



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 Plan. 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 International Conference on Harmonization (ICH).

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

Procedures

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

Changes to regulations, federal guidelines, research practices, or USA policies and procedures may require a new SOP or revision of a previously issued SOP. Each approved SOP will be

reviewed no less than five years from the date of approval as described in this policy. The review date is determined from the date of last revision.

- 1.1 The Office of Research Compliance, to include the IRB Office, reviews the SOP and provides the revised policy and procedure 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.

2. Procedures for SOP Dissemination and Training

When new or revised SOPs are approved, they will be disseminated to the appropriate individuals and departments.

- 2.1 Any new or revised policy or procedure or new regulation is disseminated to the IRB members and staff by the Office of Research Compliance and Assurance or IRB Office.
- 2.2 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. The IRB Office verifies completion of required human subjects training.

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

HISTORY

Effective Date:

Revisions: November 2018