



UNIVERSITY OF
SOUTH ALABAMA

IRB SOP 1105
IRB Procedures: Relying on a Single IRB
for Multi-Site Federally Funded Research

Purpose:

The purpose of this document is to provide guidance pre- and post- grant award on the appropriate actions to follow regarding implementation on the use of a single Institutional Review Board (sIRB) for multi-site federally funded research. The federal requirement for a sIRB comes from two separate mandates, the revised Common Rule governing Human Subjects Protections and the NIH policy.

Scope:

These procedures applies to domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subject's research. It does not apply to career development, research training or fellowship awards.

In addition, the sIRB mandate does not apply to collaborative projects in which multiple sites are involved but different sites may complete different parts of the study.

Definitions:

Lead PI: Responsible for the communication and overall conduct of the study and regulatory compliance. The Lead PI will be submitting the regulatory IRB submissions on behalf of all the sites relying on the reviewing IRB. (Note: The Lead PI may not always be associated with the reviewing IRB, but the Lead PI's responsibilities nevertheless remain the same.) [Lead PI responsibilities](#)

Multi-site Research: A subset of *collaborative* research uses the same protocol to conduct non-exempt human subjects research at more than one site.

Relying IRB: IRB that relies on the reviewing IRB for the regulatory reviews. The relying IRB is still responsible for institutional reviews (Training, Conflict of Interest, Radiation Safety, Biosafety, HIPAA Privacy, Use of Hospital Resources, and others).

Reviewing IRB: The selected IRB of record that conducts the ethical review for participating sites of the multi-site study, including initial reviews, modifications, continuing reviews, and reportable events.

Relying PI: Responsible for providing the Lead PI with necessary information according to the reviewing IRB's policies and procedures so the reviewing IRB can conduct an IRB review. The relying PI must know what is also required from their local relying IRB. [Relying PI responsibilities](#)

Single IRB (sIRB): One IRB of record (or *Reviewing IRB*), selected on a study-by-study basis, provides the ethical review for all sites participating in a specific multisite study.

Policy:

This policy applies only to federally funded research conducted under the Department of Health and Human Services. Unless other requirements must be followed under a specific federal agency's policy and/or guidelines, the University of South Alabama will follow the National Institutes of Health (NIH) policy and guidance regarding sIRB, including the costs associated with IRB review. Currently, the University of South Alabama will not serve as the Reviewing IRB for a federally funded multi-site study. [See SOP 1104: Policy on Single IRB for Multi-Site Research for additional details.](#)

Procedures:

1. Getting Started: How to Rely on a sIRB

If you're submitting a NIH grant that requires use of sIRB, the USA Lead PI should be prepared to:

- Submit to USA IRB to request the use of an external IRB.
 - Alert USA IRB that you have received funding and are ready to begin the process of establishing the sIRB review with an external site IRB or a commercial IRB (i.e. WIRB).

The USA IRB must collect preliminary information from the USA study site to determine willingness to rely on an external IRB for a particular project. The following information must be submitted via IRBNet:

- USA IRB Application Part A (Smart form)
- USA Application: IRB External Review Request Form

- Reliance agreement signed by the reviewing sIRB institution
- Current sIRB approved study protocol
- Current sIRB approval letter
- Informed consent document(s) with USA IRB required consent language

NOTE: In most instances, the Lead PI, in collaboration with the IRB office at the Lead PI's institution, will select the sIRB. The selected IRB must be willing to serve as the sIRB and all the participating sites must agree to rely on the sIRB. Finally, NIH must concur with the selection.

Currently, the USA IRB will not serve as the sIRB for multi-site studies. Instead, USA IRB will work with USA lead PIs to choose from a pre-selected list of independent IRBs (e.g., WIRB). This is consistent with the approach of many USA peer institutions.

2. Facilitate the establishment of reliance agreements between the sIRB and sites.

Each participating site will need to establish a reliance agreement with the sIRB. The reliance agreement documents the arrangement and also establishes expectations about communication, reporting, and procedures. The University of South Alabama, and majority of peer institutions have already signed a "generic" Master Reliance Agreement called the [SMART IRB Agreement](#). The SMART IRB agreement eliminates the need to establish a study-specific agreement. Studies and institutions making use of this existing agreement will have a streamlined startup process.

3. When Is the Reliance Complete?

When USA IRB has determined all requirements are met, and the appropriate reliance agreement executed, a letter of acknowledgement and USA IRB's willingness to rely on the external IRB will be issued.

4. How will sIRB review be paid for?

The costs for IRB review have traditionally been included as indirect costs under an institution's Facilities and Administration (F&A) rate and could not be described separately. The NIH sIRB policy expects that sIRBs will charge fees. Those fees will be the responsibility of the lead site. NIH has provided [guidance](#) on which IRB review fees should be charged as direct vs. indirect costs under different IRB review scenarios.

- *If you are the lead site and will use an independent IRB as the sIRB, you must work with USA IRB to obtain that IRB's fee structure.*

- *If you are the lead site and will use the IRB of another institution (e.g., one of the participating sites) as the sIRB: IRB fees vary among institutions. You will need to work directly with the sIRB to get information about their fees.*

5. Post sIRB Approval: USA IRB Submission

Upon execution of a reliance agreement for USA IRB to rely on another IRB for review/approval, the USA PI is responsible for obtaining all regulatory protocol information (approved protocol, approved consent documents, etc.) from the overall PI. Any questions or required reporting will need to go through the PI at the reviewing IRB site.

USA IRB requires the following submissions:

- Determinations made by the sIRB of serious or continuing noncompliance that take place at USA
- Determinations made by the sIRB of unanticipated problems that take place at USA
- Unresolved participant complaints at USA
- Change of USA PI
- Changes in Conflict of Interest
- Notification to the USA IRB when study is closed, terminated or suspended
- Notification of external audits (e.g., FDA)

6. USA IRB Responsibilities

The University of South Alabama retains ultimately responsibilities for maintain a human research protection plan including, but not limited to:

- Safeguarding the rights and welfare of research participants within the local context. The USA IRB retains authority to conduct audits to ensure compliance
- Conduct conflict of interest review for University of South Alabama investigators
- Overseeing human subjects training
- Implementing appropriate oversight mechanisms, within the local context, to ensure compliance with the determinations of the reviewing IRB
- Monitor any external IRB approval as part of its quality assurance program

References:

[NOT-OD-16-094](#) Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

History:

Effective Date: January 25, 2018

Last Review: February, 2020

Next Review: February, 2023

Responsible Party:

Office of Research Compliance and Assurance