

Single/Central ("sIRB") Processes:

Request & Submission Processes when Einstein is a Relying Site

This guidance document provides an overview of the process and IRB staff responsibilities. Questions about the process or comments about information in the documents should be brought to the attention of the Einstein IRB at SingleIRB@einstein.yu.edu.

Decisions about whether Albert Einstein College of Medicine, Inc. & Montefiore Medical Center ("Einstein") will enter into a Reliance Agreement ("RA") for IRB review, whereby Einstein will rely on the IRB at another institution ("Relying Institution") or will review for other institutions ("Reviewing IRB"), require specific information about the proposed research and the institutions involved. Reliance can be for a single study or series of studies. When multiple institutions will 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").

Please note that reliance cannot begin until a RA is reviewed and executed.

Investigators interested in participating in a sIRB project must first complete an online [IRB Reliance Request Information Sheet](#) (RRIS). Depending on the type of request, the RRIS may prompt investigators to complete and submit a Protocol Registration submission in [iRIS](#) along with all required study documentation, if available.

As part of the review, the Einstein IRB has the responsibility to confirm that all Einstein key personnel are appropriately listed in iRIS and have completed required training and filed all required Conflicts of Interest (COI) Disclosures. The Einstein IRB will also confirm that applicable ancillary reviews are completed before a study can be initiated by Einstein investigators, and will confirm that other University requirements and policies are appropriately addressed.

A protocol submission in iRIS will generally only be acknowledged after the sIRB for a given study has approved the master protocol and provided the Einstein IRB with a fully executed RA. In most cases, the sIRB will provide a local context review form for completion. This form may be different for each sIRB.

Provided below is a list of documents for reference. Investigators are responsible for reviewing and abiding by the information in each reference document.

<p style="text-align: center;"><u>Einstein as Relying Site:</u></p> <p style="text-align: center;">Initial Reliance Agreement & Local Context review</p>	<p><u>Documents for reference:</u></p> <ol style="list-style-type: none"> 1. Einstein sIRB Key Roles and Responsibilities (<i>attached to a protocol in iRIS once a reliance agreement is fully executed</i>) 2. Study specific Reliance Agreement
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Process Description:

1. Prior to any submission in [iRIS](#) where an external IRB is designated as the Reviewing IRB, Investigators are encouraged to reach out to the Einstein IRB with any questions (SingleIRB@einstein.yu.edu) and complete an online [IRB Reliance Request Information Sheet \(RRIS\)](#).
2. As part of the RRIS, investigators must confirm what reliance process will be used (SMART IRB, standalone IAA).
3. The initial Einstein IRB review will determine if the reliance is acceptable, and route any applicable reliance agreement for sign-off.
4. Once a reliance agreement is fully executed, the Einstein IRB will prompt investigators to create a Protocol Registration submission in iRIS. The following documents should be uploaded, if available:
 - a. sIRB approved Master Protocol
 - b. sIRB approval letter for the Master Protocol
 - c. sIRB approved template of the most current study Consent and HIPAA Authorization
 - d. HIPAA Waiver Approval from lead IRB
 - e. sIRB approved Local Context from (provided by the sIRB)
 - f. IRB Authorization Agreement (unless using BRANY)
 - i. If using SMART IRB, a SMART IRB acknowledgement letter must be attached.
 - g. A copy of the online RRIS
5. Simultaneously, if the sIRB has reviewed and approved the Master Protocol, the Einstein IRB will conduct a local context review of the study. The local context review is an abbreviated review that includes assessment of completeness and consideration of local context. The latter will focus on determining if any state/local laws or institutional policies are invoked by the procedures that are proposed, and on the consent form to ensure local language is included, e.g., research related injury, confidentiality or genetic testing language, as applicable. The local context form will then be completed and signed, if applicable, by a designated Einstein IRB staff reviewer.
6. Following review, the Einstein IRB will attach a copy of the Einstein sIRB Key Roles and Responsibilities document for the study in iRIS. The Key Roles and Responsibilities document is a one page document that delineates study related responsibilities between Einstein and another institution pursuant to agreed upon terms in an authorization agreement
7. The IRB will complete/upload any required local context form and acknowledge in iRIS that a reliance is to be put in place. The protocol will be returned with stipulations that include instructions for the protocol to be re-submitted after the sIRB has fully executed the RA and approved Einstein as a study site.

