# TABLE OF CONTENTS

- **PURPOSE** ....................................................................................................................... 3
- **POLICY STATEMENT** .................................................................................................... 4
- **RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR** ....................................... 4
- **INSTITUTIONAL BIOSAFETY COMMITTEE** ............................................................... 5
- **BIOSAFETY OFFICER** ................................................................................................. 5
- **WORKING WITH BIOHAZARDOUS MATERIALS** ...................................................... 6
- **RESEARCH ANIMALS IN THE MEDICAL CENTER** ................................................... 7
- **SHIPPING** ....................................................................................................................... 7
- **SELECT AGENTS AND TOXINS** .................................................................................. 8
PURPOSE

This policy establishes responsibility for the proper use of biohazardous agents, including recombinant DNA, infectious agents and biological toxins in research and other educational activities at the Medical University of South Carolina in order to protect students, faculty, staff, the community and the environment.

This policy is intended to ensure compliance with all applicable local, state and federal guidelines and regulations for research involving biohazardous materials. Such governing documents include:

<table>
<thead>
<tr>
<th>GOVERNING DOCUMENT</th>
<th>PURPOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH Guidelines for Research Involving Recombinant DNA</td>
<td>Oversight of research involving recombinant DNA.</td>
</tr>
<tr>
<td>Biosafety in Microbiological and Biomedical Laboratories, ed. 5</td>
<td>Safety guidelines provided by the NIH and CDC for work involving biohazards.</td>
</tr>
<tr>
<td>Select Agent and Toxins Regulations (42 CFR Part 73, 9 CFR Part 121, 7 CFR Part 331)</td>
<td>Federal regulations requiring oversight of possession and use of biological agents and toxins that have the potential to pose a severe threat to public, animal or plant health or to animal or plant products.</td>
</tr>
<tr>
<td>US PATRIOT Act</td>
<td>Federal regulation preventing “Restricted Persons” from gaining access to biological agents, toxins or delivery systems for reasons other than reasonably justified peaceful purposes.</td>
</tr>
<tr>
<td>International Air Transport Association Dangerous Goods Regulations</td>
<td>Regulations covering shipments of dangerous good/hazardous materials via air or internationally.</td>
</tr>
</tbody>
</table>
POLICY STATEMENT

All Principal Investigators (PIs) shall assume primary responsibility for the proper use, handling and disposal of all biohazardous agents in research or other educational activities conducted under their supervision ensuring compliance with the Governing Documents and MUSC policies applicable to their research. To further protect students, faculty, staff, the community and the environment, the Institutional Biosafety Committee (IBC) and the Biosafety Officer are authorized to review and monitor all research and other educational activities involving biohazardous agents, whether such research is funded or not. Failure to comply with this policy will result in a review by the IBC and possible suspension or revocation of approval or privileges by the IBC to work with biohazardous agents.

The Medical University of South Carolina reserves the right to impose additional terms and conditions on investigators who conduct research or engage in teaching activities involving biohazardous agents which may be harmful to humans, animals or the environment.

RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

The responsibilities of the Principal Investigator shall include the following:

- Instruction and training of laboratory staff in the practices and techniques required to ensure safety, including laboratory practices, proper emergency response and notification procedures in the event of an accident, injury, exposure or potential exposure. The Principal Investigator must also familiarize his/her staff with the symptoms of exposure and other pertinent information about the biohazardous agents, human materials or recombinant DNA molecules used in the research or educational activity before allowing laboratory personnel to work with such materials;

- Supervising the laboratory staff’s safety performance to ensure that the required safety practices and techniques are continuously employed;

- Informing the laboratory staff of the reasons for any precautionary medical practices advised or requested, such as immunization or serum collection;

- Selecting and providing personal protective equipment to all laboratory staff members based on the procedures used in the laboratory and the individual requirements of the staff members;

- Maintaining written documentation for all training activities, which includes instruction in laboratory safety procedures, for all laboratory staff personnel;
• Investigating and reporting in writing to the IBC and the Biosafety Officer any significant problems or incidents pertaining to the operation and implementation of containment practices and procedures;

• Complying with all applicable federal, state and IBC regulatory requirements and with the specifications of the approved research or education activity.

INSTITUTIONAL BIOSAFETY COMMITTEE

The MUSC Institutional Biosafety Committee (IBC) has been established to conduct initial and continuing review of all research proposals and projects involving recombinant DNA as outlined in the National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (April 2002)


The IBC also reviews work with infectious agents and biological toxins. The IBC shall have at least five (5) members so selected to collectively have experience and expertise in recombinant DNA technology and microorganisms, microbiological techniques and the potential risk to public health or the environment from these materials. At least two (2) members shall not be affiliated with the institution (apart from their membership on the IBC) and shall represent the interest of the surrounding Charleston community with respect to health and protection of the environment. All appointments shall be made by the Associate Provost for Research as recommended by the IBC Chairperson/Vice Chairperson. This committee reports to the Associate Provost for Research.

IBC applications can be submitted online via the ERMA system: erma.musc.edu

BIOSAFETY OFFICER

The MUSC Biosafety Officer (BSO) serves as a voting member on the IBC and performs laboratory inspections to ensure research involving biohazards can be performed in compliance with Governing Documents and any additional stipulations of the IBC. The Biosafety Officer will determine whether laboratories undergoing inspection have met satisfactory levels of compliance. Laboratories failing to meet the required standards will be re-inspected until such time that a satisfactorily completed lab inspection is achieved. At a minimum, all laboratories will be expected to comply with the standards for containment and safety practices described in the Center for Disease Control/National Institutes of Health publication, *Biosafety in Microbiological and Biomedical Laboratories*, ed 5:


Guidance for successful completion of lab inspections is available at:

www.musc.edu/biosafety/BSL2
The BSO can serve as a point of contact for faculty requiring assistance with IBC applications, laboratory inspections or other matters involving application, interpretation or compliance with the Governing Documents.

