

## **Suspension or Termination of IRB Approval of Research**

### **Content Applies To**

Mayo Clinic Human Research Protection Program

### **Policy**

The IRB has the authority to suspend or terminate IRB approval of research that is not being conducted in accordance with regulations or IRB requirements, or that has been associated with unexpected serious harm to human subjects, or where suspension or termination has been initiated by a sponsor or other outside entity.

Any suspension or termination of IRB approval of research for cause, including a statement of the reason for the IRB's action, shall be reported promptly to the investigator, the Institutional Official, and for federally-funded research, also to the Office for Human Research Protection (OHRP) and other federal agencies as appropriate.

### **Key Terms**

**Suspension for Cause:** An action initiated by the IRB to stop temporarily some or all research procedures pending future action by the IRB or by the investigator or his/her personnel. Examples of a suspension for cause might include:

- Inappropriate involvement of human subjects in research
- Violation of the rights or welfare of human subjects or others
- Serious or continuing non-compliance with Federal regulations, IRB policies or institutional policies; or
- New information regarding increased risk to human subjects or others.

**Termination for Cause:** An action initiated by the IRB to stop permanently all research procedures.

### **Investigator Responsibilities**

The investigator will:

- Cease research activities as specified in the IRB suspension notification until notified that the IRB has granted approval for resumption of the research activities, or in the case of termination, cease all research activities.
- Notify subjects of the suspension or termination as directed by the IRB.
- Report to the IRB any adverse event or unanticipated problems involving risk to subjects or others that occur while the research activities are suspended.
- Comply with all corrective action(s) as directed by the IRB.

- Consider actions to protect the rights and welfare of study subjects; for example, arranging for medical care outside of the study or transferring subjects to another study.

## **IRB Responsibilities**

The IRB will:

- Review any suspension or termination initiated by the sponsor or other outside entity.
- Notify the investigator that research activities have been suspended or terminated and provide the rationale for their action.
- Direct the investigator to undertake corrective action as appropriate. See IRB policy and procedure, "Review of Allegations of Noncompliance by an IRB Committee" for a list of possible actions.
- Direct the investigator to notify subjects of the suspension or termination as appropriate.
- Review reports of unanticipated problems involving risks to subjects or others during the time in which research is suspended for cause.
- Report any suspension for cause or termination for cause to the Institutional Official and for federally-funded research, also to regulatory agencies as appropriate. See IRB policy and procedure, "Reporting to the Institutional Official and Regulatory Agencies."
- Consider actions to protect the rights and welfare of study subjects; for example, arranging for medical care outside of the study or transferring subjects to another study.

## **Procedure**

The IRB Medical Director, IRB Administrative Committee or convened IRB:

1. The IRB Administrative Committee or the IRB Medical Director, either individually or in conjunction with a convened IRB, makes a determination that approval of a research study must be suspended or terminated.
  - Decisions to suspend or terminate approval of research/research activities are documented in the IRB electronic system.
2. Informs the investigator that IRB approval of research is suspended or terminated.

Site Administrator:

1. If the IRB Medical Director, Administrative Committee or convened IRB suspends or terminates IRB approval of research, the Site Administrator must be notified to initiate the research project's state change within the IRB electronic system.

2. The Site Administrator will:

- Modify the "Current State" of the research project in the electronic system to 'Suspended' or 'Terminated' state.
- Notify the IRB Compliance Unit (IRCU) of the suspension or termination. See IRB policy and procedure, <http://Issue Referral to the IRB Regulatory Compliance Unit>
- Generate a "Letter to PI" within the IRB electronic system notifying the investigator of the determination of the IRB.

IRB Regulatory Compliance Unit (IRCU):

1. Upon receiving notification of the IRB determination to suspend or terminate research, will review and may initiate a Regulatory Review.
2. Will document in the IRB electronic system any review IRCU performs.

**Related Documents**

[Review of Allegations of Noncompliance by an IRB Committee](#)

[Reporting to the Institutional Official and Regulatory Agencies](#)

[Issue Referral to the IRB Regulatory Compliance Unit](#)

**Approval Date**

March 1, 2016

**Revision History**

Date	Synopsis of Change
March 1, 2016	Scheduled review. Major revision.