Management of Information among Multi-Site Research Policy

Scope

Applies to Mayo Clinic Principal Investigator (PI) and the Mayo Clinic Institutional Review Board (IRB) when the Mayo Clinic IRB is the IRB of Record and when a Mayo Clinic site is the lead/coordinating site.

Purpose

To describe the management of multi-site research study information and/or communications by the lead Mayo Clinic Principal Investigator (PI) and the Mayo Clinic IRB.

Policy

Principal Investigator Responsibilities

- The lead Mayo Clinic Principal Investigator must complete a Mayo Clinic IRB electronic application and provide the following information:
    - A list of all sites/locations participating in the research study.
    - Confirmation of contact information (names, emails, addresses) for all sites/locations participating in the research study.
    - A plan for the review of each site's IRB approval notifications/minutes and consent documents.
    - A method to assure that all sites participating in the research have the most current version of the protocol.
    - A method to assure that all sites participating in the research receive, when applicable, protocol amendments.
    - A method to assure that all sites participating in the research receive study related communications.
    - A plan for the collection and management of data from all sites/locations participating in the research.
    - A process for centralized reporting and evaluation of events and protocol deviations/violations from all sites participating in the research.
    - When the research study is federally funded, confirmation that each participating site has on file a Federalwide Assurance (FWA) with the Federal Office of Human Research Protections (OHRP).
- IRB submissions (e.g. Modifications, Continuing Review report, Reportable Events, etc.):
    - When Mayo Clinic PI's internal application is the mechanism for the initial and continuing IRB review for the external Relying Organization(s), the lead Mayo Clinic PI must compile information from all participating sites and submit information to IRB in accordance with Mayo Clinic IRB policies.

Mayo Clinic IRB Responsibilities

- As the IRB of Record, the Mayo Clinic IRB will perform initial review of each research application and all documentation relevant to the protection of human subjects. The Mayo Clinic IRB will conduct the review, including, but not limited to review of Reportable Events, Modifications to previously approved research, and Continuing Review reports.
- IRB Authorization Agreements are used to document the reliance when the Mayo Clinic IRB serves as the IRB of Record for a Relying Organization or when the Mayo Clinic IRB relies on an External IRB. The Authorization Agreements specify the roles and responsibilities of the IRB of Record and the Relying Organization.

Department of Defense (DoD) Multi-site Research

For multi-site research involving the Department of Defense (DoD), the Mayo Clinic IRB and the lead Mayo Clinic Principal Investigator will adhere to additional responsibilities and requirements as set forth by the relevant DoD component(s).

Policy Notes

N/A

Related Procedures

Relying on an External IRB

Related Documents

Greater than Minimal Risk Sample Application

Mayo Clinic Serving as the IRB of Record for a Non-Mayo Relying Organization

Submitting a Reportable Event to the IRB

Submitting a Reportable Event when Mayo Clinic IRB is not the IRB of Record

Definitions

IRB Authorization Agreement (IAA): A formal, written agreement in which the reviewing IRB agrees to serve as the IRB of record for a relying institution, including an academic institution. Agreements are generally used to cover a single research study, categories of research studies or research studies within a research program.

IRB of Record: A reviewing IRB that assumes IRB responsibilities for another organization and is designated to do so through an approved Federalwide Assurance (FWA) on file with the Office for Human Research Protections (OHRP).

- **Note:** Commercial IRBs will not have FWAs, but must be registered with OHRP.

Mayo Clinic: Mayo Clinic refers to Mayo Clinic in Arizona, Florida, and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

Relying Organization: An organization, including an academic institution, with whom Mayo Clinic has either entered into an IRB Authorization Agreement or an agreement entered into as part of a cooperative research project.

References

N/A

Owner

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Contact

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Revision History

Date	Synopsis of Change
10/05/2021	Scheduled review. Updated Owner and Contact. Minor edits.
03/23/2018	Minor revision. Updated the following definitions per Glossary review: IRB Authorization Agreement (IAA); IRB of Record; Mayo Clinic; and Relying Organization.
09/22/2017	Minor revision. Updated the following definitions per Glossary review: IRB Authorization Agreement (IAA); IRB of Record; Mayo Clinic; and Relying Organization.
03/04/ 2016	Scheduled review. Updated link for Department of defense (DoD) Addendum.
11/26/2014	Scheduled review.
12/20/2012	Approval for need to establish document: Unknown