The BSO can be contacted via the Biosafety Officer’s webpage: www.musc.edu/biosafety

WORKING WITH BIOHAZARDOUS MATERIALS

It is the responsibility of the principal investigator to acquaint members of his/her laboratory with risks associated with working with biohazardous materials and agents. Each principal investigator (PI) must develop a biosafety plan that identifies the hazards present in his/her laboratory and the specific practices and procedures that need to be followed in order to reduce the risks of working with these biohazardous agents.

It is the PI’s responsibility to give specific training relevant to requirements for working in an environment with biohazardous materials that may result in deleterious effects to laboratorians, any fetus they may carry or close associates such as household contacts. Laboratory personnel should be advised of specific hazards and be required to read and to follow the biosafety plan prepared by the PI. Special care should be taken to advise at risk populations. At risk populations include, but are not limited to: immunocompromised individuals, those individuals who may be or may become pregnant and individuals of child bearing age.

Specific biohazards to pregnant women and their fetuses include, but are not limited to, those agents in the TORCH group including T, *Toxoplasma gondii*, O, *Treponema pallidum* (syphilis), R, rubella, C, cytomegalovirus (CMV) and H, herpes simplex virus. However, there is also evidence that a number of other viruses including, but not limited to, adenovirus, coxsackie virus, Epstein-Barr virus, hepatitis B virus, human parvovirus and varicella-zoster virus may result in adverse pregnancy outcomes. Further, bacterial agents of special concern are those classified as BSL3 agents and those BSL2 agents with known consequences to the fetus such as *Streptococcus agalactiae*, group B *Streptococcus* (GBS) and *Listeria monocytogenes*.

In addition to participating in training, reading and following the biosafety plan, it is also the responsibility of the laboratorian to inform their immediate supervisor of any change in their health status (such as pregnancy, taking medications resulting in reduced immunity, etc.) that may results in the employee becoming an at risk individual. Furthermore, the laboratorian may wish to consult with student or employee health and/or their personal physician to seek guidance with respect to how to best manage the risk. Appropriate action should be taken by the PI/supervisor to safeguard the health of the individual and, if necessary, the developing fetus. A written, confidential, signed plan outlining the management of the specific risk shall be placed in the laboratorian’s personnel file acknowledging their understanding and acceptance of the management plan.
RESEARCH ANIMALS IN THE MEDICAL CENTER

Research involving animals performed in the medical center must comply with MUSC Medical Center Policy 128. [https://www.musc.edu/medcenter/policy/Med/C128.pdf](https://www.musc.edu/medcenter/policy/Med/C128.pdf). This policy requires Institutional Animal Care and Use Committee (IACUC) approval for research involving animals.

The PI is responsible for registering the intended research proposal with the Patient Safety Committee for their review, comments and recommendations, which will be forwarded to the Hospital Operations Committee for subsequent approval.

The Principal Investigator is responsible for notifying Infection Control of pending research and providing the protocol. Recommendations will be provided through the Infection Control Committee (ICC) and the Biosafety Officer.

Research involving biohazardous agents (recombinant DNA, infectious agents and biological toxins) in animals must have IBC approval. A lab inspection will be provided by the Biosafety Officer and must be deemed as satisfactorily completed before research can commence.

The Infection Control Department and the Biosafety Officer possess the authority to immediately stop and study failing to adhere to the infection control recommendations set forth by the IBC and ICC.

SHIPPING

MUSC personnel shipping or transporting biological materials must be trained and certified to perform these functions in accordance with regulations set forth by the U.S. Department of Transportation (DOT) and the International Air Transport Association (IATA). The Biosafety Officer shall assist MUSC personnel in obtaining training to ship biological materials and acquisition of permits for possession or transfer of such materials.

The following webpage provides guidance for MUSC personnel shipping biological materials and provides a link to CATTS based shipping training: [www.musc.edu/biosafety/Shipping](http://www.musc.edu/biosafety/Shipping)

Federal import, export and/or transport permits may be required for shipping etiological agents. The Principal Investigator is responsible for obtaining the proper permits for possession, use and transfer of biohazards. The Biosafety Officer can be contacted to provide assistance in obtaining the proper permits. Guidance is available at: [www.musc.edu/biosafety/Permits](http://www.musc.edu/biosafety/Permits)
SELECT AGENTS AND TOXINS

The Select Agent and Toxin program was created by the federal government in the wake of the anthrax mailings of 2001 in order to regulate possessions, use and transfer of biological agents which have been assessed to pose a severe threat to the public, animal or plant health or to animal or plant products. Registration is performed through the Centers for Disease Control (CDC) for human pathogens and toxins while etiological agents of plants and animals are registered through United States Department of Agriculture Animal and Plant Health Inspection Services (USDA/ADHIS). Overlap agents, such as *Bacillus anthracis* (anthrax), which pose a threat to both animals and humans can be registered with either government organization. *All possession, use and transfer of select agents at MUSC in any quantity must be registered with the IBC.* Federal penalties for violating the Select Agent and Toxin regulations include fines for individuals up to $250,000, imprisonment for up to 5 years and institutional fines up to $500,000 per incident.

The following links provide additional information pertaining to Select Agent and Toxin regulations.

Select agent and toxin registry program homepage
http://www.selectagents.gov/

Select agent and toxin list
http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html

Exclusion criteria for attenuated strains
http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20Exclusions.html

Permissible amounts of toxins exempted from registration with the federal government
http://www.selectagents.gov/Permissible%20Toxin%20Amounts.html