

## Administrative Hold, Suspension or Termination of IRB Approval

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### POLICY:

#### I. Relevant Federal Regulations.

- A. An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects or others. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Department or Agency head [45 CFR 46.113, 38 CFR 16.113] or Food and Drug Administration [21 CFR 56.113]. (University Department Heads may be included in reporting, as applicable).

#### II. Definitions.

- A. **SUSPENSION:** A suspension means a determination from the IRB to temporarily withdraw approval of all or some specific research activities or permanently withdraw approval of some specific research activities, indicating that the specified activities must stop immediately. The appropriate party may impose additional criteria for suspension, if needed, to protect the participants from potential harm per the UIC HSPP policy *Administrative Hold, Suspension, or Termination of IRB Approval*. Suspended research projects still have IRB approval and require continuing review. For example, the IRB may stop the enrollment of new subjects, although may allow the continuation of currently enrolled subjects, if appropriate. The convened IRB would review the investigator's response, if any.
- B. **ADMINISTRATIVE HOLD:** An administrative hold is a voluntary action by an investigator or sponsor to temporarily or permanently stop some or all research activities as a modification to approved research. Administrative holds are not considered suspensions or terminations, and do not meet reporting requirements to OHRP, FDA and other federal agencies. Although the investigator may discuss this action beforehand with the IRB, IRB chair, OPRS Director, OPRS Associate Director or Assistant Director, the hold must be initiated voluntarily by the investigator and must not be used to avoid IRB mandated suspension or termination or reporting requirements. During administrative hold, the research remains subject to continuing review and requirements for reporting non-compliance and unanticipated problems involving risks to subjects or others.

- C. **TERMINATION:** A termination represents a directive from the IRB to permanently stop all previously approved research activities.

III. UIC policy provides:

- A. The IRBs have the authority to suspend or terminate their approval of research that is not being conducted in accordance with IRB requirements or federal regulations, when the research is associated with unexpected serious harm to research participants or others or when there are immediate serious issues involving participant and/or others safety.
- B. The IRB chairs, IRB members designated by the chair, and IO with the authority to suspend previously approved research when required for the urgent protection of the rights and welfare of participants and insufficient time exists for the convened IRB to review the event. Any suspension of research by the above individuals is placed on the agenda and reviewed and upheld, overturned or supplemented by the convened IRB at their next meeting.
- C. That previously approved research may only be terminated by the convened IRB, including protocols originally approved under expedited procedures.

**PROCEDURE:**

I. Administrative Hold.

- A. Investigator informs the IRB of the request for administrative hold by submitting to OPRS the UIC OPRS *Prompt Reporting to the IRB* form. The investigator:
  - 1. Explains the event or reason triggering the administrative hold and whether the hold is initiated by the investigator or the sponsor of the research;
  - 2. Describes the research activities to be stopped (e.g., recruitment; enrollment, interventions or interactions, follow-up or all);
  - 3. Indicates number of subjects currently enrolled and proposed actions to protect their rights and welfare during the hold; and
  - 4. Describes plans for implementing the proposed actions, reporting to the IRB, and rescinding the administrative hold.
- B. The Assistant Director of the relevant IRB, in consult with the IRB Chair, reviews the form for completeness, contacts the investigator if necessary for additional information and makes a preliminary assessment of whether the request for administrative hold is appropriate.
- C. If action is needed before the convened IRB meeting, the request is referred to the IRB Chair or designee. If not, it is added to the agenda of the next meeting. The action of the IRB chair or designee is reviewed by the convened IRB at the next meeting.
- D. The minimum materials provided to the IRB (or IRB chair or designee) for review and evaluation of the request for administrative hold include:
  - 1. UIC OPRS *Prompt Reporting to the IRB* form;
  - 2. Any follow-up information gathered by the OPRS staff or Chair;
  - 3. Current approved research protocol;

4. Current approved consent document; and
  5. Access to the complete research protocol file.
- E. Determinations that may be made by the IRB (or IRB chair or designee) include:
1. Approval of the administrative hold and action plan provided by the investigator;
  2. Approval of the administrative hold following acceptance by the investigator of additional IRB-mandated corrective actions;
  3. Request for further information;
  4. Disapproval of the administrative hold;
  5. Whether or not the event represents an unanticipated problem involving risks to subjects or others or serious or continuing non-compliance;
  6. Suspension or termination of part or all of the research.
- F. Actions implemented by the IRB (or IRB Chair or designee) to ensure the rights and welfare of subjects may include:
1. Notification of subjects of the administrative hold through oral or written communications approved by the IRB;
  2. Other measures to protect the rights and welfare of subjects and ensure the safe withdrawal of subjects (e.g., more frequent monitoring of research or consent process).
- G. The investigator must submit an amendment to the IRB lifting the hold and obtain approval prior to the resumption of any activities restricted by the administrative hold.

