Albert Einstein College of Medicine

sIRB Reliance Procedure

I. Purpose

This Procedure establishes the reliance processes for when Albert Einstein College of Medicine ("Einstein") or Montefiore Medical Center ("MMC") relies on the Institutional Review Board ("IRB") of another institution as well as when another site cedes responsibility to the Einstein IRB.

II. Scope

This Procedure applies to federally-funded multi-site human research that requires Single IRB review, or any other research that proposes the use of a Single IRB.[1] Non-federally funded multi-site human research studies will follow this procedure as well; however, the institution's acceptance of these types of reliance may be more limited, may be subject to an additional single IRB pass-through administrative fee, and will be accepted on a case-by-case basis.

III. Definitions

Reliance Agreement: An arrangement between institutions allowing one institution to rely on the IRB of another institution for review of human subjects research.

Institutional Official: The individual who is legally authorized to act for the institution and, on behalf of the institution, approves the Reliance Agreement.

Local Context Review: An abbreviated review by the relying institution that provides the reviewing IRB with the following:

1. Local Research Context: knowledge of the institution and community environment where human subjects research will be conducted (e.g., subject injury policy, state-specific laws, mandatory reporting of diseases, abuse, etc.).
2. Local Context Language: Language specific to the conduct of human subjects research at the relying institution (e.g., subject injury language, HIPAA authorizations, genetic testing language).
3. Local Ancillary Reviews: Institution-specific reviews that may be completed prior to initiation of a study at that institution.

[1] This procedure does not apply to industry-sponsored research reviewed by BRANY.

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

1. The Albert Einstein College of Medicine ("Einstein") and Montefiore Medical Center ("MMC") may enter into a reliance agreement for IRB review, whereby Einstein will provide IRB review for other institutions or will rely on the IRB at another institution. Reliance can be for a single study or a series of studies. Requests for Einstein to serve as the Reviewing IRB or for Einstein to rely on the IRB at another institution will be considered on a case-by-case basis. The final determination of reliance is at the discretion of the OHRA. The OHRA will also determine whether the reliance on a single IRB is appropriate versus conducting local IRB review in accordance with NIH policy on exceptions from single IRB review.

2. Protocols Under the Single IRB Mandate

2.1. The NIH Single IRB Policy[2]

2.1.1. The NIH requirement for single IRB (sIRB) review applies to non-exempt human research projects which are NIH funded and applies to US sites only. Sites that are engaged in human research must rely on a single IRB. The Einstein IRB requires a reliance agreement to be completed between the reviewing site and relying site The reliance agreement describes the division of responsibility for:

2.1.1.1. Ensuring reliance agreements are executed and proper documentation supporting the agreements is maintained;

2.1.1.2. Ensuring additional certification requirements are completed, such as Certificates of Confidentiality and NIH Genomic Data Sharing Policy.

2.2. Revised Common Rule Cooperative Research Policy

2.2.1. The Revised Common Rule's Cooperative Research Provision (45 CFR 46.114) extends the sIRB mandate to all federally funded studies which are non-exempt human research projects and only applies to US sites as well. All sites that are engaged in human research must rely on a single IRB. The Einstein IRB requires a reliance agreement to be completed between the reviewing site and relying site. The reliance agreement describes the division of responsibility for:

2.2.1.1. Ensuring reliance agreements are executed and proper documentation supporting the agreements is maintained; and

2.2.1.2. Ensuring additional certification requirements are completed, such as Certificates of Confidentiality and NIH Genomic Data Sharing Policy.

[2] See more information on sIRB mandate on NIH website: https://grants.nih.gov/policy/humansubjects/single-irb-policy-multi-site-research.htm.

3. Reliance Agreements with non-AAHRPP Accredited IRBs

3.1. The OHRA may consider deferring responsibility for IRB review to an institution not accredited by AAHRPP. To defer responsibility, the non-Einstein IRB must have an OHRP-approved Federalwide Assurance (FWA) and OHRP-registered IRB.

3.2. A reliance agreement must be executed between the two institutions.

3.3. Einstein requests the following information from the non-Einstein IRB that is not AAHRPP accredited in order to determine whether Einstein will rely on their IRB:

3.3.1. FDA or OHRP citations from the previous 5 years;

3.3.2. Confirmation by HRPP/IRB leadership that the institution has completed its own quality review process

3.3.2.1. Examples of quality review processes include, but are not limited to, signature on the SmartIRB Master Reliance Agreement; use of AAHRPP's Evaluation Instrument to conduct a self-assessment; or use of FDA's IRB self-evaluation checklist.

