



Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Suspension and Termination of IRB Approval

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1.0 Purpose

The purpose of this Standard Operating Procedure (SOP) is to outline the procedure to place an administrative hold, 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 investigator, convened IRB, or IRB designee may request an administrative hold of some or all approved research activities when, in the judgment of the investigator, convened IRB, or IRB designee, an administrative hold is appropriate. This may occur when a lead investigator is taking a leave of absence, temporary furlough, or going on sabbatical, and it is determined the research should not remain open during that time due to lack of appropriate oversight or other reasons. It is not considered a suspension or termination of IRB approval because an administrative hold would not be related to noncompliance concerns or unanticipated problems placing participants at potential risk of harm.

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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, a suspension or termination is appropriate to protect the rights or welfare of participants. This is often required due to noncompliance concerns and/or reasons to believe subjects may be placed at a greater risk of potential harm if the study were to continue without a suspension or termination.

Administrative Hold

Investigator Prompts Administrative Hold

If the investigator is placing the hold, s/he must notify the IRB in writing of the following:

1. That they are voluntarily placing a study on administrative hold;
2. A description of the research activities that will be stopped;
3. Proposed actions to be taken to protect current participants (the investigators should determine if, how, and when currently enrolled participants will be notified of the administrative hold); and
4. Actions that will be taken prior to IRB approval of proposed changes, if applicable, 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.

IRB Prompts the Administrative Hold

A. If the convened IRB places the hold, the investigator will be notified in writing of the following:

1. The IRB is placing a study on administrative hold;
2. A description of the research activities that must be stopped;
3. Actions to be taken to protect current participants, if applicable; and
4. What actions must take place before the hold can be removed.

The convened IRB can remove the hold when all items have been addressed.

B. If an IRB designee places the hold, the investigator will be notified in writing of the following:

1. The IRB is placing a study on administrative hold;
2. A description of the research activities that must be stopped;
3. Actions to be taken to protect current participants, if applicable; and

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4. What actions must take place before the hold can be removed.

The IRB office places the matter on the next available IRB agenda. The convened IRB can remove the hold when all issues have been addressed.

Truman VA Administrative Hold

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. The status cannot be used to avoid reporting deficiencies or circumstances otherwise covered by the VHA Handbooks or other federal requirements governing research. See Truman VA Hospital Human Subject Research - Special Considerations SOP for more information.

Suspension or Termination by an IRB Designee

1. 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.
2. The IRB Designee, 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.
3. 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.
4. The IRB designee documents in the IRB record the reasons for the suspension or termination, and if applicable, any actions ordered to take place.
5. The IRB designee notifies necessary IRB staff of the suspension or termination and actions ordered.
6. IRB staff communicates with the investigator following “Communication of terminations and suspensions” below.
7. IRB staff places the suspension or termination on the agenda of the next available IRB meeting, then:
 - a. IRB staff provides access to the study file in eCompliance and any supporting information relevant to the suspension or termination.
 - b. The IRB designee who ordered the suspension or termination attends the meeting and presents facts for consideration and vote.
 - c. The IRB votes to continue, reverse, or modify the suspension or termination.

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- d. If the IRB votes to continue or modify the suspension or termination, the procedures below in “Suspension or Termination by the Convened IRB” are followed.

Suspension or Termination by the Convened IRB

1. 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.
2. 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.
3. The IRB documents in the IRB minutes the reasons for the suspension or termination, and if applicable, any actions ordered to take place.
4. IRB staff communicates with the investigator following “Communication of Terminations and Suspensions” below.

Communication of Terminations and Suspensions:

1. 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:
 - a. The activities to be stopped;
 - b. Actions to be taken by the investigator;
 - c. An explanation of the reasons for the decision;
 - d. IRB action plan and established timeline for response and reporting process to the IRB;
 - e. If appropriate, require the investigator to submit the procedure for the withdrawal of currently enrolled participants that considers their rights and welfare; and if necessary, a letter or script notifying all currently enrolled participants that are affected by the suspension or termination;
 - f. A reminder that all study activities such as, reporting unanticipated problems, noncompliance, and modifications must still be reported to the IRB;
 - g. If necessary, 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;
 - h. 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; and
 - i. An offer for the investigator to respond to the convened IRB in writing.

IRB staff must follow the SOP on Reporting Requirements to communicate the suspension or termination to necessary individuals.

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VA Suspensions and Terminations

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 Truman VA Human Subject Research – Special Considerations 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.

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 may include:

1. Transferring participants to another investigator;
2. Making arrangements for clinical care outside the research;
3. Allowing continuation of some research activities under the supervision of an independent monitor;
4. Requiring or permitting follow-up of participants for safety reasons;
5. Requiring unanticipated problems or outcomes to be reported to the IRB and the sponsor;
6. Notification of current participants; and
7. 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 may be terminated.

To reinstate a project that has been terminated, the investigator may be required to submit the project to the IRB as a new application and past issues must be resolved to the satisfaction of the IRB.

Appeals

See the SOP on Appeals of IRB Decisions.

Reporting

See the SOP on Reporting Requirements.

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References:

Policy Revision Dates Prior to January 21, 2019:

May 31, 2006; December 1, 2006; December 24, 2009; June 10, 2010; July 1, 2011;
March 1, 2015; July 1, 2015; June 8, 2017, May 3, 2018