# HOLDS, SUSPENSIONS, AND TERMINATIONS

**11/20/2023**

The convened IRB, an IRB Chair, IRB Executive Director, Director of Research Review, or the Institutional Official (IO) or their designee (collectively, "IRB authority") has the authority to suspend or terminate approved research or an individual's ability to conduct research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

Suspension or termination may apply to an entire Clinical Research Unit (CRU), a CRU division, a Principal Investigator, a study team, or an individual member of a study team. Notwithstanding the above, suspensions or terminations that apply to an entire CRU or CRU division will be determined only by a convened IRB, the IO or their designee. All other suspensions or terminations can be determined by any IRB authority as defined herein. IRB actions will occur in compliance with 45 CFR 46.108(a)(4)(ii) and .113, and 21 CFR 56.108(b)(3) and .113.

## Definitions

**Administrative Hold:** A voluntary action by a PI or sponsor to temporarily or permanently stop some or all approved research activities in response to a finding of concern that does not adversely affect the safety, rights and welfare of research participants. An administrative hold may be used, for example, while the IRB is waiting to receive further information, or when a researcher takes a leave of absence and cannot find a replacement PI. An administrative hold is not a suspension or termination.

An administrative hold will not be used to avoid reporting deficiencies or circumstances that otherwise must be reported to regulatory agencies.

Studies placed under administrative hold must still submit Continuing Review applications to the IRB, and must still follow all IRB prompt reporting policies. An administrative hold cannot be used to extend IRB approval beyond the expiration date of a study, without IRB approval of Continuing Review.

**Suspension:** An action by an IRB authority or their designee to stop, temporarily or permanently, some or all previously approved research activities short of permanently stopping all research activities. Suspended protocols are not closed with the IRB and require continuing review by the IRB. The IRB must approve re-starting any suspended activities study.

**Termination:** An action by the convened IRB to stop permanently all research activities at any of the levels described in paragraph two above. An IRB authority may terminate the research activities of an individual study team member but has no authority over the employment status of the affected individual. Any decisions regarding employment of the individual will be made by the IO in consultation with Duke University School of Medicine Human Resources. In the case where a research study has been terminated, the terminated protocol is a closed protocol and no longer requires continuing review.

## Procedure

### 1. Administrative Hold

- The IRB, after consultation with the PI, determines:
  - Whether any additional procedures are needed to protect the safety, rights and welfare of current research participants, and
  - How and when currently enrolled participants will be notified of the administrative hold.
- The PI must notify the IRB in writing of:
  - A description of the research activities that will be stopped
- The actions that have been taken prior to IRB review and approval to eliminate apparent immediate harm to research participants. The IRB Specialist will place the study on the agenda for review by the next available convened IRB.

### 2. Immediate Suspension or Termination of IRB Approval by an IRB Chair, Executive Director, or the IO or their Designee

- The Chair, Executive Director, or the IO or their designee (collectively, "Reviewer") considers whether any immediate actions are needed to protect the safety, rights and welfare of current participants or to eliminate an apparent hazard.
- The Reviewer documents with the IRB the reasons for the suspension or termination and any actions taken.
- The Reviewer communicates this information to the PI.
- The IRB Specialist places the suspension or termination on the agenda of the next available IRB meeting:
  - The convened IRB votes to continue, reverse or modify the suspension or termination.
- If the convened IRB votes to continue or modify the suspension or termination, the procedure described below in item 3 is used.

### 3. Suspension or Termination of IRB Approval by the Convened IRB

- The IRB considers whether any action is needed to protect the safety, rights and welfare of current participants.
- Actions might include:
  - Transferring subjects to another PI

- Making arrangements for clinical care outside of the research
- Allowing continuation of some research activities under the supervision of an independent monitor
- Notification of current participants
- Notification of former participants
- For terminated studies:
  - Requiring or permitting follow-up of participants for safety reasons
  - Requiring adverse events or outcomes to be reported to the IRB and the sponsor.

- In the IRB minutes, the convened IRB must document the reason for the suspension or termination, and if applicable, any actions taken.
  The IRB Chair, working with the IRB Specialist and Executive Director, communicates these findings to the PI, the IO, appropriate institutional officials, and any applicable funding or regulatory agencies. Suspensions and terminations will be reported within 30 days of the recognition of a reportable event.

**4. Reasons for Suspensions/Terminations**

An IRB authority may immediately suspend the conduct of research for a variety of reasons. These include, but are not limited, to the following:

- Non-compliance and/or failure to resolve findings of non-compliance by the PI and/or study team.
- New information becomes available that could alter the original determination by the IRB to approve the study.
- Allegations of research misconduct that may indicate a potential risk of harm to the human subjects.

Previous Version Date(s): 3/7/2016, 5/9/2011, 6/5/2008, 7/30/2021