3.4. When deemed appropriate and/or for greater than minimal risk research, the ORHA will request that the non-Einstein IRB submit their HRPP/IRB policies regarding the following:

3.4.1. Initial Review;

3.4.2. Continuing Review;

3.4.3. Adverse Event/Unanticipated Problem/Protocol Violation Review; and

3.4.4. Reporting of serious/continuing noncompliance, unanticipated problems involving risks to subjects or others, and suspension or termination of research.

3.4.5. Additional policies/procedures may be requested at the Einstein IRB staff's discretion.

4. Department of Defense (DoD) Covered Research

4.1. The Einstein IRB does not serve as the Single IRB for DoD-covered studies.

5. Initial Reliance Request Process

5.1. Investigators that wish to request a reliance agreement for multi-site research must first discuss their request with the OHRA.

5.2. The Reliance Team will review the request to determine if reliance is acceptable and confirm the next steps with investigators.

6. Einstein as a Relying Site

6.1. Initial Submission and Review

6.1.1. Once a reliance is determined to be acceptable, the Einstein PI and/or designee will be responsible for submitting a Protocol Registration Application to the OHRA once the required study documents are available for review.

6.1.2. This submission will help facilitate the Local Context Review, personnel training confirmation, Conflict of Interest (COI) disclosures, and departmental signoffs.

6.1.2.1. The OHRA will review the COI disclosures of all investigators listed in the protocol registration file in accordance with Einstein's COI policies. If any COIs are identified, the COI management plan will be uploaded to the protocol file and communicated to the reviewing IRB.

6.1.2.2. The OHRA will review the submission for institutional COIs. If an institutional COI is identified, the institutional COI management plan will be communicated to the reviewing IRB.

6.1.3. The following documentation should be included with the submission, as applicable:

6.1.3.1. Reviewing IRB approval letter

6.1.3.2. Reviewing IRB approved protocol

6.1.3.3. Reviewing IRB approved consent & HIPAA authorization

6.1.3.4. Waiver of HIPAA authorization, if applicable

6.1.3.5. Local Context form, if available
6.1.3.6. Reliance Agreement

6.1.4. The Reliance Team will facilitate the execution of the Reliance Agreement and return to the Einstein PI any required local context form or other paperwork requested by the Reviewing IRB.

6.1.5. After the Reviewing IRB approves Einstein as a study site, Einstein Investigators will submit the approval letter and any updated documents to the OHRA. Once the OHRA confirms that all local context items are addressed, the OHRA will issue a formal acknowledgment.

6.1.6. Study expiration dates will reflect those issued by the Reviewing IRB.

6.1.7. Formal acknowledgment must be obtained before the proposed research may begin. It is the PI's responsibility to ensure that all applicable institutional requirements (such as coverage analysis, PRMC, contract review, etc.) be completed prior to the start of the proposed research activity.

6.1.8. The Reviewing IRB will stamp documents in accordance with its policies. The OHRA does not stamp documents for externally reviewed studies.

6.2. Amendments and Continuing Review

6.2.1. Any changes proposed for this protocol must be submitted to the Reviewing IRB for review and approval prior to implementation unless such a change is necessary to avoid immediate harm to the participants.

6.2.2. A change in PI must be submitted to both the OHRA and the Reviewing IRB.

6.2.3. Any other changes in key personnel must be submitted to the OHRA.

6.2.4. Protocol changes that may require additional local context considerations must be submitted to the OHRA following approval by the Reviewing IRB (i.e. addition of a new vulnerable population, substantive protocol changes, or changes that increase risk level, changes that may require local ancillary reviews[i.e. COI, radiation safety committee, etc.], study status changes, changes that may require consideration of state-specific regulations, funding source changes, etc.).

6.2.5. The progress report must be submitted to the OHRA after the Reviewing IRB has re-approved the study. The progress report must be submitted to the OHRA within 30 days of re-approval by the Reviewing IRB.

6.2.5.1. Failure to submit a progress report within 30 days of re-approval by the Reviewing IRB is considered to be noncompliance with institutional procedures, and as such subject to the "Research Noncompliance" procedure.

6.2.6. The progress report submission should include the latest versions of the consent form and protocol, if applicable.

