Verification of No Material Changes Since Previous IRB Review Procedure

Scope

Mayo Clinic Human Research Protection Program

Research for which Mayo Clinic IRB is IRB of Record

Purpose

This procedure describes the criteria the Mayo Clinic Institutional Review Board (IRB) uses to determine which projects require verification from sources other than the investigators that no changes have occurred since last review; the procedures for conducting the verification process; and the actions to be taken if the verification process reveals that the investigator has implemented changes to the research since last IRB review.

Equipment/Supplies

N/A

Background

The IRB shall follow written procedures for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review [45 CFR 46.103 (b)(4)(ii)].

Procedure

Criteria for Determining Which Projects Require Verification

The IRB may determine that it needs verification from sources other than the investigator that no material changes have occurred since the last IRB review. The verification process may be initiated at any time and due to information derived from any source, including information regarding studies recognized to be similar or related. The IRB may consider independent assessment for situations including, but not limited to:

- Upon review of complex projects involving unusual levels or types of risk to subjects;
- Protocols or investigators under review or corrective action by the IRB, such as instances in which the IRB has required a mentor to guide the investigator, an audit of study procedures, or increased frequency of Continuing Review;
- When concerns have been raised, through IRB review or from other sources, about possible material changes occurring without IRB approval;
- Other circumstances for which the IRB deems independent verification is needed.

Conducting the Verification Process

The IRB Medical Director, IRB Chair, an assigned reviewer through the IRB Chair, or a convened IRB may request that an independent agent review the relevant research documents or observe the conduct of the research and/or consent process to verify the accuracy of the information presented to the IRB and to ensure that no material

changes have been instituted without IRB approval. The individual requesting the verification shall indicate the specific reason for the request and the subject matter to be verified. Potential parties who may conduct the verification include, but are not limited to:

- IRB staff
- Office of Research Regulatory Support - Compliance
- IRB members
- An independent person hired by the IRB, and paid for by the investigator's funds
- Others as appropriate

Verification may be obtained from one or more of several potential sources, depending on the nature of the study. Potential sources of verification include, but are not limited to:

- Research records
- Literature search
- Observation of the consent process
- Data Safety Monitoring Boards
- Grant applications
- Sponsors
- Pharmacy records
- The Office of Research Regulatory Support - Compliance, as part of an Internal Compliance Review

Reporting Results of the Verification Process

The individual performing the verification will provide a written summary of the verification, which will be attached to the history log for the specific study in the IRB electronic system. Additional reporting of findings will vary based on how the verification was initiated and who conducted the verification. Findings may also be reported to:

- A convened IRB or designated Expedited Reviewer when the verification is requested during the course of reviewing a modification, continuing review report, or reportable event
- The IRB Medical Director, Chair, IRB Administrator, or Administrative Committee
- The Institutional Official

If after evaluation it is established that material changes may have been made, the IRB Medical Director, Chair, Administrator, or Administrative Committee may refer the instance to the Office of Research Regulatory Support - Compliance to follow the procedure for Internal Compliance Review of Allegations of Suspected or Actual Noncompliance or refer the report to a convened IRB to determine whether the unapproved change rises to the level of serious or continuing noncompliance. If applicable, the Medical Director, Chair, IRB Administrator, or Administrative Committee will notify the investigator and direct him/her to submit a modification via the electronic system.

Troubleshooting

N/A

Procedural Notes

N/A

Related Documents

Internal Compliance Review of Allegations of Suspected or Actual Noncompliance

Definitions

N/A

References

N/A

Owner

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Revision History

Date	Synopsis of Change
07/12/2017	Scheduled review - updated "IRB Regulatory Compliance Unit" to "Office of Research Regulatory Support - Compliance" and administrative text edit