1. Purpose

This policy establishes responsibilities for the identification, classification, and control of biological hazards, and the use of recombinant DNA. The University will pursue biological safety through ensuring prudent practices to protect both people and the environment from biological hazards and will conform to state and federal biosafety directives and guidelines. The NIH Guidelines require an Institutional Biosafety Committee (IBC) be established to ensure that research conducted at or sponsored by the University complies with the National Institute of Health (NIH) Guidelines and NIH/CDC Biosafety in Microbiological and Biomedical Laboratories. This requirement is primarily met through the review and approval of all applicable research by this review body. The University’s concern is for all biosafety issues, but in particular, it is concerned with activities involving:

- Infectious agents
- Recombinant DNA
- Select Agents
- Potentially biologically hazardous materials

Non-University entities renting, leasing, or otherwise using University property, equipment or facilities, that are using or storing biological material or agents identified as potential biological hazards must notify the Office of Research Compliance and Assurance. The University has the authority to prohibit unacceptable use and storage of materials.

2. Applicability

This policy applies to all research, sponsored and unsponsored, conducted under the auspices of the University. This policy applies to all University locations.

3. Definitions

Biosafety promotes safe laboratory practices, procedures, and the proper use of containment equipment and facilities among University staff and visitors.
Biological materials include:

- Pathogenic agents (bacteria, fungi, viruses, parasites, prions, and select agents)
- Plants, animals or derived waste which contain or may contain pathogenic hazards
- Human and nonhuman primate tissue, blood and body fluids
- Administration of hazardous materials to animals

Laboratory Personnel - refers to anyone, including students and trainees, conducting research on or otherwise handling biohazardous material.

Principal Investigator – the faculty member or other University employee in whose assigned space a research activity is conducted. The Principal Investigator is responsible for compliance with all institutional policies and procedures and the safety of all visitors, students, staff, and other faculty working in their designated laboratories.

Recombinant DNA Molecules - recombinant DNA molecules are defined as either molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or DNA molecules that result from the replication of those molecules described above. Both the recombinant DNA molecules and organisms and viruses containing recombinant DNA molecules are included in this definition.

Select Agents – infectious agents and biological toxins which have been declared by the Department of Health and Human Services (DHHS) or by the United States Department of Agriculture (USDA) to have the potential to pose a severe threat to public health and safety.

4. Policy Guidelines

University research involving biological materials must be reviewed and approved by the Institutional Biosafety Committee (IBC) prior to initiation of the work. The IBC review process is coordinated by the IACUC/IBC Administrator in the Office of Research Compliance. University projects involving the use of biohazardous materials at other institutions should receive Institutional Biosafety Committee (IBC) approval from the cooperating institution.

A detailed overview of the University’s biological safety program policies and procedures is found in the USA Biosafety Manual and Exposure Control Plan.

4.1 Responsibility

It is the University's policy that planning and implementation of control measures will be a part of every laboratory activity in which biological hazardous materials are used. Responsibility for the control of biohazards/recombinant DNA and the safety of employees and the public rests with the following individuals and groups.
4.1.1 Principal Investigators (PI)

The PI is accountable for all activities occurring in the lab and is responsible for full compliance with applicable regulatory standards, guidelines, and policies/procedures set forth by the University. The PI will:

- Establish, follow, and enforce rules, procedures, and methods for the proper control of biohazardous agents, organisms, and recombinant DNA
- Comply with University policies involving handling, storage, disposal, inventory, security/access, and transportation of biological hazards
- Make the initial determination of the required level of physical and biological containment in accordance with NIH and the Center for Disease Control (CDC) Guidelines
- Adequately train personnel in safety practices. The PI or designee must provide protocol-, agent- and laboratory-specific training.
- Ensure that all safety and containment equipment is maintained in good condition and functionally verified as necessary
- Report any significant problems or potential exposures via the University’s online Incident Reporting System. Instructions for submitting incident reports are posted on the Biosafety website
- Amend IBC protocols before changes in personnel, methods, locations, or biohazardous material use occur
- Report any deviations from approved protocols and procedures; and describe the actions taken to rectify the error and ensure compliance with future actives
- Renew approved projects with the IBC every three years

