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Mayo Clinic Institutional Review Board (IRB) as the Reviewing IRB for an External Relying Organization Policy

Scope

Applies to the Mayo Clinic IRB and Mayo Clinic investigator(s) when Mayo Clinic is serving as the Reviewing IRB for an external Relying Organization.

Purpose

To describe how the Mayo Clinic IRB may serve as the Reviewing IRB for a Relying Organization not otherwise affiliated with Mayo Clinic or not covered by Mayo Clinic's Federalwide Assurance (FWA).

Policy

- Mayo Clinic IRB may serve as the Reviewing IRB for a Relying Organization not otherwise affiliated with Mayo Clinic or not covered by Mayo Clinic's FWA when a Mayo Clinic Principal Investigator (PI) is engaged in a multi-site, non-exempt human subjects research study. Pre-arrangement and approval by the Mayo Clinic IRB Reliance team (IRBReliance@mayo.edu) is required.
- When the Mayo Clinic IRB agrees to serve as the Reviewing IRB for a Relying Organization:
    - The Mayo Clinic IRB accepts responsibility for initial and ongoing IRB review of human subjects research. Other oversight of the protection of the rights, privacy, and welfare of the human subjects may be distributed between the Reviewing IRB and the Relying Organization and will be documented in an IRB Authorization Agreement.
    - The Mayo Clinic PI and Study Team accepts additional responsibilities, including but not limited to:
        - Informing all Relying Organization study teams about the single IRB reliance arrangement as well as the review processes, policies, and reporting requirements of the Mayo Clinic IRB.
        - Coordinating communications and submissions to the Mayo Clinic IRB (the Reviewing IRB) on behalf of all Relying Organizations.
        - Ongoing communication with all Relying Organization study teams regarding the conduct and status of the study and, as applicable, new information and/or problems that may affect the conduct of the study or the rights and welfare of research participants, such as unanticipated problems and serious noncompliance.
        - Accountability for the adequacy of resources (personnel, processes, systems, etc.) to uphold the responsibilities.
- 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 FWA.
- If a Relying Organization receives a grant and then contracts out human research to investigators at Mayo Clinic, the Mayo Clinic IRB may agree to serve as the Reviewing IRB for the research project(s).
- Mayo Clinic employees conducting research to fulfill 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 a qualifying 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.
- For multi-site studies subject to the NIH single IRB review policy, should the NIH grant an exception from single IRB review, the rationale for not relying upon a single IRB review will be documented for that study within the IRB electronic system (IRBe). In the case when a select participating organization is granted an exception from the requirement for single IRB review, it is necessary for that participating organization to obtain its own IRB review/determination. An IRB Authorization Agreement (IAA) would not be executed with this organization.
- The Mayo Clinic IRB may serve as the Reviewing IRB for Department of Defense (DoD)-conducted and/or -supported research. If the Mayo Clinic IRB (a non-DoD IRB) agrees to serve as the Reviewing IRB for a DoD Relying Organization, the following conditions must be met:
    - Each organization engaged in non-exempt human participant research must have a current Federalwide Assurance (FWA).
    - The non-DoD Reviewing IRB must be registered in accordance with Subpart E of 45 CFR 46.
    - The DoD Relying Organization reviews the protocol to ensure all applicable local and DoD requirements are addressed in the protocol.
    - The DoD Relying Organization and non-DoD Reviewing IRB must have a written agreement defining the responsibilities and authorities of each organization in complying with all legal requirements. This agreement must specify that the non-DoD Reviewing IRB will apply the DoD requirements specified in DoD Instruction (DoDI) 3216.02, including but not limited to non-DoD organizational responsibilities defined under DoDI 3216.02 section 3.6(b).
    - If the research constitutes classified human participant research, the applicable DoD Component Office of Human Research Protections (COHRP) must approve the agreement to rely on the non-DoD Reviewing IRB.

