Suspension or Termination of IRB Approval of Research

Content Applies To

Mayo Clinic Human Research Protection Program

Purpose

Suspensions of terminations represent actions by the IRB to temporarily or permanently withdraw approval for research that is not conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to participants.

Policy

The IRB has the authority to suspend or terminate IRB approval of research that is not being conducted in accordance with IRB requirements, Federal regulations, or that has been associated with unexpected serious harm to human subjects.

Any suspension or termination of IRB approval of research for cause, including a statement of the reason for the IRB's action, is 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 deemed 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:

- Report to the IRB any suspension or termination initiated by the sponsor or other outside entity.
- Cease research activities as specified in the IRB suspension notification until notified that the IRB has granted approval of the research activities to resume, or in the case of termination, the investigator will 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 designated 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 to another study.

IRB Responsibilities

The IRB will:

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

Procedure

IRB Medical Director, IRB Administrative Committee or IRB Convened Committee

1. The IRB Administrative Committee or the IRB Medical Director, either individually or in conjunction with an IRB convened committee, 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 application.
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 Committee decide to suspend or terminate IRB approval of research, the Site Administrator is contacted to initiate the research project's state change.
2. The Site Administrator will:
    - Locate the research project in the electronic system and modify the status to the 'Suspended' or 'Terminated' state,

- Create a Reportable Event in the electronic system so the IRB Regulatory Compliance Unit receives notification of the suspension or termination, and
- Generate a "Letter to PI" notifying the investigator of action(s) taken by the IRB.

IRB Regulatory Compliance Unit

1. An automated e-mail from the system is generated to notify the IRB Regulatory Compliance Unit staff when a reportable event form is submitted to the IRB.
2. The IRB Regulatory Compliance Unit, upon receiving a reportable event reflecting the IRB determination to suspend or terminate research may initiate an internal compliance review of the reportable event submission.
3. The IRB Regulatory Compliance Unit will document in the electronic system any review which it performs.

Related Documents

Review of Allegations of Noncompliance by an IRB Committee

Reporting to the Institutional Official and Regulatory Agencies