

# **University of South Alabama**

## **Policy on Regulatory Issues**

### Overview

Sponsored research at the University of South Alabama strives to maintain the highest level of compliance with all regulations and regulatory bodies to which it is responsible. Certain regulatory are defined in the Office of Management and Budget circulars; others are driven by internal University policies and procedures.

### Animal Care & Use Committee

The Institutional Animal Care and Use Committee (IACUC) is a federally-mandated committee that oversees and approves all use of animals in research and teaching. No animals may be purchased or used without prior approval by the committee. The Comparative Medicine office will provide guidelines and application forms for animal use protocols. Investigators and animal facilities are subject to unannounced federal inspections and semi-annual inspections by the IACUC. Violations of federal regulations or university policy can result in loss of the privileges to use animals and cancellation of grants by federal and private funding agencies. (Source: USA College of Medicine Faculty Reference Manual, 1996)

### Human Subjects Committee

The Institutional Review Board (IRB) is a federally-regulated (45 CFR 46) university committee which requires all research that in any way involves human subjects, materials or information from a human source be pre-approved by the IRB. Exemptions are allowed by the regulations, but the IRB, not the individual investigator, must determine which projects are exempt, and exemptions must be documented. The IRB office will provide guidelines and instructions for preparing submissions to the committee. The committee and investigators are subject to unannounced federal inspections. Penalties for violations can include loss of all federal funding to the entire institution. (Source: USA College of Medicine Faculty Reference Manual, 1996)

### Institutional Bio-safety Committee

Biological hazards are defined as human pathogens, and regulations administered by OSHA are in effect for classification and use of such materials. These hazards include pathogenic organisms such as viruses, bacteria, parasites, fungi, etc. which may infect humans, and specified recombinant DNA activities. All research use of biological hazards, including human or primate blood, body fluids and tissues, must be registered with the Biosafety Committee. Clinical use of such materials is not registered with this committee. Faculty are responsible for training technical staff in the use of safe laboratory procedures, and must keep a copy of the Biosafety manual (the "Red Book"), available from the Institutional Biosafety Committee (IBC) office, in research laboratories. Regulations are also in place for clinical facilities. Procedures for handling biohazardous materials and accidents are found in the University of South Alabama Medical Center's Hospital Policy Book II. Doctor's Hospital's procedures are in the

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Administrative Policy Manual. These manuals are placed in all departments and nursing stations. (Source: USA College of Medicine Faculty Reference Manual, 1996)

### Radiation Safety Office

There are extensive Federal and State regulations governing the purchase, storage, use and disposal of radioactive materials and the use of radiation emitting equipment. All users must be licensed and are responsible for assuring that their technical staffs are trained. There is a comprehensive Radiation Safety Procedures Manual that should be requested from the Radiation Safety Office well in advance of any intent to use ionizing radiation. Licensees receive authorization for specific isotopes in limited amounts. (Source: USA College of Medicine Faculty Reference Manual, 1996)

### USA Research Policies

The following policies concerning sponsored research are contained within the Faculty Handbook, updated 5/28/99.

- Animal Care and Use Policy
- Consulting Policy
- Financial Conflict of Interest Policy
- Human Subjects - Institutional Review Board
- International Programs Policy
- Inventions, Discoveries, Patents, and Copyrights Policy
- Scientific Misconduct Policy