Definitions:

Research animals (RA) – Research animals can either be “purpose bred”, conventional or feral animals. “Purpose bred” animals such as common laboratory rodents are bred specifically for use in research. Some species are specifically bred and raised in a disease free environment not to just control all naturally occurring pathogens but to eliminate them completely. Conventional animals are from various and uncontrolled health backgrounds. Usually, they have received vaccinations and/or treatment for specific diseases. Feral animals have been obtained from their natural habitat. Feral animals pose the greatest risk because of the indigenous microbial flora. These animals may harbor known and unknown human pathogens. Domestic cats and dogs can be “purpose bred” but most are conventional animals obtained from animal dealers or shelters. The latter animals often have been exposed to and are harboring many diseases common to that species. Even “purpose bred” cats and dogs may still harbor naturally occurring agents that may be transmissible to humans. Farm animals (horses, cows, pigs and sheep) are conventional animals.

Principle Investigator (PI) - The medical professional who is overseeing the clinical/research trial. The PI is responsible for ensuring that Institutional Animal Use and Care Committee (IAUCC), Institutional Biosafety Committee (IBC) and all MUSC Medical Center policies are adhered to.

Policy:

IBC is responsible for ensuring that any RA experiment involving recombinant DNA and/or infectious agents is conducted with proper facilities, procedures, and practices to minimize potential risk to public health or the environment. The Biosafety Officer will inspect the MUSC Medical Center facility to be used as laboratory space to assist the PI, his/her staff and members of the MUSC Medical Center facility to maintain and use safe conditions and procedures in their research. Upon completion of satisfactory facility inspection and resolution of discrepancies, appropriate Biosafety Level (BSL) signs will be provided to the PI for posting in the MUSC Medical Center facility during the time of the experiment.
The IAUCC reviews all research activities involving animals and must approve those activities before work can be conducted.

A. Approval:

1. All RA projects using noninvasive hospital equipment and/or patient care areas must be reviewed and approved by the IAUCC. If recombinant DNA or infectious agents have been administered, the IBC must review and approve prior to beginning the study protocol.

2. The PI is responsible for submitting the protocol to the Patient Safety Committee for their review, comments and recommendations, which will be forwarded to the Hospital Operations Committee for subsequent approval.

3. 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. These recommendations will be noted on the attached form and will be signed by the ICC representative, the Biosafety Officer and the PI. See attachment 1.

4. A safety protocol based on these recommendations should be written by the PI and signed by those directly involved in the project. This will ensure all staff know the safety precautions to take.

5. Employee Health Services will be informed of the Research study proposal by the PI.

B. Responsibility for Research Animals in the Hospital:

1. The PI has the ultimate responsibility to comply with all hospital approved standards and procedures which ensure the safety of the healthcare workers, patients and visitors. The RA will be transported in a thoroughly cleaned cage(s) with fresh bedding. The cage is to be draped to conceal it from view. RA will be transported through the least traveled hallway to and from procedure area. RA will board only empty elevators. The transportation route for each project will be determined based on the location of the RA, and the hospital equipment being utilized. If the animal(s) is accidently released, Infection Control should be notified immediately.

Only IAUCC trained research personnel will transport, handle, position or restrain animals. IAUCC trained research personnel is responsible for monitoring the animals vital signs and medication administration.

2. All research animal study procedures will be scheduled by the department manager when patients are no longer in the department. Research projects should not negatively affect patient care, scheduling of patients, and/or perception of patients and families. Times will be coordinated between the department manager and the PI.
Unanticipated patient needs will take precedent over prescheduled research times. The department manager will identify staff to assist in the research project. The department manager, PI/designee, Biosafety Officer and/or Infection Control Practitioner (ICP) will provide hospital staff with training and education to promote safety and minimize employees’ exposure to animals and other potential sources of infection. Staff and employee education will be completed prior to starting the project. The department manager will maintain a list of employees involved in each research study. The department manager will provide the scheduled research times to Infection Control, Safety, Security and Volunteer Services, Environmental Services, Occupational Safety Health Program, Employee Health Services and the Biosafety Officer.

3. If the project is to be performed at BSL 2, the appropriate BSL 2 signs should be displayed on all doors leading into the facility by the PI once the research animal arrives in the hospital department. The department manager/designee is responsible for ensuring this is done. The procedure cannot continue until proper signage is displayed. The department manager is to notify staff members and clinicians not involved in the study protocol that the area is a BSL 2 restricted area. The BSL 2 sign indicates that the designated facility is a secured “laboratory” site and unauthorized personnel cannot enter or exit.

4. Personal protective equipment (PPE) is required for all persons in attendance during the study project and will include:
   a. Fluid resistant disposable gowns.
   b. Exam gloves.
   c. Full face protection covering the eyes, nose, mouth and respiratory tract may be necessary based on the specific pathogen involved in the study.

5. All hospital equipment will be protected from direct contact with the RA. Barriers should be fluid resistant and disposable. All environmental surfaces/equipment will be cleaned with a hospital approved disinfectant. Disinfectant directions regarding appropriate use and recommended contact time will be followed.

6. After the RA have been returned to transport cages, PPE will be removed and placed in biohazard bags provided by the PI. Hands will be washed immediately after removal of PPE. Biohazard bags will be returned to the PI’s lab for proper disposal.

7. Employees will report any injuries/exposures immediately to the department manager and Employee Health Services for appropriate follow-up.

8. All disposable equipment will be returned to research lab for disposal. Any used sharps will be disposed of in a sharp’s container and returned to the PI’s lab for disposal.
9. The Infection Control Department or Biosafety Officer will have the authority to immediately stop any study that is not adhering to the infection control recommendations set forth by the IBC and ICC.

Appendices:

Appendix A - Animal Research Biosafety/Infection Control Approval/Recommendations
Appendix A

ANIMAL RESEARCH
BIOSAFETY/INFECTION CONTROL
APPROVAL/RECOMMENDATIONS

RESEARCH PROJECT NAME/NUMBER________________________________________

PRINCIPAL INVESTIGATOR_______________________________________________

RECOMMENDATIONS/COMMENTS__________________________________________

ICC REPRESENTATIVE_______________________________________DATE______

BIOSAFETY OFFICER______________________________________DATE_______

PRINCIPAL INVESTIGATOR______________________________________DATE_____

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