NIH Single IRB (sIRB) Request Process:

NIH's Single IRB (sIRB) Policy is applicable to new and competing renewal applications/proposals for NIH funding that are due on or after January 25th, 2018, and contract solicitations issued on or after January 25, 2018. It is applicable to NIH-funded multi-site domestic studies involving non-exempt human subjects' research. The Policy does not apply to foreign sites, career development (K), institutional training (T), and fellowship awards (F), and current active awards. However, foreign sites may choose to rely on the sIRB that is selected for domestic sites.

Einstein as the Lead Site and/or Einstein/BRANY as the Single IRB

The process below describes the steps that must be followed when Einstein will serve as the sIRB, when BRANY serves as the Lead IRB or when Einstein is the applicant organization but another site will serve as the Lead IRB.

When Einstein is the applicant organization (i.e., will be the "Lead Site" or "Prime Awardee") – regardless as to which organization will serve as the lead IRB the following elements must be included in the grant application:

- sIRB Plan, which must include the following:
  - Describe how you will comply with the NIH Policy on the Use of a sIRB for Multi-Site Research
  - Provide the name of the IRB that will serve as the sIRB of record
  - Indicate that all identified participating sites have agreed to rely on the proposed sIRB and that any sites added after award will rely on the sIRB
  - Briefly describe how communication between sites and the sIRB will be handled
  - Indicate that all participating sites will, prior to initiating the study, sign an authorization/reliance agreement that will clarify the roles and responsibilities of the sIRB and participating sites
  - Indicate which institution or entity will maintain records of the authorization/reliance agreements and of the communication plan
- sIRB fee schedule

To allow adequate time for budget and interinstitutional document preparation, it is highly recommended that **two weeks prior to any submission of an NIH grant application involving multi-site research**, investigators do the following:

1. Submit a Reliance Request Information Form to the Einstein IRB via Qualtrics.
   This request form will elicit the information necessary for the Einstein IRB to determine whether the request is appropriate and/or whether the Einstein IRB can serve as the sIRB.

2. Investigators will receive confirmation of their sIRB request via email.
   a. Please note that a Reliance Request ID number will be generated as part of the request process. Investigators should retain this ID number for their records.

3. The Einstein IRB will consider the sIRB request and will make every effort to respond within 2-3 business days.
    - If the request is **denied**, the rationale for this determination will be provided to the PI. The determination will include contact information for the IRB Reliance Analyst should investigators which to discuss the request outcome.
    - If the request is **approved**, the Einstein IRB will provide a Letter of Support (LOS). The LOS will address the items that are required to be included in the grant application's sIRB Plan. Please note, it is the PI's responsibility to upload the LOS in Cayuse.
      ***Note that this Letter of Support should NOT be considered approval to proceed with this project without following the rest of the steps noted below.*

NOTE: Whether Einstein or BRANY serve as the Lead IRB, the additional costs associated with sIRB review **are allowable as direct costs** and should be budgeted accordingly.

4. I**f Einstein is serving as the sIRB**, information on what to include in the budget for sIRB costs will be provided by the Einstein IRB at this time. Costs associated with using the Einstein IRB must be included in all subcontracts as direct costs.

5. **When sIRB responsibilities are delegated to BRANY**, BRANY will provide a budget breakdown. Einstein will facilitate fee negotiation with BRANY on behalf of the PI. Costs associated with using the Einstein IRB must be included in all subcontracts as direct costs.

6. **If another site is serving as the sIRB,** information on what to include in the grant budget for sIRB costs will be provided by that site's IRB.
    a. Once the Letter of Support is issued, the Lead PI and their team will be responsible for working with each of the other research sites to confirm their commitment, in writing, to rely on the proposed sIRB (Einstein or BRANY). In many situations, this commitment will be provided by the collaborating site's IRB Office. Lead site PIs are responsible for maintaining a record of each site's responses.

7. Appendix A of this document includes template language regarding the sIRB plan.

After the Notice of Grant Award (NOA) is issued, the PI is responsible to notify the IRB so that all collaborative arrangements can be finalized with partner institutions:

1. Contact the Einstein IRB at SingleIRB@einstein.yu.edu to advise them of the NOA.

2. Submit a NOA Reliance Request Information Form request to provide information needed to initiate the formal Reliance set-up process.

3. The IRB Reliance Analyst will meet with the Einstein PI and research team to review the roles and responsibilities of the sIRB and of the Lead research team.

4. The IRB Reliance Analyst will assist with determining the most appropriate Reliance Agreement, and provide assistance on obtaining executed Agreements.

5. Once the fully executed Reliance Agreements are obtained, the IRB Reliance Analyst will outline the iRIS Submission and Review process to be followed.

6. If delegated to BRANY, representatives from their IRB will work with investigators to review their reliance process.

Einstein as a Relying Site

(*When Einstein is NOT the Applicant Organization and relies on another site for IRB review*)

The process below describes the steps that must be followed when Einstein is NOT the applicant organization and will serve as a Relying site with another institution serving as the Lead IRB.

When Einstein is engaged in human subjects' research but another site is the applicant organization on a grant application subject to the NIH sIRB Policy, the applicant organization will need to provide a sIRB Plan to address the requirements of the NIH sIRB Policy. One of the requirements of the sIRB Policy is that each of the participating sites agree to rely on the proposed sIRB.

The process below describes the steps the Einstein researcher must follow in these situations:

1. Submit a Reliance Request Information Form to the Einstein IRB via Qualtrics.
   This request form will elicit the information necessary for the Einstein IRB to determine whether the sIRB request is appropriate and whether the Einstein IRB agrees to rely on the designated sIRB.

