Relying on an External IRB - Procedure

Scope

Mayo Clinic's Human Research Protection Program

Purpose

This document describes how the Mayo Clinic IRB may rely on an external IRB to serve as the IRB of Record for a Mayo Clinic site or Investigator.

Equipment/Supplies

N/A

Procedure

Mayo Clinic may rely upon the IRB of another organization provided investigators at Mayo Clinic and at the external organization are participating as investigators on a research project and the IRB of the external organization is better prepared to review the research OR Mayo Clinic researchers receive a grant (or other federal funds) and contract out all human subject research to employees or agents at an external organization OR Mayo Clinic and other participating organizations agree to rely on a commercial IRB.

When relying on an external IRB, whether it is for a single research project or a portion of the organization's research portfolio, the external IRB will meet Federal regulations for the conduct of research and IRB review. Non-commercial IRBs will have a Federalwide Assurance and will be accredited by an independent accrediting body, or will document an equivalent level of standards for protection of human subjects through satisfactory completion of the Mayo Clinic IRB Evaluation Checklist. The checklist is maintained by the Mayo Clinic IRB Reliance team at IRBRELIANCE@mayo.edu. Commercial IRBs will be registered with OHRP and will be accredited by an independent accrediting body.

When Mayo Clinic relies on an external IRB to serve as the IRB of record, the external IRB will be evaluated by the Mayo Clinic IRB to determine if it meets specific criteria for the protection of human research subjects and, if so, written agreements outlining specific responsibilities of each party are executed.

There will be a formal written authorization agreement between Mayo Clinic and the external IRB delineating the roles and responsibilities of each party.

Evaluation of Requests to Rely on an External IRB

1. The investigator seeks approval from the Mayo Clinic IRB Medical Director and IRB Administrator to use an external IRB to serve as the IRB of Record and provide justification for reliance on the external IRB.

2. The IRB Medical Director (or designated IRB staff) assesses whether an external IRB is qualified to serve as the IRB of Record for the Mayo Clinic human subject research project by verifying the following:
    - Is the organization's Human Research Protection Program accredited by an independent accrediting body, or has the organization documented an equivalent level of standards for protection of human subjects through satisfactory completion of the Mayo Clinic IRB Evaluation Checklist?
    - Does the non-commercial IRB have an active Federalwide Assurance (FWA) on file with the Federal Office for Human Research Protection?
    - Is the commercial IRB registered with OHRP?
    - Has the organization or external IRB received any recent FDA warning letters or OHRP determination letters within the last year?
    - Does the Board Membership satisfy the requirements of 45 CFR 46.107 and 21 CFR 56.107?
    - Does the external IRB have a process in place to notify the Mayo Clinic IRB and researcher(s) of its approvals, determinations, reportable events, suspensions, and terminations?
    - In the opinion of Mayo Clinic IRB leadership, can the external IRB fulfill its responsibilities as outlined in the written authorization agreement?
3. If it is determined that the external IRB is qualified to serve as the IRB of Record, a written authorization agreement is initiated, either by the external IRB or the Mayo Clinic, which documents the agreement of both parties. The written authorization agreement must outline the responsibilities of the external IRB and the Mayo Clinic IRB and the researcher/s. The authorization agreement is kept in Mayo Clinic IRB administrative files and will be made available upon request
4. The following information from the external organization is provided to the Mayo Clinic IRB Administrator or their designee:
    - A copy of the non-commercial IRB's Federalwide Assurance (FWA)
    - The commercial IRB's Institution/organization (IORG) number
    - The contact information for the external IRB's Institutional Official (name, address, telephone number, e-mail address)
    - The contact information for the external IRB's Administrator and/or designated point of contact (name, address, telephone number, e-mail address)

Mayo Clinic Investigator Responsibilities

The Mayo Clinic researcher has the responsibility to:

- Comply with the external IRB's requirements and directives per the Authorization Agreement.
- Must not enroll individuals in research prior to review and approval by the external IRB.

