



UNIVERSITY OF  
SOUTH ALABAMA

## **Standard Operating Procedures: Relying on a Single IRB (sIRB)**

**EFFECTIVE DATE: January 25, 2018**

### **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 for an External Institution to Serve as Reviewing IRB
- 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.

- **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.

## **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.

## **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.*

## **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)

## **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 reseach 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

## **Responsible Party:**

Office of Research Compliance and Assurance

## **Next Review Date:**

January 2020

## **References:**

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

[USA Policy on Single Institutional Review Board \(sIRB\) for Multi-Site Federal Grants Policy](#)