- The Relying Organization which is engaged in the research must have a FWA with the Federal Office for Human Research Protections (OHRP). The FWA is the only type of assurance currently accepted and approved by OHRP. Through the FWA, an institution commits to the Department of Health and Human Services (HHS) that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR Part 46.
    - Mayo Clinic and the Relying Organization must each maintain a separate, active FWA with the Federal Office for Human Research Protections (OHRP).
    - The Relying Organization is responsible for meeting the terms and conditions of their FWA.
- The method by which the Mayo Clinic IRB documents its agreement to serve as the Reviewing IRB is an IRB Authorization Agreement (IAA), also known as a reliance agreement.
    - An IAA may be made for a single research study or multiple different studies conducted by the Relying Organization.
    - An IAA must be executed between the Mayo Clinic IRB and the Relying Organization.
        - These agreements may include the SMART IRB agreement. Relying Organizations are encouraged to sign the joinder to SMART IRB.
        - However, if a Relying Organization is unable or unwilling to sign the SMART IRB joinder, the Mayo Clinic IRB will utilize its IAA template to execute an agreement with the Relying Organization.
    - When serving as the Reviewing IRB for a Relying Organization, Mayo Clinic IRB will ensure that any written agreement will describe the role and responsibilities of each organization, including but not limited to:
        - Providing education to researchers and research staff.
        - Conducting scientific review.
        - Reviewing potential noncompliance, including complaints, protocol deviations, and results of audits:
            - Identifying which organization is responsible for deciding whether each allegation of noncompliance has a basis in fact.
            - Identifying which organization’s process is used to decide whether each incident of noncompliance is serious or continuing.
        - Obtaining management plans for researcher and research staff conflicts of interest. If the Relying Organization maintains responsibility for this issue, the management plan must be provided to the Reviewing IRB in the IRB application form prior to the decision by the Reviewing IRB.

        - Identifying, evaluating, managing, and minimizing or eliminating and organizational conflicts of interest related to the research, and notifying the Reviewing IRB in a timely manner prior to the decision by the Reviewing IRB.
        - Ensuring that, should termination of a reliance agreement occur, one of the parties clearly is responsible for continued oversight of active studies until closure or a mutually agreed upon transfer of the studies.
        - A description of which organization is responsible for meeting additional certification requirements, such as Certificates of Confidentiality or the NIH Genomic Data Sharing Policy.
    - The IAA becomes effective on the last signature on the agreement or when accepted alternate documentation of reliance is completed.
    - The IAA 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.
    - Upon study closure or study termination, by the Principal Investigator, Mayo Clinic IRB, or Relying Organization, the IAA will be considered inactive, and the document will be archived.
    - Either the Reviewing IRB or the Relying Organization may terminate the agreement if any party's FWA is suspended, terminated, or expires.
    - Should termination of the agreement occur, one of the parties must be designated as responsible for continued oversight of active studies until closure or a mutually agreed upon transfer of the studies.
    - Copies of the signed IAA 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.

Policy Notes

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.

Related Procedure(s)

Mayo Clinic Institutional Review Board (IRB) as the Single Reviewing IRB for an External Relying Organization - IRB Reviewer Procedure

Mayo Clinic Institutional Review Board (IRB) as the Single Reviewing IRB for an External Relying Organization - Mayo Clinic Principal Investigator and Study Team Procedure

Mayo Clinic Institutional Review Board (IRB) as the Single Reviewing IRB for an External Relying Organization - Reliance Team Procedure (TBD)

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: 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).

Guidance: Engagement 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. An IRB Authorization Agreement documents the agreement and signatures of the Signatory Officials from the Relying Organization and Reviewing IRB. The roles and responsibilities of the Reviewing IRB and the Relying Organization are outlined in the IRB Authorization Agreement.

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.

Reviewing IRB: An 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.

References

Department of Defense Instruction 3216.02 Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research

National Institutes of Health Single IRB for Multi-Site or Cooperative Research

OHRP Guidance on Engagement of Institutions in Human Subject Research

U.S. Department of Health and Human Services Register IRBs & Obtain FWAs

Owner

Michelle Daiss

Contact

Jackie Sheeran, Ellen Olson

Revision History

Date	Synopsis of Change
July 15, 2024	Revisions to address AAHRPP recommendations regarding Mayo Clinic sharing oversight with Relying Organizations: distribution of responsibilities for additional certification responsibilities (such as Certificates of Confidentiality or the NIH Genomic Data Sharing Policy), documentation of NIH-granted exceptions for single IRB review, and conditions for DoD-conducted and/or -supported research under single IRB review. Edited title. Removed procedure statements and added related procedure titles. Removed related documents. Updated Owner and Contact
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”.

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Reviewer(s):

Approver(s):

Michelle K. Daiss

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