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

Scope

This document applies to the Mayo Clinic IRB and Mayo Clinic investigator(s) when Mayo Clinic is serving as the IRB of Record for a non-Mayo organization.

Purpose

To summarize the responsibilities of Mayo Clinic as the IRB of Record, and the responsibilities of Relying Organizations and its agents.

Policy

- When the Mayo Clinic IRB serves as the IRB of Record for a Relying Organization, it accepts the responsibility for the oversight of the protection of the rights, privacy and welfare of the human subjects.
- The method by which the Mayo Clinic IRB will serve as the IRB of Record for a Relying Organization not otherwise affiliated with Mayo Clinic or not covered by Mayo Clinic's Federalwide Assurance is an *IRB authorization agreement*.
- An IRB Authorization Agreement may be made for a single research study or multiple different studies with a Relying Organization.
- Employees and agents of a Relying Organization will not be added to the Mayo Clinic IRB application as *Mayo Clinic study team members, without a Mayo Clinic appointment (as applicable)*. These individuals are not considered agents of Mayo Clinic and are not covered under Mayo Clinic's Federalwide Assurance.
- If a Relying Organization receives a grant and then contracts out all human research to investigators at Mayo Clinic, the Mayo Clinic IRB may agree to serve as the IRB of Record for the research project(s).
- Students fulfilling degree requirements from an academic institution are considered agents of the academic institution and, thus, the academic institution is engaged in the research regardless of where the research takes place.
- Students engaged in research at Mayo Clinic are required to have an appointment at Mayo Clinic.
- The Mayo Clinic IRB may not serve as the IRB of record for Department of Defense (DoD), Veterans Administration (VA), military, or international research sites.

Related Procedure(s)

N/A

Related Document(s)

Request to Rely on Mayo Clinic IRB Form (IRB 10483)

Authorization Agreement - Mayo is IRB of Record (IRB 10446 - For IRB Use Only)

IRB Record and Retention

Definitions

Agent: For purposes of this document, an institution's employees or agents refers to individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. "Employees and agents" can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

Assured Institution: An institution with a Federalwide Assurance (FWA) filed with the Federal Office for Human Research Protections (OHRP). Employees and agents of the institution holding an approved FWA are covered whenever they are involved in the conduct of the research covered by the FWA. Employees and agents are individuals performing institutionally designated activities and acting on behalf of the institution or exercising institutional authority or responsibility.

Coordinating Center: A coordinating center is an entity that agrees to be responsible for the conduct, administrative and /or coordinating functions of a multi-center research project.

- The term *Coordinating Center* differs from the term *IRB of Record* in that a coordinating center is responsible for assuring that IRB approval is obtained for each participating site whether by individual institutional IRB approval or via an IRB of Record process.
- It is important to note that even when a Mayo Clinic investigator serves in the *Coordinating Center* capacity for a multicenter research project, the Mayo Clinic IRB is not necessarily the *IRB of Record*, *unless it has agreed to do so with an external site via an executed IRB authorization agreement.*

Engagement of Institutions in Human Subject Research: An Organization is considered engaged in human research when its employees, students, or agents, for the purposes of a non-exempt research project, obtain:

- Data about the subjects of the research through intervention or interaction with them;
- Identifiable private information about the subjects of the research;
- The informed consent of human subjects for the research; or
- The institution receives a direct federal award to conduct human subject research, even when all activities involving human subjects are carried out by a subcontractor (i.e. employees, students, or agents of another institution).

Federalwide Assurance (FWA): A formal, written, and binding attestation in which an institution assures to Department of Health and Human Services (DHHS) that it will comply with applicable regulations governing research with human subjects.

Institutional Official: The Institutional Official (IO) is the signatory on the FWA filed with OHRP to assure compliance with regulations governing protection of human subjects. OHRP requires the Institutional Official to be a high-level official who has the authority to represent the institution named in the FWA.

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

IRB Authorization Agreement (IAA): A formal, written, agreement in which the reviewing IRB agrees to serve as the IRB of Record for a Relying Organization, 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 Federal Office of Human Research Protections (OHRP).

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.

Procedure Statements

1. The Relying Organization which is engaged in the research must have a Federalwide Assurance (FWA) with the Federal Office for Human Research Protections (OHRP). The Federalwide Assurance (FWA) is the only type of assurance currently accepted and approved by OHRP. Through the FWA, an institution commits to HHS that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR Part 46.
    a. Mayo Clinic and the Relying Organization must each maintain a separate, active FWA with the Federal Office for Human Research Protections (OHRP).
    b. The Relying Organization is responsible for meeting the terms and conditions of their FWA.
2. An *IRB Authorization Agreement* must be executed between the Mayo Clinic IRB and the Relying Organization:
    a. An IRB Authorization Agreement documents the agreement and signatures of the Signatory Officials from the Relying Organization and the Mayo Clinic Institutional Official.
    b. The roles and responsibilities of the reviewing IRB and the Relying Organization are outlined in the IRB Authorization Agreement.
    c. Copies of the signed IRB Authorization Agreement must be kept on file at both organizations and made available upon request to the Federal Office for Human Research Protections (OHRP) or any agency supporting research to which the FWA applies.

