

sIRB Principal Investigator Responsibilities

I. Purpose

This Policy describes the responsibilities of Principal Investigators (“PIs”) when engaged in multi-site human research under Single IRB (“sIRB”) review.

II. Scope

This Policy applies to all PIs at Albert Einstein College of Medicine (“Einstein”) or Montefiore Medical Center (“MMC”) who engage in multi-site human research under sIRB review.

III. Definitions

Principal Investigator (PI): The individual at each institution who is personally responsible for the overall conduct of a specified human research study or clinical investigation at that institution.

Lead Principal Investigator (Lead PI): the overall Principal Investigator who acts as a liaison between local PIs and the reviewing IRB.

Local Principal Investigator (Local PI): the Principal Investigator at the relying site.

Relying Site (RS): The site that relies on another organization’s IRB for review of human research.

Reviewing IRB: The IRB that assumes IRB responsibilities for another organization. When multiple institutions conduct the same study and one IRB will conduct the review for all study sites, the reviewing IRB may be called a Single or Central IRB (collectively, “sIRB”).

IV. Policy

Lead PI for a Multi-Site Study under sIRB Review by the Einstein IRB

The responsibilities of the lead PI for a multi-site study under sIRB review by the Einstein IRB depend on the terms of the reliance agreement. In general, the below responsibilities apply, in addition to those of a PI for a local, single-site study¹:

¹ See the policy, “Principal Investigator Responsibilities.”

- Consult with the Office of Human Research Affairs (OHRA) to determine whether the Einstein IRB can act as the sIRB for all or some institutions participating in the study or whether an external IRB would be appropriate;
- Identify all sites that will be engaged in human research and thus need IRB coverage;
- Work in collaboration with the OHRA to determine and document specific roles and responsibilities for communicating and coordinating key information to relying sites. This includes developing a plan for communicating with collaborators across the lifetime of the study (i.e., regular conference calls, site initiation procedures, and training materials). In addition, the PI will designate a study liaison from their study team, the contact person responsible for funneling information/documents from the lead study site to the relying sites and vice versa;
- Respond promptly to questions or requests for information from study teams and IRB/Human Research Protection Program personnel at institutions who are relying on the Einstein IRB;
- Provide relying site investigators with the policies of the Einstein IRB; this includes, but is not limited to, policies for reporting unanticipated problems, noncompliance, and subject complaints;
- Prepare and submit the Einstein IRB application on behalf of all sites. This includes initial review, modifications, personnel updates, local reportable events, and study-wide information for continuing review;
- Provide relying site investigators with the Einstein IRB-approved versions of all study documents;
- Establish a process for obtaining and collating information from all sites regarding local variations in study conduct, such as recruitment materials and process, consent process and language, and subject identification process;
- Assist relying study teams in ensuring consent documents follow the Einstein IRB's template form and include applicable site-specific required language from each relying site;
- Notify relying site investigators of all Einstein IRB determinations and communications, including those for initial review, continuing review, amendments, and reportable events;
- When agreed upon in coordination with the Einstein IRB, promptly report to the relying site investigators any unanticipated problems involving risks to subjects or others or significant subject complaints that are related to or may affect subjects participating in the research at the relying site;
- Report the absence of continuing review information from relying sites if they do not provide the required information before submission of the continuing review materials to the Einstein IRB, and notify the relying site of their lapse in approval and any applicable corrective action plans;
- Provide access, upon request, to study records for audit by the Einstein IRB, relying site, and other regulatory or monitoring entities;
- Follow all requirements of the relying site with regard to the ceded review, such as ensuring administrative requirements for documenting ceded review have been met before study activation occurs at a relying site.
- Follow all requirements of the relying site with regard to processing amendments, such as whether their local clearance is required for an amendment to be considered "active" at their site and whether any local ancillary reviews are required. The relying PI is tasked to inform the lead PI of these requirements.
- The PI is responsible for research integrity, budget compliance, and accuracy of personnel for the completed work.

Local PI for a Multi-Site Study under sIRB Review by an External IRB

The responsibilities of a local PI when relying on an external IRB depend on the terms of the reliance agreement provided to the PI upon its execution. In general, the below apply:

- Submit a reliance request to the OHRA to determine if Einstein/MMC may rely on an external IRB for the research;
- Obtain local institutional approval (after reviewing IRB approval) before initiating research activities;
- It is the PI's responsibility to ensure that all applicable institutional requirements (such as coverage analysis, PRMC, contract review, etc.) are completed before the proposed research activity starts.
- Maintain appropriate copies of all approvals and other correspondence documenting the review and approval of the research as required by the regulations;
- Report proposed changes to the research to the reviewing IRB and the Einstein IRB as described in the "sIRB Reliance Procedure."
- Report unanticipated problems and other reportable events to the reviewing IRB and the OHRA in accordance with the reportable events requirements of both the reviewing IRB and the OHRA;
- Submit progress reports to the OHRA within 30 days of re-approval by the reviewing IRB;
- Submit study closure to the OHRA once the reviewing IRB has provided the study closure letter.
- The PI is responsible for research integrity, budget compliance, and accuracy of personnel for the completed work.

V. Effective Date

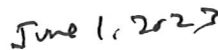
Effective as of: June 1, 2023

VI. Policy Management and Responsibilities

Einstein's Office of Human Research Affairs is the Responsible Office under this Policy. Einstein's Executive Dean is the Responsible Executive for this Policy. Einstein's OHRA Director is the Responsible Officer for the management of this Policy.

VII. Approved (or Revised)

Responsible Executive



Date