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:

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,

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.