Mayo Clinic Principal Investigator Responsibilities

1. To request Mayo Clinic IRBs to serve as the IRB of Record for a Relying Organization, the Principal Investigator or their designee will complete the Request to Rely on Mayo Clinic IRB Form (IRB10483), located on the IRB *Forms & Templates* webpage.
2. The Principal Investigator or their designee will send the completed form and associated attachments to the IRB Operations Manager or designee.
3. The IRB Operations Manager, or designee, forwards the request, associated documents, the link to the IRB application, and if available, the link to the Relying Organization's web site, to the IRB Administrator for evaluation and final approval.

IRB Administrator Responsibilities

Mayo Clinic IRB leadership or their designee(s) will evaluate the request for Mayo Clinic to serve as the reviewing IRB for a Relying Organization and either approve or not approve of the research affiliation or reliance to serve as the IRB of Record.

If the IRB of Record request is approved, the IRB Operations Manager or designee:

1. Initiates the *IRB Authorization Agreement (IRB10446).* The template is located on the IRB staff webpage.
2. Obtains signatures from the Institutional Officials at Mayo Clinic and the Relying Organization.
3. Emails a signed copy of the IRB authorization agreement to the Institutional Official or Human Protections Administrator (or their designee) named on the Relying Organization's FWA.
4. Emails a signed copy of the authorization agreement to the Principal Investigator named on the Mayo Clinic IRB application.
5. Instructs the Principal Investigator to complete the *Study Locations* section of the IRBe application and upload the IRB Authorization Agreement.
    - Note: In some research projects that have previously been approved by the IRB, the Principal Investigator may need to submit a modification to complete the *Study Locations* section and to upload the *IRB Authorization Agreement*.
6. The IRB Operations Manager or designee will email IRB operations, leadership staff, and the IRB Systems Team that an Authorization Agreement has been executed with the Relying Organization.
7. Once an Authorization Agreement has been obtained, the IRB Operations Manager or their designee will provide the MIRIS IT Team with the Relying Organization's contact information (name and e-mail address). This information is uploaded in the IRB electronic system so that the Relying Organization's contact/s receives IRB notifications.

8. The following text is used (or modified) in the IRB minute or notification to document acceptance of Mayo Clinic IRB serving as the IRB of Record for a Relying Organization:

    The Committee accepts the appointment of the Mayo Clinic IRB as the IRB of Record for the Relying Organization (name of organization), and notes receipt of the fully executed IRB Authorization Agreement.

If the IRB of Record request is not approved:

The IRB Operations Manager (or designee) will inform the Principal Investigator or student (when applicable) of the determination not to approve the affiliation or reliance and the reason/s why.

Record Keeping:

1. IRB authorization agreements must be kept in the Researcher's IRBe file and available to OHRP, FDA, or assessors upon request.
2. The IRB maintains a copy of the Authorization Agreement on the IRB webpage: (http://intranet.mayo.edu/charlie/irb/home/authorization-agreements/).
3. Authorization Agreements are retained per IRB Record and Retention policy.
4. Upon study closure or study termination, by either the Principal Investigator, Mayo Clinic IRB, or Relying Organization, the authorization agreement will be considered inactive and the document will be archived.

Termination of IRB Authorization Agreements:

1. The authorization agreement becomes effective on the last date signed by the Institutional Signatory Official.
2. The authorization agreement shall continue for the duration of and until the cessation of the Principal Investigator's or the Relying Organization's participation in the research study.
3. Either the Institution's IRB or the Relying Organization may terminate the agreement in the event that any party's FWA is suspended, terminated, or expires.

References

OHRP Guidance on Engagement of Institutions in Human Subject Research

DHSS Assurance Process - FAQs

DHSS IRBs and Assurances

Approved by

Pamela Kwon on behalf of the Office for Human Research Protections 9/6/2016

Owner

Pamela Kwon on behalf of the Office for Human Research Protections

Contact

Roberta Drury

Revision History

Date	Synopsis of Change
September 6 , 2016	Scheduled review. 1) Moved content into new policy template. 2) Clarification of student affiliation; 3) Requirements to be affiliated with Mayo; 4) Removing student affiliation information from definition of "Agent"; and 5) Other editorial changes; 6) Added that “The Mayo Clinic IRB does not serve as the IRB of record for Department of Defense (DoD), Veterans Administration (VA), military, or international research sites”.