Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Suspension and Termination of IRB Approval

Suspension and Termination of IRB Approval

Effective Date:	May 31, 2006	
Original Approval Date:	May 31, 2006	
Revision Date:	December 1, 2006	December 24, 2009
	June 10, 2010	July 1, 2011
	March 1, 2015	July 1, 2015
	June 8, 2017	May 3, 2018

Approved By: Michele Kennett, JD, MSN, LLM
Associate Vice Chancellor for Research

Michele Kennett

Table of Contents

1.0 Purpose

The purpose of this Standard Operating Procedure (SOP) is to outline the procedure to suspend or terminate approved research.

2.0 Scope

This SOP applies to all human subject research falling under the purview of the University of Missouri Institutional Review Board.

3.0 Policy/Procedure

The IRB or IRB designee shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with IRB, federal, state or local requirements, or has been associated with unexpected serious harm to participants.
The convened IRB or IRB designee may request an administrative hold of approved research when, in the judgment of the convened IRB or IRB designee, an administrative hold is appropriate to protect the rights or welfare of participants.
The convened IRB or IRB designee may order a suspension or termination of approved research when, in the judgment of the convened IRB or IRB designee, an investigator will not cooperate with an administrative hold and a suspension or termination is appropriate to protect the rights or welfare of participants.

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 staff 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.

If this policy is less restrictive than the VA administrative hold policy, the VA policy must be applied for VA research.

Administrative hold does not apply to interruptions of VA research related to concerns regarding the safety, rights or welfare of human research participants, research investigators, research staff or others. Nor can the status be used to avoid reporting deficiencies or circumstances otherwise covered by the VHA Handbooks or other federal requirements governing research.

Suspension or termination by IRB designee

If deemed appropriate by the Director, in consultation with the IRB Chair, suspension or termination may be ordered prior to the meeting of a convened IRB.
The Director, in consultation with the Chair, may act alone to suspend or terminate previously approved human subject research or an investigator's privilege to conduct human subject research if the alleged serious or continuing non-compliance with the requirements or determinations of the IRB, or any incidence that has been associated with the unexpected serious harm to participants, appears to pose imminent threat to subject safety.
The IRB designee considers whether any actions need to be implemented to protect the rights and welfare of current participants as described in "Protection of currently enrolled participants" below and orders any actions that need to be taken prior to review by the convened IRB in order to eliminate apparent immediate hazards.
The IRB designee documents in the IRB record the reasons for the suspension and if applicable, any actions ordered to take place.
The IRB designee notifies IRB staff of the suspension or termination and actions ordered.
IRB staff communicates with the investigator following "Communication of terminations and suspensions" below.

IRB staff places the suspension or termination on the agenda of the next available IRB meeting, then:

- IRB staff distributes to all IRB members a copy of the current protocol, the current consent documents, and any supporting information relevant to the suspension or termination.

- The IRB designee who ordered the suspension or termination attends the meeting and presents facts for consideration and vote.

- The IRB votes to continue, reverse or modify the suspension or termination.

- If the IRB votes to continue or modify the suspension or termination, the procedures in "Suspension or termination of IRB approval by the convened IRB" are followed.

Suspension or termination by the convened IRB

The IRB considers whether any actions need to be implemented to protect the rights and welfare of current participants as described in "Protection of currently enrolled participants" below and votes on the actions to be taken.

The IRB may request an ad hoc review from an independent source with expertise in the type of research being conducted or expertise in the specific area of concern.
The IRB documents in the IRB minutes the reasons for the suspension and, if applicable, any actions ordered to take place.

The IRB considers whether any additional procedures need to be followed to protect the rights and welfare of current participants as described in "Protection of currently enrolled participants" below.

IRB staff communicates with the investigator following "Communication of terminations and suspensions" below.

Communication of terminations and suspensions:

The IRB staff drafts a letter to the investigator, with copies to the institutional official, IRB chair, IRB director, IRB members, and the immediate supervisor or chair of the investigator. The IRB chair reviews and signs the letter. The letter includes:

- The activities to be stopped
- Actions to be taken by the investigator
- An explanation of the reasons for the decision
- IRB action plan and established timeline for response and reporting progress to the IRB
    - If appropriate, require the investigator to submit:
        - Procedure for the withdrawal of currently enrolled participants that considers their rights and welfare
        - Letter or script notifying all currently enrolled participants that are affected by the suspension or termination
- A reminder that all study activities such as, reporting unanticipated problems, revisions to investigator brochures, and updated package inserts must still be reported to the IRB.
- 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 why they might be harmed
- In the case of a suspension or termination of IRB approval by an IRB designee, the date and time of the IRB meeting at which the suspension or termination will be reviewed by the convened IRB.
- An offer for the investigator to respond to the convened IRB in writing
- IRB staff follows the SOP on Reporting to communicate the suspension or termination to the IRB, organizational officials, and regulatory agencies.

VA research that has been suspended or terminated by the IRB will be promptly reported to the VA R&D and the Facility Director. It is the responsibility of the Facility Director to report to other VA authorities and external agencies, as required. For information regarding suspension of VA research see VA SOP.

For suspended research involving the VA, continuation of research interventions or interactions in already enrolled subjects should only continue when the IRB Chair, in consultation with the VA Chief of Staff, finds it in the best interest of the subject(s) to do so.

To facilitate the process, the PI or study staff must immediately submit a list of participants for whom suspension would cause harm.

FDA requirements will be followed in FDA-regulated studies. The IRB will promptly report the suspension to the sponsor, if applicable.

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

Reinstatement of a Project

To reinstate a project that has been suspended, the investigator must satisfactorily resolve any pending issues required by the IRB. If the issues have not been resolved after one year, the study will be terminated.

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.

Appeals

If the investigator responds to the convened IRB in writing the response follows the SOP on Appeals of IRB Decisions.

Reporting

For reporting of suspensions and terminations see “Reporting Requirements SOP”

Return to Table of Contents