Verification of No Material Changes Since Previous Institutional Review Board (IRB) Review Procedure

Scope

Applies to Mayo Clinic IRB staff and members when conducting verification of changes since the last review.

Purpose

To describe the criteria for identifying research projects that require verification from sources other than the investigators that no changes have occurred since last review, the verification process, and actions to be taken if the process reveals that the investigator has implemented changes to the research since last IRB review.

Equipment/Supplies

N/A

Procedure

The IRB will follow written procedures for determining which research projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review as outlined in 45 CFR 46.108 (a)(3)(ii).

Criteria for Determining Which Research 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 due to information derived from any source, including information from studies recognized to be similar or related. The IRB may consider independent assessment of situations including, but not limited to:

- Unusual levels or types of risk to subjects upon review of complex projects;
- Protocol(s) or investigator(s) under review or corrective action by an 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 about possible material changes occurring without IRB approval have been raised through IRB review or from other sources;
- Other circumstances for which the IRB deems independent verification is required.

Conducting the Verification Process

The IRB Medical Director, IRB Chair, an IRB designated Expedited Reviewer, or a convened IRB may request an independent agent review the relevant research documents or observe the conduct of the research and/or consent process, in order 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 and/or IRB members

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

Verification may be obtained from 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 conduct of the research and/or consent process
- Data Safety Monitoring Boards
- Grant applications
- Sponsors
- Pharmacy records
- The Office of Research Regulatory Support (ORRS) - Compliance, as part of an Internal Compliance Review

Reporting Results of the Verification Process

The individual(s) 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 review of a modification, continuing review report, or reportable event
- The IRB Medical Director, Chair, IRB Administrator, or Executive Committee
- The Institutional Official

If after evaluation it is established that material changes may have been made, the IRB Medical Director, Chair, Administrator, or Executive Committee may refer the instance to the ORRS - 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(s) rises to the level of serious or continuing noncompliance. If applicable, the Medical Director, Chair, IRB Administrator, or Executive Committee will notify the investigator and direct him/her to submit a modification via the IRB electronic system.

Troubleshooting

N/A

Procedural Notes

N/A

Related Documents

N/A

Definitions

N/A

References

N/A

Owner

Michelle K. Daiss on behalf of Office for Human Research Protection

Contact

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Revision History

Date	Synopsis of Change
08/09/2022	Scheduled review. Updated Owner and Contact.
07/12/2017	Scheduled review - updated "IRB Regulatory Compliance Unit" to "Office of Research Regulatory Support - Compliance" and administrative text edit
10/14/2011	Approval for need to establish document: IRB