Administrative Hold Activation by the Principal Investigator

Content Applies To

Mayo Clinic Human Research Protection Program

Research for which Mayo Clinic IRB is the IRB of Record

Purpose

The purpose of this procedure is to describe how a Principal Investigator (PI) may place subject enrollment or all study activities on administrative hold and what response actions are required by the IRB Regulatory Compliance Unit and the PI.

Key Terms

PI Initiated Administrative Hold: An action initiated by the Principal Investigator whenever specific research activities, including subject enrollment, are placed temporarily on hold.

Policy

It is the investigator's responsibility to voluntarily place a research project on administrative hold either based on his/her judgment and/or in consultation with the Sponsor, FDA, or other appropriate request. IRB Staff will not initiate an Administrative Hold on behalf of an Investigator.

Investigator Responsibilities

The principal investigator is responsible for:

1. Notifying the IRB using the PI Initiated Administrative Hold activity in the IRB electronic system whenever specific research activities, including subject enrollment, are placed on hold temporarily and this action differs from the approved research project plan.
2. Providing the rationale for the PI Initiated Administrative Hold and including supporting documents.
3. Continuing to report via the IRB electronic system unanticipated problems involving risk to subjects or others that occur while the research activities are on PI Initiated Administrative Hold.
4. Notifying the IRB, through a modification via the IRB electronic system, of the intent to resume research activities when the issues that led to the PI Initiated Administrative Hold have been resolved.
5. Awaiting notification from the IRB before resuming research activities subject to the hold.

IRB Regulatory Compliance Unit (IRCU)

The IRB Regulatory Compliance Unit is automatically notified when a PI Initiated Administrative Hold application is submitted by the Principal Investigator. The IRCU implements an inquiry per the *Internal Compliance Review of Allegations of Suspected or Actual Noncompliance* procedure.

Related Documents

Internal Compliance Review of Allegations of Suspected or Actual Noncompliance

Reporting an Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) to the IRB

Effective Date

October 20, 2014