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]

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 in which 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.

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

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

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 series of studies. Requests for Einstein to serve as the Reviewing IRB or Einstein to rely on the IRB at another institution will be considered on a case-by-case basis. Final determination of reliance is at the discretion of the OHRA.

2. Reliance Request Process

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

2.2. The OHRA Reliance Manager will review the request to determine if reliance is acceptable, confirm the next steps with investigators, and route any applicable reliance agreement to the Institutional Official and legal counsel, if necessary, for sign-off.

3. Einstein as a Relying Site

3.1. Initial Submission and Review

3.1.1. Once a Reliance Agreement is in place, the Einstein PI and/or designee will be responsible for submitting a Protocol Registration Application to the OHRA.

3.1.2. This submission will help facilitate the Local Context Review, personnel training confirmation, Conflict of Interest (COI) disclosures, and departmental sign-offs.

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

3.1.3.1. Reviewing IRB approval letter

3.1.3.2. Reviewing IRB approved protocol

3.1.3.3. Reviewing IRB approved consent & HIPAA authorization

3.1.3.4. Waiver of HIPAA authorization, if applicable

3.1.3.5. Local Context form, if available

3.1.4. The OHRA will return to the Einstein PI any required local context form or other paperwork requested by the Reviewing IRB.

3.1.5. 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 acknowledgement.

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

3.1.7. Formal acknowledgement of the research is considered the institutional approval and must be obtained before the proposed research may begin.

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

3.2. Amendments and Continuing Review

3.2.1. 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.

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

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

3.2.4. 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, study status changes, changes that may require consideration of state-specific regulations, etc.).

3.2.5. 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.

3.2.5.1. 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.

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

3.3. Unanticipated Problems and Other Reportable Events

3.3.1. 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.

3.3.2. 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.

3.4. Study Closure

3.4.1. 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.

4. Einstein as the Reviewing IRB

4.1. Initial Submission and Review

4.1.1. 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.

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

4.1.2.1. Einstein IRB approved Protocol

4.1.2.2. Einstein IRB approved Consent and HIPAA Authorization templates

4.1.2.3. Protocol Specific Local Context Worksheet

4.1.3. 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.

4.1.4. 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.

4.2. Continuing Review

4.2.1. 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.

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

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

4.3. Protocol Amendments

4.3.1. 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.

4.3.2. 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.

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

4.4. Financial Conflicts of Interest

4.4.1. 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.

4.4.2. 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.

4.4.3. 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.

4.5. Study Closure

4.5.1. Upon completion of 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

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.