Single IRB (sIRB) Plan for NIH Grant Applications

This information is drawn from the NIH FAQs on the Single IRB Policy for Multi-site Research and the PHS Human Subjects and Clinical Trials Information Form Application Guide. It describes a new requirement for NIH multi-site grant applications.

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Requirement

Effective January 25, 2018, NIH requires multi-site grant applications to include a plan for the use of a sIRB. See Section 3.2 of the PHS Human Subjects and Clinical Trials Form Information Application Guide.

Information Required

Description of compliance with the NIH sIRB policy.

Name of the IRB serving as the sIRB of record

Acknowledge that identified participating sites agree to rely on the proposed sIRB

Brief description of how communication between sites and the sIRB is handled. SMART IRB provides a template communication plan, for possible use.

All participating sites will, before study initiation, sign a reliance agreement outlining roles and responsibilities of the sIRB and participating sites

Denote the institution/organization that maintains records of the reliance agreements and communication plan

NOTE: Delayed-onset multi-site research
Delayed-onset are for those studies which there is no defined, detailed plan for human subjects involvement at the time of submission. If the research will involve multiple sites, a delayed onset justification attachment must be provided and include:

- Information regarding how the study will comply with the sIRB policy, and
- State that a sIRB plan will be provided prior to initiating the study.

Grant Application: Forms-E

A new form (FORMS-E) for Human Subjects and Clinical Trial Information must be included in grant application packages/contracts for clinical trial and/or human subjects research applications. The sIRB plan is uploaded as an attachment to Question 3.2 of the new FORMS-E. The new form is a "smart" form which combines human subjects/clinical trial-related information in one place. The sIRB plan is uploaded as an attachment to Question 3.2 of the new FORMS-E.

FORMS-E application instructions are available from NIH on the How to Apply – Application Guide website.

NOTE: Delayed-onset study
FORMS-E has specific questions for delayed-onset studies. The sIRB plan should be uploaded with the answers to those questions.

Supporting Documentation

- **From the single IRB**
  USA IRB believes it is best practice to require a Letter of Support from the sIRB indicating its willingness to serve as the IRB of record.

- **From the USA IRB**
  USA requires grant applications to include a Letter of Support from the USA IRB documenting its support for the use of a sIRB.

- **From participating sites**
  NIH states that sites should agree to a sIRB arrangement prior to the grant submission, and "the applicant should indicate the participating sites' willingness to rely on the selected single IRB". Therefore, Letters of Support for each participating site is appropriate for meeting this expectation. Note: Signed IRB reliance agreements are not required to be in place prior to receiving NIH funding.

Letter of Support for a Single IRB

From USA IRB

USA requires grant applications to include a Letter of Support from the USA IRB documenting its support for the use of a sIRB. That may also be required by the lead PI. Contact the IRB Office at irb@southalabama.edu or 460-6308 to request a Letter of Support. The request should occur at least a week in advance.

- **USA is a participating research site:**
  The request should include the following information. The USA IRB must receive this template language from the USA research site.

- Name of USA PI
- Name of Lead PI / Lead Site
- Name of proposed sIRB, if already identified
- Title of the study/grant
- Grant deadline
- Copy of or link to the NIH Request for Applications or Funding Opportunity Announcement
- Role(s) USA will perform in the research
- Identify if grant is for a single study, multiple studies and/or a network that will design and conduct studies.
- Additional relevant information, such as whether the SMART IRB Master Reliance Agreement will be used.

NOTE: At this time, the USA IRB will not serve as the lead site or coordinating center. (i.e., sIRB of record)