- Document the reliance arrangement and the research study in the Mayo Clinic IRB electronic system (see related section "Documenting the Reliance on an External IRB of Record, below).
- Ensure the safe and appropriate performance of the research. This includes, but is not limited to ensuring the qualifications of research staff; monitoring protocol compliance; maintaining compliance with state, local or organizational requirements related to the protection of human subjects; providing a mechanism to receive and address concerns from local study subjects and others about the conduct of the research; and investigating, managing, and providing notification to the external IRB of any study-specific incidence, experience, or outcome that rises to the level of an unanticipated problem and/or serious or continuing non-compliance.
- Provide the external IRB with any local context issues relevant to the research protocol.
- Disclose financial conflicts of interest according to the agreed upon process and comply with any conflict management plans that may result.
- Promptly report to the external IRB any proposed changes in the research. The investigator must not initiate changes in the research (including changes in the consent document) without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.
- When responsible for enrolling subjects, will obtain, document, and maintain records of consent for each subject or subject's legally authorized representative as stipulated by the external IRB. The investigator will utilize the Mayo Clinic consent, assent, and/or HIPAA templates, as appropriate.
- Will provide to the external IRB any data and safety monitoring reports they receive, either at continuing review, upon request by the reviewing IRB, or on an emergent basis, if appropriate.
- Provide updates to the external IRB whenever a principal investigator is no longer the responsible party for a research project under the purview of the external IRB.
- Provide the contact person and contact information for the Mayo Clinic IRB [i.e. IRB Administrator] to the external IRB.

External IRB Responsibilities

The responsibilities include, but are not limited to:

- Conduct review of research according to all applicable regulations and laws, including initial review, continuing review, and review of modifications to previously approved research.
- Conduct review of potential unanticipated problems, adverse events, and/or serious or continuing non-compliance.
- Provide notification to researcher staff and relying organization in writing of its determinations and decisions.
- Make available relevant IRB minutes, IRB membership rosters, and standard operating procedures to the relying organization upon request.

- When appropriate, conduct on-site or remote post-approval monitoring or audits, unless delegated to the relying organization.
- Maintain an IRB membership that satisfies the requirements of 45 CFR 46.107 and 21 CFR 56.107 and which provides special expertise as needed to adequately assess all aspects of each study.
- Promptly notify the Mayo Clinic Institutional Official and the IRB if there is a suspension or termination of the external IRB's authorization to review a study.
- Provide the Mayo Clinic IRB, the contact person and contact information for the reviewing IRB.
- Maintain appropriate documentation per record retention policies, including an OHRP-approved Federalwide Assurance (non-commercial IRBs) for human subjects research.

Documenting the Reliance on an External IRB of Record

When an External IRB serves as the IRB of Record for Mayo Clinic, the Mayo Clinic investigator (or designee) is responsible to:

1. Complete a "Request to Rely on an External IRB" application in the IRB electronic system to document the External IRB reliance arrangement and the research study for institutional oversight purposes.
2. Upload supporting documentation and correspondence in the Mayo Clinic IRB electronic system using the "Record External IRB Information" activity. This is an ongoing responsibility during conduct of the study.
3. Supporting documentation and correspondence includes:
    - Authorization agreement between Mayo Clinic IRB and the External IRB of Record
    - Current External IRB-approved research study protocol
    - External IRB approval notifications and/or IRB minutes related to the study
    - Consent form approved by the External IRB of Record for use by the Mayo Clinic investigator. The investigator will utilize the Mayo Clinic consent, assent, and/or HIPAA templates, as appropriate.
    - Communications received from the External IRB of Record
    - Correspondence from the External IRB of Record such as records of continuing reviews, protocol modifications, approval notifications/minutes, reportable events

Troubleshooting

N/A

Procedural Notes

N/A

Related Document(s)

External IRB Qualification Form IRB 10443 (For IRB internal use only - to document the qualifications)

IRB Authorization Agreement Template IRB 10444 (For IRB use only - to document the reliance)

Authorization Agreements - External

Definitions

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 Protection (OHRP). Note: Commercial IRBs will not have FWAs, but must be registered with OHRP.

IRB Authorization Agreement: A formal, written agreement in which the reviewing IRB agrees to serve as the IRB of Record for a Relying Organization.

Relying Organization: A relying organization has entered into an IRB Authorization Agreement with another organization's IRB.

Engagement of Organizations in Non-Exempt Human Subject Research: An organization is considered engaged in human research when its employees or agents, for the purposes of the 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) informed consent of human subjects for the research; OR 4) a direct federal award to conduct human subject research, even when all activities involving human subjects are carried out by subcontractors (i.e. employees or agents of another organization).

HHS Guidance: Engagement in Human Subjects Research

References

Association for the Accreditation of Human Research Protection Programs (AAHRPP) version 1/2012

45 CFR Part 46 - Basic HHS Policy for Protection of Human Research Subjects

21 CFR Part 56 - Organizational Review Boards

Approved by

Pamela Kwon on behalf of the Office for Human Research Protections 02/01/2017

Owner

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Contact

Mayo Clinic IRB Reliance team at IRBRELIANCE@mayo.edu.

Revision History

Date	Synopsis of Change
3/1/2017	Revisions allow the Mayo Clinic IRB to consider reliance on an external, non-accredited IRB. Updating of description of IRB electronic system activities.