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Suspension or Termination of Institutional Review Board (IRB) Approval of Research Policy

Scope

Applies to personnel at the Mayo Clinic Human Research Protection Program and the IRB when suspending or terminating the IRB approval of Research.

Purpose

To detail the expectations of the IRB when the IRB approved research warrants suspension or termination of research.

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, to the Office for Human Research Protection (OHRP) and other federal agencies as appropriate.

Policy Notes

N/A

Related Procedures

Issue Referral to Office Research Regulatory (ORRS) Compliance Team Procedure

Related Documents

Review of Allegations of Noncompliance Procedure

Reporting to the Institutional Official and Regulatory Agencies Procedure

Definitions

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 designated 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.

References

45 CFR 46

21 CFR 50

21 CFR 56

Owner

Michelle Daiss on behalf of the Institutional Review Board

Contact

Aleisha Chappell and Bill Rossini

Revision History

Date	Synopsis of Change
01/10/2024	Updated Owner and Contacts. Updated links to Related Documents.
01/11/2021	Updated Owner and Contact. Removed steps from policy to a separate procedure.
01/24/ 2018	Annual review. Moved content to the procedure template. Changed IRCU to ORRS and IRB Admin to IRB Executive. Updated a related document name.
03/01/2016	Scheduled review. Major revision.
03/02/2018	Reviewed
03/01/2016	Reviewed
06/09/2014	Reviewed
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Applicable Sites

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Arizona

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Florida

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