

## Human Subjects

The University of South Alabama holds its faculty to the highest standards for respecting the rights and welfare of persons involved as subjects of research. This also includes the responsibility of faculty to supervise their students' research. The Office of Research Compliance and Assurance administers and enforces University-wide procedures for protecting human research subjects. At the core of these procedures is the Institutional Review Board (IRB) charged with reviewing research involving human subjects.

All research conducted at the University of South Alabama involving human participants, their records, or materials from a human source must be reviewed and approved by the Institutional Review Board (IRB) prior to the commencement of the research activity or favorably screened by the IRB for exemption. The proposal must comply with the University's Federal-wide Assurance (an agreement on file with the U.S. Department of Health and Human Services (DHHS), in accordance with Federal Policy 45 CFR 46). A detailed explanation of these University policies may be obtained from the IRB Guidelines Manual posted on the human subjects website.

The IRB has oversight responsibility for the review of all University projects which involve human participants to ensure that the rights and welfare of the participants are adequately protected. In most cases, the IRB review involves approval of a clearly worded consent form which assures that the participant is fully informed of the risks inherent in participation and of the benefits which might be reasonably expected. The IRB's jurisdiction includes projects which involve the participation of University of South Alabama personnel, including members of the faculty, employees, students, hospital and clinic employees, as well as use of the facilities of the University of South Alabama and affiliated hospitals and clinics. Any project that is done in cooperation with an outside affiliate also requires IRB approval. All research is subject to audit by the Office of Research Compliance and Assurance and university, state and federal regulatory agencies.

Approved research must be renewed at least once annually, or more often as recommended by the IRB. No student or faculty research involving human subjects may proceed until it has been approved by the IRB or favorably screened by the IRB for exemption from such review. Any revisions or amendments to the approved research activity must be submitted to the IRB prior to implementing the new activity in order to determine the need for additional committee review.

The Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rule provides additional protection for protected health information (PHI), which is defined as "individually identifiable health information" including demographic information collected from an individual. Compliance with the Privacy and Security Rule requires that each institution "must train all members of its workforce on the policies and procedures with respect to protected health information, as necessary and appropriate for the members of the workforce to carry out their function within the covered entity." This education requirement applies to investigators and research staff (research coordinators, research assistants and other key research personnel) who are conducting human subjects research that involves protected health information and falls within the covered entity. **USA is a hybrid entity; the Privacy and Security regulations are principally limited to covered entities to include: USA's hospitals, clinics, Mitchell Cancer Institute, Psychology Clinic, and the Speech and Hearing Clinic.** Individuals conducting human subjects research who fall within the covered entity must complete the online HIPAA research tutorial at: <http://199.33.132.100/hipaa/index.htm>.

Any unanticipated problem involving risks and/or complications to participants or others must be reported immediately by telephone to the IRB. A written report of such a problem must also be submitted promptly.

Additional information and appropriate institutional forms are available at:

<http://www.southalabama.edu/researchcompliance/humansubjects.html>

Investigators and their key personnel are required to complete education in research involving human participants prior to the start of the project. (Note: research that meets exemption category #4 [i.e., retrospective chart reviews] does not require completion of training).