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.
- For a multi-site study, the Mayo Clinic IRB will limit the number of relying organizations to no more than twelve sites, including conduct of the study at Mayo Clinic. Exceptions to this limit may be considered on a case-by-case basis, at the discretion of the Mayo Clinic IRB.
- 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 international research sites or research site located on a tribal reservation.

Effective January 20, 2020, Single IRB Mandate for Cooperative Research:

Per 45 CFR Part 46.114 (b)(1) Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States.

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

Prior to approval of the reliance:

1. To request Mayo Clinic IRB 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 reliance staff at the IRB Reliance inbox (IRBReliance@mayo.edu).

After the approval of the reliance:

1. The Mayo Clinic Principal Investigator is responsible for providing the Mayo Clinic IRB with information concerning the Relying Organization and the Relying Organization's site-specific documents (consent/HIPAA form(s), subject contact material(s), etc., if applicable) at the time of original submission within IRBe requesting approval of the addition of the Relying Organization.
2. The Mayo Clinic Principal Investigator is responsible for communicating determinations with and ensuring that study-related information from the Mayo Clinic IRB is received by the Relying Organization.
3. The Mayo Clinic Principal Investigator is responsible for providing the Mayo Clinic IRB with information concerning study status for the Relying Organization at the time

of continuing review in accordance with Mayo Clinic IRB's Continuing Review of Research Projects policy.

4. The Mayo Clinic Principal Investigator is responsible for submitting to the Mayo Clinic IRB modifications to the study on behalf of the Relying Organization.
5. The Mayo Clinic Principal Investigator is responsible for submitting events that occur at the Relying Organization that meet the definition of a Reportable Event to the Mayo Clinic IRB in accordance with Mayo Clinic IRB's Submitting a Reportable Event to the IRB Policy.

IRB Reliance Staff 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 reliance staff:

1. Proposes the type of reliance agreement to be used to the Relying Organization. Examples of types of reliance agreements are an IRB Master Authorization Agreement, including the Smart IRB Master Common Reciprocal IRB Authorization Agreement or a single study agreement.
2. Documents the use of an IRB Master Authorization Agreement (through a Determination Letter, Exhibit, Acknowledgement Letter, etc…) or obtains signatures from the Institutional Officials at Mayo Clinic and the Relying Organization for a single-study IRB Authorization Agreement, if applicable.
3. Emails a signed copy of the IRB Authorization Agreement or documentation of the use of an IRB Master Authorization Agreement to the Principal Investigator named on the Mayo Clinic IRB application. This email will:
    a. Include the IRB operations, leadership staff, and the MIRIS IT Team (cc'd)
    b. Provide the Relying Organization's Principal Investigator's name and email address and an alternative contact's name and email address. This allows the Relying Organization's PI and contact to receive IRB notifications from IRBe.
4. Instructs the Principal Investigator to complete the Study Locations section of the IRBe application and upload the IRB Authorization Agreement or documentation of the use of an IRB Master 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 or documentation of the use of an IRB Master Authorization Agreement.
5. 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/Reviewer 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 IRB Authorization Agreement on the IRB webpage: (http://intranet.mayo.edu/charlie/irb/home/authorization-agreements/).
3. IRB Authorization Agreements are retained per IRB Record and Retention policy.
4. Upon study closure or study termination, by the Principal Investigator, Mayo Clinic IRB, or Relying Organization, the IRB Authorization Agreement will be considered inactive and the document will be archived.

Termination of IRB Authorization Agreements:

1. The IRB Authorization Agreement becomes effective on the last signature on the agreement or when the documentation of reliance (through a Determination Letter, Exhibit, Acknowledgement Letter, etc…) is completed.
2. The IRB 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.

Policy Notes

N/A

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

Submitting a Reportable Event to the IRB Policy

Continuing Review of Research Projects

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. A student's affiliation with an academic institution makes him or her an agent of that institution; and thus the

academic institution is engaged in the research regardless of where the research takes place.

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: An institution, department or center that agrees to be responsible for the conduct and administrative or coordinating functions of a multicenter research project.

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

1. Data about the subjects of the research through intervention or interaction with them;
2. Identifiable private information about the subjects of the research;
3. The informed consent of human subjects for the research; or
4. When 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 (that is, employees or agents of another institution). See OHRP Guidance on Engagement of Institutions in Human Subjects Research.

Federalwide Assurance (FWA): A formal, written, binding attestation in which an institution ensures to the 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) who is the signatory on the Federalwide Assurance (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.

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.

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

OHRP Guidance on Engagement of Institutions in Human Subject Research

DHSS Assurance Process - FAQs

DHSS IRBs and Assurances

Owner

Tammy Neseth on behalf of the Office for Human Research Protections

Contact

Jackie Sheeran, Ellen Olson

Revision History

Date	Synopsis of Change
January 28, 2019	Added information about January 20, 2020 Single IRB Mandate for Cooperative Research. Changed Owner to T. Neseth.
July 31, 2018	Clarified that Mayo Clinic will not serve as the IRB of Record for a research site located on a tribal reservation. Clarified the Mayo Clinic Principal Investigator's responsibilities when Mayo Clinic is serving as the IRB of Record for a Relying Organization. Administrative and editorial changes.
January 31, 2018	Removed “for Department of Defense (DoD), Veterans Administration (VA), military”
September 29, 2017	Added that the Mayo Clinic IRB will not serve as the IRB of record for more than 12 organizations in a single study (including Mayo Clinic). Exceptions at the discretion of the Mayo IRB.
September 6, 2017	Minor revision. Updated the following definitions per Glossary review: Coordinating Center, Engagement of Institutions in Human Subject Research, Federalwide Assurance (FWA), Institutional Official, IRB Authorization Agreement (IAA), IRB of Record, and Mayo Clinic.
March 14, 2017	Updated definition for Agent as a minor revision.
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”.