



UNIVERSITY OF
SOUTH ALABAMA

IRB SOP 1104

Single IRB Policy for Multi-Site Federally Funded Research

Purpose:

The purpose of this document is to clarify how the University of South Alabama implements federal agency requirements regarding the use of a single Institutional Review Board (sIRB) for multi-site 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:

This policy 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.

Definitions:

Central IRB: IRB of record (also known as the *Reviewing IRB*) provides the ethical review for all sites participating in more than one multisite study. The sites are usually in a network, consortium or particular program, e.g. NCI's CIRB.

Commercial IRB: Commercial or independent IRBs are contracted agencies that are not affiliated with specific institutions and are paid to conduct reviews of research with human subjects, e.g., WCG IRB.

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:

- I. This policy does not supersede or alter other related University of South Alabama policies.
- II. This policy applies only to federally funded research.
- III. 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.
 - A. Reviewing IRB means the "IRB of record" to which authority for IRB review and oversight has been ceded by another institution for one or more research studies.
 - B. Multi-site study means a study that uses the same protocol to conduct non-exempt human subjects research at more than one site.
 - C. The NIH policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program.

1. NIH policy does not apply:
 - a. to career development, research training or fellowship awards;
 - b. to foreign sites;
 - c. when prohibited by a federal, tribal, or state law, regulation, or policy;
 - d. collaborative projects in which multiple sites are involved but different sites may complete different parts of the study;
 - e. or, in limited circumstances, when there is a compelling justification for an exception and the NIH grants an exception following an assessment of the need.

D. The NIH policy states that the activities of the sIRB will generally fall into two categories, primary activities and secondary activities and defines these activities as follows:

- a. Primary activities refer to the activities associated with conducting the ethical review of the proposed research protocol that will be carried out at all of the participating sites and the review of the template informed consent document describing the study.
- b. Secondary activities refer to the activities associated with the review of site-specific considerations for all of the participating sites, including investigator qualifications, institutional capabilities, state/local regulatory requirements, and community ethos.

Following initial approval, there are additional activities associated with fulfilling IRB oversight responsibilities, including:

- reviewing reportable events from all participating sites (e.g., unanticipated problems, protocol deviation) and reporting them as appropriate to the Office for Human Research Protections (OHRP) and the funding Institute or Center
- receiving and reviewing any complaints that arise with regard to the conduct of the study
- notifying all participating sites of serious or continuing non-compliance and all other determinations
- communicating with participating sites on matters related to sIRB determinations.

- E. In general, the University of South Alabama will treat primary activities as those costs already included in an organization's Federally-approved indirect cost rate agreement.
 - 1. Secondary activities may be charged for work performed for the relying institutions and paid from direct costs as part of the budget proposal for federal funding with appropriate budget justification.

- IV. Proposals submitted to NIH to support human subjects research on or after the NIH implementation date (1/25/2018) must include a plan describing the use of an sIRB that will be selected to serve as the IRB of record for all study sites. See Single IRB Plan for NIH Grant Applications for assistance in preparing sIRB plan.
 - A. This plan should include:
 - 1. a statement confirming that participating sites will adhere to the sIRB Policy
 - 2. and a description of how communications between sites and the sIRB will be handled.

 - B. When an investigator plans on submitting a funding proposal to a federal agency that requires the use of an sIRB for the research, the investigator must contact the University of South Alabama IRB office for assistance with:
 - 1. identification of the Reviewing IRB,
 - 2. budgeting for sIRB review
 - a. College of Medicine: Health Systems Grants Administration and Development
 - b. Other: Departmental Grant Administrators/Sponsored Projects Administration
 - 3. identifying any other regulatory issues that may need to be addressed as part of the proposal to use an sIRB.

 - C. The IRB office will review the request to assess the appropriateness and feasibility (e.g. resources and expertise needed) of:
 - 1. the proposed Reviewing IRB (whether an internal or external IRB is proposed)

2. and the plan describing how communications between sites participating and the sIRB will be handled

Adopted By: Cross Campus Human Research Protection Program (HRPP) Committee

References:

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

[NOT-OD-16-109](#) Scenarios to Illustrate the Use of Direct and Indirect Costs for Single IRB Review under the NIH Policy on the Use of a Single IRB for Multi-site Research Standard Operating Procedures: NIH Mandate - Relying on a Single IRB (sIRB)

[FAQs: NIH Implementation of the sIRB policy](#)

History:

Effective Date: January 25, 2018

Last Review: February, 2020

Next Review: February, 2023

Responsible Party:

Office of Research Compliance and Assurance