Management of Information among Multi-Site Research Policy

Scope
Mayo Clinic Human Research Protection Program
Research for which the Mayo Clinic IRB is the IRB of Record

Purpose
This document describes the management of multi-site research study information and/or communications by the lead Mayo Clinic Principal Investigator (PI) and the Mayo Clinic Institutional Review Board (IRB), when the Mayo Clinic IRB is serving as the IRB of Record.

Policy

Principal Investigator Responsibilities
1. The lead Mayo Clinic Principal Investigator is responsible for completing a Mayo Clinic IRB electronic application and providing the following information:
   - A list of all sites/locations participating in the research study.
   - Confirmation of contact information (names, e-mails, 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).

2. IRB submissions (e.g. modifications, continuing review report, reportable events, etc.):
   - If the 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 is responsible for receiving reports from all participating sites and submitting information to IRB in accordance with Mayo Clinic IRB policies.
   - If an external reference application is the mechanism for the initial and continuing Mayo Clinic IRB review for the external Relying Organization,
the PI for the external reference application is responsible for submitting information to the 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 IRB 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 as set forth in the "Department of Defense (DoD) Addendum". The DoD Addendum is a formal agreement between the Mayo Clinic IRB and DoD organizations specifying requirements, roles, and responsibilities.

**Policy Notes**

N/A

**Related Procedures**

- [Mayo Clinic Serving as the IRB of Record for a Non-Mayo Relying Organization](#)
- [Relying on an External IRB](#)
- [Submitting a Reportable Event to the IRB](#)
- [Submitting a Reportable Event when Mayo Clinic IRB is not the IRB of Record](#)
- [Department of Defense (DoD) Addendum](#)

**Related Documents**

- [Greater than Minimal Risk Application](#)

**Definitions**

**External Reference Application**: A Mayo Clinic IRB application submitted by an external researcher from a Relying Organization for which the Mayo Clinic IRB is the IRB of Record. The external researcher is engaged in collaborative research with a lead Mayo Clinic PI who has a Mayo Clinic internal application. Select application materials will be referenced from the Mayo Clinic PI's internal application.

**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 Federal-wide 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.

**Regular Internal Application:** The standard Mayo Clinic IRB application available to Mayo Clinic research personnel.

**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. Policy

When serving as the IRB of Record, the Mayo Clinic IRB is responsible for the review and tracking of information (including but not limited to reportable events, modifications to previously approved research, and continuing review reports) for approved multi-site research studies involving human subjects. The Mayo Clinic lead Principal Investigator serves as an agent of Mayo Clinic and is responsible for the receipt and dissemination of all multi-site research study information.

**Owner**
Pamela Kwon on behalf of Office for Human Research Protection

**Contact**
Michelle Daiss

**Revision History**

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<thead>
<tr>
<th>Date</th>
<th>Synopsis of Change</th>
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<tr>
<td>March 23, 2018</td>
<td>Updated to new Policy template, no other changes at this time due to AAHRPP Accreditation cycle.</td>
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<tr>
<td>September 22, 2017</td>
<td>Minor revision. Updated the following definitions per Glossary review: IRB Authorization Agreement (IAA); IRB of Record; Mayo Clinic; and Relying Organization.</td>
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<tr>
<td>March 4, 2016</td>
<td>Scheduled review. Updated link for Department of defense (DoD) Addendum.</td>
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