2. Investigators will receive confirmation of their sIRB request via email.
   a. Please note that a Reliance Request ID number will be generated as part of the request process. Investigators should retain this ID number for their records.

3. The Einstein IRB will consider the request and will make every effort to respond within 2-3 business days
   - If the request is **denied**, the rationale for this determination will be provided. The determination will include contact information for the IRB Reliance Analyst should investigators which to discuss the request outcome.
   - If the request is **approved**, the Einstein IRB will provide a Letter of Support (LOS) confirming Einstein's agreement to rely on the proposed Single IRB.
     ***Note that this Letter of Support should NOT be considered approval to proceed with this project without following the rest of the steps noted below.*

After the Notice of Grant Award (NOA) is issued:

1. Contact the Einstein IRB at SingleIRB@einstein.yu.edu to advise them of the NOA.

2. Submit a NOA Reliance Request Information Form to provide information needed to initiate the formal Reliance set-up process.

3. The Einstein IRB will manage all necessary institutional reviews (i.e., IRB Chair, Office of the General Counsel, OCT, etc.)

4. The IRB Reliance Analyst will meet with the Einstein PI and research team to review the roles and responsibilities outlined in the Reliance Agreement.

5. Once a fully executed Reliance Agreement is in place, **submit a Protocol Registration submission in iRIS.**
   a. The rest of this process is outlined in full in the Einstein sIRB Submission and Review Guidance.

APPENDIX A

Boilerplate Language for the sIRB Plan when Einstein or BRANY (acting on our behalf) will be the sIRB

Special Note for this Attachment in the Application:

Format: attach this information as a PDF file. See NIH's Format Attachments page.

Although one sIRB attachment per application is sufficient, you must include a file ***for each study within your application****. All file names within your application* ***must be unique****. You may either attach the same sIRB plan (with different file names) to different studies or attach a file that refers to the sIRB plain in another study within your application. For example, you may attach a file that says "See sIRB plan in 'My Unique Study Name' study."*

[INCLUDE THE FIRST PARAGRAPH ONLY IF YOUR APPLCIATION WILL HAVE A DELAYED ONSET]

This is a delayed onset study, and the determination of which entity will serve as the Single IRB of record cannot be determined at this time. If awarded, we will communicate our plans for use of a sIRB to our NIH Program Official prior to initiating the study.

Einstein/BRANY (*select as appropriate*) will be serving as the Single IRB (sIRB) in this proposed multi-site study involving human subjects' research. As the sIRB, Einstein/BRANY (*select as appropriate)* will fulfill the requirements set out in 45 CFR Part 46, and 21 CFR Parts 50, 56, 312, 600, 812, as applicable, by conducting initial and continuing reviews of protocols for all participating domestic sites, including amendments, unanticipated problems, protocol deviations, and required reporting to federal oversight agencies. The sIRB will also serve as the Privacy Board, as applicable, to fulfill the requirements of the HIPAA Privacy Rule for use or disclosure of protected health information for research purposes.

The participating sites identified in the Project/Performance Site Locations section of this proposal have indicated their willingness to rely on Einstein/BRANY (*select as appropriate*) as the selected sIRB and the PI has obtained documentation of their agreement via *[select: letter/note/email or some other means]*. In turn, the Einstein/BRANY (*select as appropriate*) IRB has provided a Letter of Support indicating its commitment to serve as the sIRB.

At the time of award, Einstein/BRANY (*select as appropriate*) sIRB representatives will meet with the PI and Research Study Team to review their responsibilities, as outlined in the relevant Reliance/Authorization Agreements (AA), and to review Einstein's/BRANY's (*select as appropriate*) sIRB Policies. It may be determined during this meeting that the use of the Streamlined, Multisite, Accelerated Resources for Trials (SMART) IRB Reliance platform, funded by the National Center for Advancing Translational Sciences (NCATS), is the most efficient model for implementing the authorization agreements among the participating sites.

Prior to the signing of AAs between Einstein/BRANY (*select as appropriate*) and the participating sites, the sIRB will work with the PI and Research Study Team to ensure that the

AA is signed by both institutions. The PI will communicate the terms of the agreements with each participating site. AAs will be considered fully executed once signed by the Institutional Officials at both Lead and Relying Sites.

As outlined in the AAs, the relying institutions will be expected to contact the Lead PI when there are study events, required reports, and other significant issues that must be reported to the sIRB. The Lead PI will communicate with the sIRB for guidance. The sIRB will offer, as needed, to communicate directly with the relying sites to resolve issues.

The PI will obtain prior approval from NIH to request additional sites to the study. If approved, the PI will coordinate with the participating site to obtain a signed AA. The same processes as described above will apply.

The Einstein/BRANY (*select as appropriate*) IRB Office will maintain the signed Authorization Agreements and will provide copies to the relying sites.

Requests for sIRB Exception

For sites requesting an exception based on compelling justification: Indicate which site(s) is(are) requesting an exception to the use of the sIRB and provide compelling justification based on ethical or human subjects protection issues or other well-justified reasons. NIH will determine whether to grant an exception following an assessment of the need. Note: If you intend to request an exception to the sIRB policy based on compelling justification, do not account for this exception in your proposed budget. The proposed budget must reflect any necessary sIRB costs without an exception (i.e., applicants should not assume that an exception will be granted when considering what sIRB costs to include in the budget).

NOTE: NIH has stated that exceptions will rarely be granted. Examples for when an exception may be appropriate are when Federal, State, Tribal, local laws/regulations/policies require local review, or when a compelling justification is made for local IRB review.