****THE iRIS PROTOCOL WILL NOT BE APPROVED AT THIS POINT.**

8. After the Reviewing IRB approves Einstein as a study site, Einstein Investigators will re-submit the study in iRIS. Once it is confirmed that all local context items are addressed, the protocol will be acknowledged.
9. **Expiration dates** will reflect those issued by the sIRB.
10. In most cases, consent forms and other study-specific documents are not stamped with the Einstein IRB approval stamp. The Einstein sIRB Key Roles and Responsibilities document will confirm if there is a situation in which documents will be stamped.

<p style="text-align: center;"><u>Einstein as Relying Site:</u></p> <p style="text-align: center;">Modifications/Continuing Review</p>	<p><u>Documents for reference:</u></p> <ol style="list-style-type: none"> 1. Einstein sIRB Key Roles and Responsibilities (<i>attached in iRIS</i>) 2. Study specific Reliance Agreement
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Process Description:

1. The following 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.
 - a. A change in PI must be submitted to both the Einstein IRB via iRIS as well as to the Reviewing IRB.
2. Any other changes in study personnel must be submitted to the Einstein IRB via a modification in iRIS.
 - b. Protocol changes that may require additional local context considerations may require submission to the Einstein IRB in iRIS following approval by the reviewing IRB (i.e. addition of a new vulnerable population, protocol changes that increase risk level, changes that may require local ancillary reviews, etc.). The sIRB should confirm when such changes must be brought to the attention of the Einstein IRB.
3. Continuing Review by the sIRB of any study where Einstein is a Relying Site, and submission of a Renewal application with the sIRB approval letter, is required prior to the expiration date of the sIRB approval for the study.

<p style="text-align: center;"><u>Einstein as Relying Site:</u></p> <p style="text-align: center;">UP/Other Reportable Events</p>	<p><u>Documents for reference:</u></p> <ol style="list-style-type: none"> 1. Einstein sIRB Key Roles and Responsibilities (<i>attached in iRIS</i>) 2. Study specific Reliance Agreement
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Process Description:

1. Applicable reporting requirements will be detailed in a given study’s Einstein Site Responsibility form attached in iRIS but PIs should be sure to follow the most recent version of both Einstein’s SOPs and the Lead IRB’s SOPs.

**In most cases, each study PI or his/her designee is responsible for promptly reporting to the sIRB and to the Einstein IRB any Reportable Event of which he/she becomes aware in accordance with the requirements described in the respective reliance agreement and Einstein Site Responsibility form attached in iRIS.

2. When a reportable event is submitted in iRIS, Investigators must confirm that the event has been reported to the sIRB. If the sIRB has not yet been informed of a reportable event, the local study team must be advised to do so in a timely manner.
3. Any reportable event report should be attached in iRIS when it becomes available from the sIRB.

<p><u>Einstein as Relying Site:</u></p> <p style="text-align: center;">Closure</p>	<p><u>Documents for reference:</u></p> <ol style="list-style-type: none"> 1. Einstein sIRB Key Roles and Responsibilities (<i>attached in iRIS</i>) 2. Study specific Reliance Agreement
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Process Description:

1. Upon completion of any sIRB Study, the study team is responsible for submitting relevant documentation for study closure in iRIS, including sIRB approved plans for the storage and disposition of specimens and data at Einstein, consistent with applicable law, policies and regulations, as applicable, and confirmation that the sIRB has approved the study closure.
2. The Einstein IRB will maintain appropriate IRB records relating to each Consortium Study for a minimum of three years after the closure of such Study or longer if required by law, the applicable sponsor or Einstein or Montefiore institutional policies.