

## Single IRB Plan for Multisite Study NIH Grant Applications – Emory Prime

### Guidance and Instructions

Effective for applications received on or after January 21, 2019, certain multi-site studies with federal or NIH funding require the use of a single IRB. If you are going to be submitting an application for Federal or NIH funding, you MUST SPEAK WITH YOUR NIH PROGRAM OFFICER OR FEDERAL SPONSOR REPRESENTATIVE to find out if the Single IRB requirement applies to your particular protocol.

**If it does: Please email a Single IRB Intake Form (on the website) to the IRB Reliance Listserv as soon in the grant application process as possible and wait for the Emory IRB's response before moving forward with the Single IRB Plan. Emory has designated Western IRB (WIRB) as its IRB of Record for these studies except in very limited circumstances. You must also send the Single IRB Quote Request Form (also on the website) to WIRB and factor the cost of a single IRB into your budget.**

**Note:** A formal, fully executed reliance agreement is NOT required to be in place prior to receiving funding; nor is a final decision about which IRB will be used. It is sufficient to include in the Single IRB Plan that the participating sites are dedicated to using a single IRB to be determined in the future. Additionally, letters of support from participating sites can express that they are dedicated to relying on a single IRB, even if that single IRB has not yet been chosen, or if the decision to rely is contingent upon the institution's vetting of the single IRB's policies and procedures.

#### **What content is needed in the sIRB plan? (See template document on website for language.)**

- Describe how you plan to comply with the single IRB requirement. If requesting an exception for some or all participating sites, see [NIH Guidance for Requesting an Exception](#) (see guidance in red below).
- Provide the name of the IRB which will serve as the single IRB of record (sIRB), or if no single IRB chosen yet, you can leave the language generic (*you must send the Single IRB Intake Form prior to doing this!*)
- State that all currently identified participating sites have agreed to rely on said sIRB (or on a single IRB in general, if one has not been chosen).
- State that any sites which will be added in the future must agree to rely on the chosen sIRB.
- Describe the communication policy between the sIRB and participating sites (see the Communication Plan Table).
- State that all participating sites will sign an individual authorization agreement (IAA), also known as a reliance agreement, prior to initiating the study. State that the IAA/reliance agreement will specify the division of responsibilities between the sites.
- State which institution(s) will be responsible for maintaining records related to the IAA/reliance agreements and for maintaining a copy of the communication plan.
- *If your study meets the criteria for "delayed onset" human subjects research, do not create a separate sIRB plan, and instead see below.*

### Where do you include the sIRB plan?

Upload the plan as an attachment to Question 3.2 of the [FORMS-E Human Subjects and Clinical Trial Information form](#).

### Delayed-onset multi-site research?

Delayed-onset human subjects studies are those for which there is no well-defined, detailed plan for human subjects involvement at the time of submission. If the delayed-onset research is likely to involve multiple sites, the delayed onset justification attachment (*not* a separate single IRB attachment) must:

- Include information about how the study will comply with the sIRB policy, and
- State that a sIRB plan will be provided prior to initiating the study. Other documents?

### Letters of Support/Commitments to Rely on Single IRB

While the sponsors will not specifically require Letters of Support, providing Letters of Support is one way to confirm that all participating sites are willing to rely on the selected sIRB (or on some sIRB, if none has yet been selected). See our template here:

<http://irb.emory.edu/forms/external-irbs/index.html>

Emory IRB does not require letters of support. If another institution is submitting a grant application and asks Emory for a letter of support, please contact Emory IRB.

### Who do I contact for more information?

- At Emory IRB-
  - IRB Reliance Listserv, [IRB-RELIANCE@LISTSERV.CC.EMORY.EDU](mailto:IRB-RELIANCE@LISTSERV.CC.EMORY.EDU)
  - Primary Contact- Hannah Helmstetter, Reliance Specialist, [Hannah.helmstetter@emory.edu](mailto:Hannah.helmstetter@emory.edu)
  - Secondary Contact- Rebecca Rousselle, Director, [Rebecca.rousselle@emory.edu](mailto:Rebecca.rousselle@emory.edu)

**If an exception applies to your study under the requirement, you MUST draft a short paragraph claiming the exception and upload it in place of the Single IRB Plan. If you do not claim this exception, you lose it.**