Administrative Hold Activation by the Principal Investigator (PI) Policy

Scope

Applies to PIs of Human Subjects Research when placing subject enrollment or all study activities on administrative hold and Mayo Clinic Institutional Review Board (IRB) is the IRB of Record.

Purpose

To describe how a PI may place subject enrollment or all study activities on administrative hold and what response actions are required by the Office of Research Regulatory Support Compliance (ORRS - C) and the PI.

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, Food and Drug Administration (FDA), or another appropriate request. IRB Staff will not initiate an Administrative Hold on behalf of an Investigator.

Investigator Responsibilities

The Principal Investigator must:

1. Notify the IRB within 5 working days 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. Provide the rationale for the PI Initiated Administrative Hold and including supporting documents.
3. Continue to report via the IRB electronic system Unanticipated Problems Involving Risk to Subjects or Others (UPIRTSO) that occur while the research activities are on PI Initiated Administrative Hold.
4. Notify 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. Await notification from the IRB before resuming research activities subject to the hold.

Office of Research Regulatory Support Compliance (ORRS - C)

The Office of Research Regulatory Support (ORRS - C) is automatically notified when a PI Initiated Administrative Hold application is submitted by the Principal Investigator. The ORRS-C implements an inquiry.

Policy Notes

A PI Initiated Administrative Hold automatically triggers the status in Protocol Lifecycle Management (PLM) to temporary close for participating sites on the study.

Related Procedures

N/A

Related Documents

Reporting Timelines for IRB Submission when Mayo Clinic is Serving as the IRB of Record

Submitting a Reportable Event to the IRB Policy

Definitions

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

Unanticipated Problem Involving Risk to Subjects or Others (UPIRTSO): An Unanticipated Problem Involving Risk to Subjects or Others is defined as any problem or event which, in the opinion of the local Investigator, meets all three of the following criteria:

- Serious: Serious problems or events that result in significant harm, (which may be physical, psychological, financial, social, economic, or legal) or places subjects or others at a greater risk of harm than was previously known or recognized. Note that actual harm need not have occurred for there to be a change in the risk/benefit ratio.
- Unanticipated: A problem or event is "unanticipated" when it was unforeseeable at the time of its occurrence and is:
    - Not already described as a potential risk in the approved informed consent
    - Not already described as a potential risk in the approved protocol
    - Not listed in the Investigator's Brochure
    - Not part of an underlying disease
    - Occurred at an increased frequency or at an increased severity than expected
- Related: A problem or event is "related" if it is possibly related to the research procedures.

References

N/A

Owner

Michelle K. Daiss on behalf of Office for Human Research Protection

Contact

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Revision History

Date	Synopsis of Change

3/22/2024	Added Policy Note regarding PLM status change.
01/24/2023	Outside of scheduled review. Minor edits. Updated links under Related Documents. Owner and contact updated.
04/28/2021	Transferred to current template. Updated Owner and Contact. Added definition of a UPIRTSO and other minor edits.
06/01/2018	Moved the related documents to under related procedures. Added a related document. Updated to reflect IRB submission timelines.
03/16/2018	Scheduled Review. Updated to new template, Changed IRCU name to ORRS - C., no other changes at this time due to AAHRPP Accreditation cycle.
02/18/2016	Scheduled Review: Replaced *Reporting an Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) to the IRB* with *Submitting a Reportable Event to the IRB* under "Related Documents"

Content Information Stamp

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Applicable Sites

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Arizona

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Florida

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