SMART IRB

Overview

The Streamlined, Multi-Site, Accelerated Resources for Trials, or SMART IRB, is NOT an IRB. SMART IRB is an open source web-based system designed to facilitate reliance agreements. As part of SMART IRB, institutions may choose to rely on another IRB or have their IRB act as the Reviewing IRB with other institutions relying on it. The Reviewing IRB takes on IRB oversight responsibilities associated with that study throughout its duration. Relying Institutions provide key local context information about state law, study team member training and qualifications, and any applicable conflict of interests. Investigators and institutions retain their respective responsibilities for the protection of human subjects, compliance with applicable laws, regulations, ethical standards, and the terms of institution's FWA.

Development of the SMART IRB platform was funded and supported by NIH to further its new policy [View Policy Notice] mandating all multisite clinical studies it funds to use a single IRB (sIRB) effective 1/25/18.

The University of South Alabama is a member of SMART IRB. The <u>SMART IRB</u> <u>Portal</u> provides resources—forms, templates, agreements and sample Standard Operating Procedures that investigators can use to coordinate, harmonize and streamline IRB review of dual or multi-site studies they propose to conduct in the United States.

How does it work?

The Overall Principal Investigator (PI) of a multisite study works with the Points of Contact (POCs) for each participating institution involved in the study to determine an appropriate reliance arrangement. Together they will identify a Reviewing IRB and determine which institutions will rely upon that IRB for the review and oversight of the research. Additional details on these processes are available in the SMART IRB SOPs on "Establishing Reviewing IRBs and Relying Institutions" and "Initial Review Submission and Review Process."

How do I get started?

Currently, the University of South Alabama will only serve as the Relying IRB. The University of South Alabama will serve as the relying IRB, therefore the USA study site must complete an IRB Reliance Request/Registration Form. This form serves as the application to request an external institution to serve as the Reviewing IRB (IRB of Record). Follow instructions outlined in the form for additional documents required to register project in IRBNet.

SMART IRB Resources

SMART IRB Standard Operating Procedures
SMART IRB FAQ
SMART IRB Authorization Agreement

If you have any questions about SMART IRB or other reliance partnerships, and whether they are appropriate for your research study, contact dlayton@southalabama.edu