## II. Suspension.

- A. Suspension of approved research by the IRB may arise from an evaluation of unanticipated problems involving risks to subjects or others, substantive allegations of serious or continuing non-compliance, or findings arising from continuing review or monitoring of research activities.
- B. The review process depends on the event (i.e., unanticipated problem/event, non-compliance) triggering the determination of suspension. Minimum materials provided to the IRB (or IRB chair or designee) include:
1. Report of event prompting consideration of suspension;
  2. Any follow-up information gathered by OPRS staff or Chair;
  3. Current approved research protocol;
  4. Current approved consent document; and
  5. Access to the complete research protocol file.
- C. The IRB (or IRB Chair, designee, or IO) determines and documents whether or not to suspend the research, the reason for suspending the research and the activities to temporarily stop (e.g., recruitment, enrollment, some or all interventions or interactions, follow-up, data analysis or all research activities).
- D. When approval of all or part of the protocol is suspended, the IRB (or individual ordering the suspension) considers actions to protect the rights and welfare of currently enrolled subjects, including, but not limited to:

1. Notification of subjects of the suspension through oral or written communications approved by the IRB;
  2. Allowing currently enrolled subjects to continue if it is in their best interest (for research at the JBVAMC, the Chair will consult with the COS in making this decision);
  3. Changes to the protocol, consent form or other documents to correct any deficiencies and protect the rights and welfare of subjects;
  4. Procedures for withdrawal of current subjects, when necessary, that take into account their rights and welfare (for research at the JBVAMC, the Chair will consult with the COS in making this decision), such as:
    - a) Transfer of subjects to another investigator;
    - b) Arrangement for clinical care outside of the research;
    - c) Continuation of some research activities under the supervision of an individual monitor;
    - d) Permitting follow-up for safety reasons
  5. Follow-up procedures permitted or required by the IRB; or
  6. Requiring the reporting of unanticipated problems involving risks to subjects or others.
- E. The IRB notifies the PI in writing of the suspension. The communication contains:
1. Description of the research activities that are suspended;
  2. Reasons for the suspension;
  3. Corrective actions mandated by the IRB and measures needed to lift the suspension;
  4. A request for the number of currently active subjects and any measures needed to protect their rights and welfare if some or all research activities are stopped;
  5. Timelines for implementing the proposed actions and follow-up reporting to the IRB;
  6. Notification that any request by the investigator for the IRB to reconsider the suspension should be submitted within 30 days.
- F. When the PI has addressed the concerns, the convened IRB may lift the suspension. If the concerns are not addressed, the IRB may terminate the research or take other action to protect the rights and welfare of subjects or others (e.g., make a finding of serious or continuing non-compliance).

### III. Termination.

- A. Termination of approved research by the IRB may arise from an evaluation of unanticipated problems involving risks to subjects or others, findings of serious or continuing non-compliance, or findings arising from continuing review or monitoring of research activities.
- B. The review process depends on the event (i.e., unanticipated problem/ event, non-compliance) triggering the determination of termination. Minimum materials provided to the IRB:
  1. Report of event prompting consideration of suspension;
  2. Any follow-up information gathered by OPRS staff or Chair;

3. Current approved research protocol;
  4. Current approved consent document; and
  5. Access to the complete research protocol file.
- C. The IRB determines and documents whether or not to terminate the research and the reason for terminating the research.
- D. The IRB considers actions to protect the rights and welfare of currently enrolled subjects or others, including, but not limited to:
1. Notification of subjects of the termination through oral or written communications approved by the IRB;
  2. Procedures for withdrawal of current subjects, when necessary, that take into account their rights and welfare (for research at the JBVAMC, the IRB will consult with the COS in making this decision), such as:
    - a) Transfer of subjects to another investigator;
    - b) Arrangement for clinical care outside of the research;
    - c) Continuation of some research activities under the supervision of an individual monitor;
    - d) Permitting follow-up for safety reasons.
  3. Follow-up procedures permitted or required by the IRB;
  4. Requiring the reporting of unanticipated problems involving risks to subjects or others if follow-up procedures are permitted.
- E. The IRB notifies the PI in writing of the termination. The communication contains:
1. Reason for the termination;
  2. Corrective actions mandated by the IRB;
  3. A request for the number of currently active subjects and any measures needed to protect their rights and welfare if some or all research activities are stopped;
  4. Timelines for implementing the proposed actions and follow-up reporting to the IRB;
  5. Notification that any request by the investigator for the IRB to reconsider the termination should be submitted within 30 days.
  6. If the investigator wishes to pursue re-starting the research, he/she must address all concerns noted by the IRB and then re-submit a new proposal for IRB review and approval.

#### IV. Reporting.

- A. The communication to the PI is sent within 10 working days and copied to the Director of OPRS, Academic Department Head, UIC HPA, other relevant UIC oversight committees (e.g., investigational drug service, Institutional Biosafety Committee, radiation safety, cancer center), JBVAMC R&D Committee (if JBVAMC is a performance site), EC (if UIC IRB#4), NU OPRS (if NU is a performance site), relevant IRB and the UIC OPRS protocol file.
- B. The suspension or termination is promptly reported by the HPA or Director of OPRS to appropriate IOs and federal agencies as described in the UIC HSPP policy, *Reporting requirements to IOs, supporting agency heads, and regulatory agencies for unanticipated problems/events requiring prompt*

*reporting, serious or continuing non-compliance, and suspensions or terminations.*

**REFERENCES:**

[21 CFR 56.108\(b\)\(3\), 21 CFR 56.113](#)  
[38 CFR 16.103\(b\)\(5\)\(ii\), 38 CFR 16.113](#)  
[45 CFR 46.103\(b\)\(5\)\(ii\), 45 CFR 46.113](#)  
[VHA Handbook 1200.05 para 7](#)