6.3. Unanticipated Problems and Other Reportable Events

6.3.1. In most cases, each study PI or his/her designee is responsible for promptly reporting to the Reviewing IRB and the OHRA any Reportable Event of which he/she becomes aware in accordance with the reportable events requirements of both the Reviewing IRB and the OHRA. The PI is responsible for submitting the following types of reportable events to OHRA concurrent to the submission to the reviewing IRB:

6.3.1.1. Events or new information that may represent unanticipated problems involving risks to subjects or others

6.3.1.2. Events or new information that may represent serious or continuing non-compliance

6.3.1.3. Suspension and/or termination of IRB approval

6.3.2. When a reportable event is submitted to the OHRA, the PI must confirm that the event has also been reported to the Reviewing IRB. If the Reviewing IRB has not yet been informed of a reportable event, the local study team must promptly do so. Once the Reviewing IRB has made a determination, the PI must submit the determination documents to OHRA.

6.4. Study Closure

6.4.1. Upon completion of the study, the study team is responsible for submitting relevant documentation for study closure to the OHRA, including confirmation that the Reviewing IRB has approved the study closure. The study team is responsible for properly storing and disposing of specimens and data according to relevant legal agreements.

7. Einstein as the Reviewing IRB

7.1. Initial Submission and Review

7.1.1. The Einstein PI and/or designee will submit a master protocol application to the Einstein IRB for review, which will be reviewed in accordance with initial review procedures.

7.1.2. After the Einstein IRB has approved the master protocol, the Einstein PI will send each relying site the following documents, as applicable:

7.1.2.1. Einstein IRB approved Protocol

7.1.2.2. Einstein IRB approved Consent and HIPAA Authorization templates

7.1.2.3. Protocol-Specific Local Context Worksheet

7.1.2.4. Reliance Agreement

7.1.3. Each Relying Site will be responsible for 1) revising the Consent Form template that will be used at such Site to comply with any local requirements, and 2) completing the protocol-specific Local Context Worksheet to inform the Einstein IRB of any relevant local context issues, such as specific requirements of state or local laws, regulations, policies, standards, or other factors applicable to the Relying Site that would affect the conduct of the study. 3) Completion of any applicable local institutional ancillary reviews (i.e., PRMC, COI, radiation safety committee, etc.) 4) identifying COIs and communicating the COI management plan to OHRA.

7.1.4. The Reliance Team will facilitate the execution of the Reliance Agreement.

7.1.5. The Einstein PI and/or designee will submit to the OHRA the local context worksheets, revised consent forms, and any other required documents from all relying sites.

7.1.6. Relying sites are added via amendment submissions after the initial protocol submission has been approved.

7.1.6.1. For full board studies: The addition of a study site that conducts the same protocol will be reviewed via the expedited procedure as a minor amendment. If the addition of the site impacts the potential risk to subjects, the amendment will be reviewed by full board committee. Examples of amendments that impact the potential risk include the addition of new procedures or subject population at the relying site.

7.1.6.2. For expedited studies: The amendment will be reviewed through expedited review, unless it adds new potential risks that no longer make it qualify for expedited review.

7.2. Continuing Review

7.2.1. Prior to study expiration, the Einstein PI and/or designee is responsible for submitting a progress report for the master protocol in accordance with the Einstein IRB's Continuing Review procedure.

7.2.2. The Einstein PI and/or designee is responsible for obtaining information required for the progress report submission from each Relying Site.

7.2.3. If such information is not obtained from a Relying Site, that site will not be re-approved.

7.3. Protocol Amendments

7.3.1. The Einstein PI and/or designee will be responsible for submitting both study-wide amendments that apply to all sites and site-specific amendments to the Einstein IRB for review.

7.3.2. The Einstein IRB does not review key personnel changes at relying sites unless the change involves the relying site's PI or it includes a conflict-of-interest management plan.

7.3.3. The Einstein IRB will notify the Lead PI once such amendments have been approved.

7.4. Financial Conflicts of Interest

7.4.1. Relying institutions are responsible for assessing financial conflict and proposing management plans based on their own institutional policy. Relying institutions will forward their management plans to the Einstein IRB.

7.4.2. The Einstein IRB approves the submitted management plan, or proposes more stringent requirements. Modified management plans will be returned to the relying site for comment prior to final approval.

7.4.3. Any changes to the financial conflict of interest management plan are reviewed at the Relying Institution level. The change is then submitted to the Einstein IRB for approval.

7.5. Study Closure

7.5.1. Upon completion of the study for which the Einstein IRB is the Reviewing IRB, the lead PI and/or designee will submit relevant documentation for study closure. Each site is responsible for the storage and disposition of specimens and data according to relevant legal agreements.

V. Effective Date

Effective as of: 17 December 2019

Revised as of: 2 October 2023

VI. Procedure Management and Responsibilities

Einstein's Office of Human Research Affairs ("OHRA") is the Responsible Office under this Procedure. The Executive Dean is the Responsible Executive for this Procedure. Einstein's OHRA Director is the Responsible Officer for the management of this Procedure.