UNIVERSITY OF SOUTH ALABAMA

IRB SOP 107
Policies and Procedures Maintenance

Purpose

The purpose of this document is to state the IRB's commitment to maintain and follow up-to-date policies and procedures that adhere to regulatory mandates and ethical principles.

Policy

The University of South Alabama Institutional Review Board (IRB) functions independently. 45 CFR 46 and the USA IRB Administration through the Vice President for Research and Economic Development grant the IRB this authority as part of the Human Research Protection Program. The IRB maintains a current Federal Wide Assurance (FWA) and follows the regulations and guidance of the Office for Human Research Protections (OHRP) for all studies conducted under that assurance. Research that is not federally funded and that is outside of the FWA is subject to the same scrutiny except where otherwise described in the USA IRB Policy and Procedures. The IRB follows the regulations and guidance of the U.S. Food and Drug Administration (FDA), and the Department of Health and Human Services (DHHS).

Standard Operating Policies and Procedures (SOPs) provide the framework for the ethical and scientifically sound conduct of human research. Supported by institutional policies and guidance documents, the IRB ensures that the rights and welfare of human research participants are overseen and protected uniformly, regardless of personnel changes.

Procedures

1. **Procedures for Review, Revision and Approval of Policies and Procedures**

   In conjunction with other University offices, the Office of Research Compliance and Assurance monitors changes to federal, state, and local regulations and guidelines,

research practices, and USA policies and procedures. The Office of Research Compliance and Assurance, to include the IRB Office, will make the determination on when updates to previously issued SOPs are required or when a new SOP is warranted. All updates will be made by the Office of Research Compliance and Assurance.

All new and revised SOPs are presented to a designated member(s) of the IRB Committee for approval, if necessary. If significant changes to a policy must be made, the revised policy and procedure may be sent to the full Committee for approval.

All approved SOPs will be reviewed by the Office of Research Compliance and Assurance no less than two years from the date of last review to assure continued compliance with federal, state, local, and institutional regulations and guidelines.

2. Procedures for SOP Dissemination and Training

All current SOPs are posted publically on the Office of Research Compliance and Assurance website.

Any new or revised SOP or regulation is disseminated to the appropriate individuals and departments by the Office of Research Compliance and Assurance as appropriate. New or revised SOPs will be published to the website for public access upon implementation.

New IRB members or staff must review all applicable SOPs and regulations as well as complete currently required human subjects training prior to undertaking any IRB responsibilities.

3. Procedures for Creating and Using IRB Forms

Forms are used to ensure that policies are integrated into the daily research and review operations and enable the IRB to manage review, tracking, and notification functions. Forms are not subject to the standards of control cited in sections 1 and 2. Forms include templates, checklists, (electronic) application forms and notifications.

3.1 Forms are created and revised by the IRB Office, in conjunction with the Office of Research Compliance and Assurance. Updates to SOPs may prompt the need for revisions to IRB forms.

3.2. As applicable, forms are implemented in the IRBNet online management system by the IRB Office.

HISTORY

Revisions: November 2018, March 2025