



UNIVERSITY OF
SOUTH ALABAMA

IRB SOP 102
Mission and Authority

Purpose

The purpose of this SOP is to describe the mission and authority of the USA IRB.

Policy

The mission of the USA IRB mission is to protect the rights and welfare of human research subjects. To achieve this, the IRB must advise investigators in designing research projects in a manner to minimize potential harm to human subjects, review all planned research involving human subjects prior to initiation of the research, approve research that meets established criteria for protection of human subjects, and monitor approved research to ascertain that human subjects are indeed protected.

- 1.0 The mission of the Human Subject's Protection Program is to:
 - 1.1 Administratively supporting the University's IRB
 - 1.2 Review all research involving human subject's research before it is initiated, regardless of the funding source
 - 1.3 Work to protect the rights and welfare of human subjects by fostering and advancing the ethical and professional conduct of persons engaged in research
 - 1.4 Provide education to researchers and staff
 - 1.5 Conduct periodic reviews of research involving human subjects, and
 - 1.6 Serve as the institutional HIPAA Privacy Board
- 2.0 IRB Authority

The IRB has the authority to place restrictions on, suspend or terminate approval of any human subject's research study. Non-exempt human subjects research activities must be reviewed, prospectively approved and subject to continuing oversight (some

exceptions for minimal risk studies) by the IRB to ensure the safety and welfare of participants, pursuant to the regulation provided in 45 CFR 46. The IRB conducts review and approval for all human subjects research activities conducted under its jurisdiction. This jurisdiction includes research conducted or directed:

- By USA faculty, staff, students, affiliates or outside researchers and occurs on the property of the University of South Alabama regardless of funding sources
- By an outside researcher involving USA faculty, staff, students, or affiliates.

The VP for Research and Economic Development is the Institutional Official for the institution for IRB purposes through the Federalwide Assurance Agreement.

The IRB shall have authority to determine if an activity constitutes human subjects research or exempt status research as defined in federal regulations. The IRB shall employ a review process which conforms to the Federal Policy for Protection of Human Subjects, and the current assurance, between University of South Alabama and DHHS Office of Human Research Protections.

2.1 Agreements to provide IRB review of research conducted by unaffiliated investigators

Occasionally the University of South Alabama may be asked to provide IRB review for investigators who are unaffiliated with the institution. Circumstances in which this arrangement might be considered would typically involve a study based at University of South Alabama in which the unaffiliated investigator is collaborating. It will generally not be considered appropriate to extend IRB oversight to research by unaffiliated investigators in which University of South Alabama is not otherwise engaged. All requests for University of South Alabama to serve as the IRB of record for an unaffiliated investigator should be referred to the [Director, Office of Research Compliance and Assurance](#). The Director, in consultation with the IRB and the Institutional Official as appropriate, will determine whether the institution will agree to extend IRB oversight to the unaffiliated investigator. If the decision is that the University of South Alabama will provide IRB oversight for the unaffiliated investigator, the Director, Office of Research Compliance and Assurance will be responsible for executing an "Unaffiliated Investigator Agreement" documenting this arrangement. In most instances this agreement will apply to a single research project; less often, to a defined group of studies involving the unaffiliated investigator.

2.2 Agreements for deferral of IRB review from one FWA institution to another

On some occasions when two FWA institutions are engaged in the same research study, it may be appropriate for one institution to rely on the IRB of the second for review and continuing oversight of that research. Circumstances in which this arrangement might be considered would typically involve studies primarily based at

one institution, with somewhat peripheral involvement by investigators at the other. In effect, this constitutes a deferral of the right of review by the institution with lesser involvement, which retains responsibility for ensuring compliance with all IRB requirements. An “IRB Authorization Agreement” is the form of agreement executed between the institutions to document this delegation of IRB oversight. The University of South Alabama may be either the institution deferring to another institution or the institution to which the IRB review is delegated. All requests for such delegations should be referred to the Director, Office of Research Compliance and Assurance. The Director, in consultation with the IRB and the Institutional Official as appropriate, will determine whether the institution will agree to the deferral. If the decision is to agree to the IRB delegation, the Director will be responsible for executing the agreement.

2.2.1 Human Research Activities Performed at Other Institutions

All research activities performed by, or under the direction of, USA personnel or which use University resources or facilities, must comply with applicable USA policies and procedures, regardless of funding and whether performed in USA facilities or at offsite locations.

2.2.2 Requirements for Approval of Research at Non-USA Facilities

Any human subjects research conducted in whole or in part outside of USA facilities must be reviewed and approved by USA IRB prior to initiation if it satisfies any of the following criteria.

- It is conducted by or under the direction of USA personnel in connection with his or her USA responsibilities.
- It uses USA property, facilities, or resources to support or carry out the research.
- The name of the University of South Alabama is used in applying for funds (intra or extramural).
- The name of the University of South Alabama is used in explanations and/or representations to subjects.
- The investigator plans to use his/her University of South Alabama association in any publication or public presentation resulting from the research.
- Non-public information from USA will be used to identify or contact human research subjects or prospective subjects.

2.3 Number and Scope of IRBs

The Institutional Official has authorized two IRBs to review research involving human participants conducted by faculty, staff and students of the University. In general, IRB applications involving biomedical research or clinical trials are assigned to IRB #1

(Biomedical Research). Research involving educational, social and behavioral sciences are reviewed by IRB #2 (Non-biomedical).

University Related Documents

SOP: Human Research Protection Program

HISTORY

Effective Date:

Revisions: November, 2018