

# Administrative Hold Activation by the Principal Investigator (PI) Policy

## Scope

Applies to Office of Human Research Protection (OHRP) Program and research when 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 is responsible for:

1. Notifying 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. 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 (UPIRTSO) 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.

## 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 per the [Internal Compliance Review of Allegations of Suspected or Actual Noncompliance](#) procedure.

## Policy Notes

N/A

## Related Procedures

[Internal Compliance Review of Allegations of Suspected or Actual Noncompliance](#)

[Submitting a Reportable Event to the IRB](#)

## Related Documents

[Reporting Timelines for IRB Submission when Mayo Clinic is Serving as the IRB of Record](#)

## 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

[Tammy S. Neseth, M.A.](#) on behalf of Office for Human Research Protection

## Contact

## Revision History

Date	Synopsis of Change
04/28/2021	Transferred to current template. Updated Owner and Contact. Added definition of a UPIRTSO and other minor edits.
06/1/2018	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 <i>Reporting an Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO)</i> to the IRB with <i>Submitting a Reportable Event to the IRB</i> under "Related Documents"

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Workflow Approver Name(s): Tammy S. Neseth, M.A.  
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