4.1.2 Institutional Biosafety Committee

The IBC will use the biosafety levels (BSL) published by the CDC, NIH, and the USDA as the usual standards of containment to be set for work with a given biological agent. They will:
• Review and approve recombinant DNA/RNA research projects for compliance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*

• Review and approve select agent research

• Review and approve research with all other potentially infectious materials

• Review any significant violation of policies, practices, and procedures reported by the Office of Research Compliance and Assurance

• Review and advise on matters relating to the safe handling, transport, use and disposal of biological materials

• Review of policies, programs, and directives regarding biological hazards in research and animal care activities

• Conduct start-up/new lab inspections, as applicable. This involves an assessment of containment facilities and practices to ensure they are appropriate for the biological hazards and affiliated procedures.

• Annually inspect registered research laboratories

4.1.3 IACUC/IBC Administrator

The IACUC/IBC Administrator is a professional staff member in the Office of Research Compliance. This individual works closely with the IBC, the Executive Director, and Research Compliance to ensure that research with biologically hazardous materials and organisms at the University is conducted in accordance with all applicable local, state and federal regulations. The IACUC/IBC Administrator will:

• Oversee the registration review process and communicates with the IBC for registration review

• Prepare IBC agenda/minutes

• Provide administrative support to the IBC and PIs

• Notify the PI of the outcome of a registration review

• File the IBC Annual Report for the University of South Alabama to the NIH/Office of Science Policy

• Interface between the IBC and other University oversight committees like the Institutional Animal Care and Use Committee (IACUC) and the Institutional Review Board (IRB).

4.1.4 Laboratory Personnel will:

• Complete all required training

• Wear and properly maintain any personal protective equipment necessary to perform each assigned task

• Use engineering controls and safety equipment properly
• Follow good personal and laboratory hygiene practices
• Read, understand, and sign off on laboratory-specific procedures
• Inform the PI if any deficiencies are noted in the laboratory facility, equipment, and procedures
• Report to their PI any incident that results in injury or exposure to a hazardous substance.
• Report any significant problems or potential exposures via the University’s online Incident Reporting System. Instructions for submitting incident reports are posted on the Biosafety website
• Inform their PI of any personal condition such as illness, medications, pregnancy, or reduced immunity which could make their work more hazardous to themselves and others
• Know what to do in case of an emergency

5. Procedures

5.1 Registration and Review of Work with Biohazardous Materials

All work with biohazardous materials must be registered with the IBC using the Biosafety Application Form and IACUC/IBC Application (wizard form) submitted via IRBNet. The IACUC/IBC Administrator will coordinate the review and approval with the IBC. The PI responsible for the proposed research may attend the scheduled meeting of the IBC, on their own volition or through invitation, to clarify any problems or to brief the committee on the proposed research. The PI is responsible for responding to any requests for additional information in a timely manner. The Biosafety review will:

• Determine appropriate risk groups and biological safety containment levels
• Identify recombinant or synthetic nucleic acid molecule activities
• Determine the adequacy of the laboratory for the research activities
• Determine and establish appropriate biosecurity measures
• Determine bloodborne pathogens exposure risk
• Determine and develop necessary and appropriate training/training tools
• Determine medical surveillance needs
• Comply with all applicable regulations
• Determine appropriate shipping and transport procedures
• Identify related environmental issues (waste handling, facility ventilation)
• Assist emergency response planning.

Registrations expire three years from the date of first approval. The Office of Research Compliance and Assurance will provide 60 and 30 day notices of expiration.

Additionally, the IBC must be notified using the amendment process before:
• New agents and materials are brought into the laboratory
• New procedures are conducted with existing agents
• Location of existing work changes
• Addition of personnel

6. Enforcement

The Committee has final authority to approve or disapprove activities involving the use of biological materials.

The responsible parties for oversight and enforcement of this policy are:

**Policy Oversight** – Institutional Biosafety Committee
**Policy Enforcement** – Office of Research Compliance and Assurance

7. Related Documents

- University Biosafety Manual and Exposure Control Plan
- USA Biosafety Website
- NIH Guidelines for Research Involving Recombinant DNA Molecules
- CDC/NIH Biosafety in Microbiological and Biomedical Laboratories, (BMBL), 5th Edition
- DHHS/USDA regulations controlling the use of Select Agents & Toxins (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121)