures for Communication of Terminations and Suspensions below.

4. Procedures for Communication of terminations and suspensions to Investigators

- 4.1. 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 Chair, 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.
- 4.2. The investigator may appeal or respond to the convened IRB in writing.
- 4.3. IRB staff will follow the SOP 905 (Reporting Procedures) on reporting the suspension or termination of approved research by the IRB to appropriate organizational officials, sponsors, coordinating centers and regulatory agencies.