Laws and Regulations Applicable to Research Utilizing Animals

Animal Welfare Act
Scientists and the universities in which they carry out animal-based research or teaching fall under the “Animal discomfort of animals while under experimentation”. The Act covers nonhuman primates, dogs, cats, rabbits, guinea pigs, hamsters, gerbils, and aquatic mammals and any other warm blooded animals used for biomedical research. Mice (Mus) and rats (Rattus) bred for research and birds are not covered by the Animal Welfare Act. In essence, the Act mandates unannounced inspections to ensure compliance with respect to humane care of animals used in research, their housing, and medical care including "the appropriate use of anesthetic, analgesic, or tranquilizing drugs, when such use would be proper in the opinion of the attending veterinarian at the research facility." Annual reports are required, which the Department and the Institutional Animal Care and Use Committee staff prepares on behalf of the university. The Animal Welfare Act regulations (9 CFR Subchapter A, Parts 1, 2 and 3) are, for the most part, in congruence with the Public Health Service Policy outlined below. The Animal Welfare Act also mandates an annual review of all research by the Institutional Animal Care and Use Committee and semiannual inspections of facilities by the Committee. In addition, procedures that may cause more than momentary or slight pain or distress to the animals require a written narrative description of the methods and sources (e.g., the Animal Welfare Information Center of the National Agricultural Library) used to determine that alternatives to these procedures are not available. This narrative is required in the animal protocol, which must be submitted to the Institutional Animal Care and Use Committee for review and approval. In addition, there must also be written assurance that the activities do not unnecessarily duplicate previous experiments. The protocol must also describe the qualifications and training of the personnel with respect to the procedures to be performed. These points are all addressed in the instructions accompanying the Institutional Animal Care and use Committee

Enforcement of Animal Welfare Act regulations is carried out by veterinary inspectors from Animal Care, United States Department of Agriculture who make unannounced site visits every year to research facilities. Reports filed by these inspectors are available to the public under the Freedom of Information Act.

Public Health Service Policy on Humane Care and Use of Laboratory Animals
The Public Health Service policy requires that each institution receiving Public Health Services (PHS) funds (e.g. from NIH) for research involving animals submit detailed information in an Animal Welfare Assurance Statement of Compliance regarding the institution's program for the care and use of animals. Salisbury University has such an Assurance on file with the NIH Office of Laboratory Animal Welfare (OLAW). Awardee institutions are required to identify an institutional official who is ultimately responsible for the institution's program for the care and use of animals, and a veterinarian qualified in laboratory animal medicine who will participate in the program. Institutions are also required to designate clear lines of authority and
responsibility for those involved in animal care and use in PHS-supported activities. The policy defines the role and responsibilities of Institutional Animal Care and Use Committees and will enhance the involvement of such committees in all aspects of PHS-supported research at those institutions. The policy requires that Institutional Animal Care and Use Committees include an individual unaffiliated with the institution, a veterinarian who has program responsibilities and who has training or experience in laboratory animal science and medicine, a practicing scientist experienced in research involving animals, and a member whose concerns are in a nonscientific area. The policy requires institutions to develop mechanisms to review and approve those sections of applications for PHS funds that relate to the care and use of animals (Vertebrate Animals Section) before PHS funds may be awarded. Salisbury University intends to implement mechanisms which will assure that all uses of animals for research, testing or instruction will be in accordance with the principles outlined below.

**U.S. Government Principles for Use of Animals**
These principles were prepared by the Interagency Research Animal Committee. The committee's principal concerns are the conservation, use, care, and welfare of research animals. Its responsibilities include information exchange, program coordination, and contributions to policy development.

**U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training**
The development of knowledge necessary for the improvement of the health and well-being of humans or animals requires *in vivo* experimentation with a wide variety of animal species. Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible institutional official shall ensure that these principles are adhered to:

I. The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. 2131 *et.seq.*) and other applicable Federal laws, guidelines and policies.

II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.

III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and *in vitro* biological systems should be considered.

IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.

V. Procedures with animals that cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.
VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided as indicated.

VIII. Investigators and other personnel shall be appropriately qualified and experienced to conduct procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.

IX. Where exceptions are required in relation to the provisions of these principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an institutional animal care and use committee. Such exceptions should not be made solely for the purposes of teaching or demonstration. Failure to adhere to these regulations, policies and guidelines could lead to severe sanctions including civil and/or criminal penalties, loss of funding and university disciplinary action.

**Institutional Review of Animal Protocols**

*Animal Care and Use Committee*

The Institutional Animal Care and Use Committee (IACUC) oversees the University's animal care and use programs, facilities and procedures and ensures the appropriate care, use and humane treatment of animals being used for research, testing and education. The IACUC is also responsible for reviewing all animal use protocols, ensuring compliance with federal regulations, inspecting animal facilities and laboratories and overseeing training and educational programs. The IACUC serves as a resource to faculty, investigators, technicians, students, and staff, providing guidance in planning and conducting all animal use procedures in accordance with the highest scientific, humane, and ethical principles. The faculty members of this committee are appointed by the Provost.

*Alternatives to Animals in Research*

The University shares society's concern that animal-based research should be appropriate and use no more animals than is necessary. Therefore, all scientists are urged to consider techniques that use minimal numbers of animals and are asked if they have investigated alternative methods to animal experimentation at the time of submission of research grant applications and animal use protocols for Animal Care and Use Committee.

*Use of Animals in Teaching Laboratories*

The IACUC policy regarding the use of animals in teaching laboratories is that 1) the use of animals in teaching is appropriate, 2) students will not be required to participate in the use of animals in teaching exercises against their will, 3) when possible, alternatives to the use of live
animals be explored, and 4) the guidelines established by the Institutional Animal Care and Use Committee should be observed in all courses using animals for teaching.

**Protocol Submission**
Research activities which use live vertebrate animals require annual review and approval by the Institutional Animal Care and Use Committee. In order to accomplish this all investigators must submit experimental protocols on the **Salisbury University Animal Protocol Form**. Some research activities which use tissue acquired from dead vertebrate animals may also involve annual review and approval by the Institutional Animal Care and Use Committee. In order to accomplish this all investigators must submit the **Animal Tissue Protocol Form**. Please contact the IACUC to determine if your research involving vertebrate animal tissue requires the submission of the **Animal Tissue Protocol Form**. Periodically, updates are made to these forms. To prevent delays in processing the protocol, download and use the newest version of the protocol template from the URS website. After approval, the detailed protocol must be resubmitted and reviewed every three years; abbreviated annual renewal forms must be completed to assure continued access to animal use in the intervening two years. Requests for significant changes to previously approved protocols must be submitted on the appropriate amendment form. Completed forms should be submitted to the Institutional Animal Care and Use Committee as indicated below. The protocol review forms have been designed to provide the committee with the necessary information to adequately review the proposed animal work. The questions asked are required by both the Federal Animal Welfare Act regulations and the Public Health Service.

**Public Health Service Policy.**
Institutional Animal Care and Use Committee approval is necessary for all vertebrate animals used in testing, research, and training at Salisbury University. All investigators will be required to provide protocol approval numbers at the time of ordering animals or arranging for billing. Amendments must be approved before the new procedures can be performed. Submission of an amendment is not sufficient; it must go through the review process and be approved. All individuals involved in the handling or procedures performed on animals must be included in the protocol.

**Committee Review of Protocols**
Protocols must be submitted by the first business day of each month in order for the Institutional Animal Care Committee to review it during the committee’s monthly meeting on the third Thursday of the month. Protocols will be assigned to individual members of the Committees who will act as primary reviewers. These reviewers will contact the investigator with any questions or suggestions before the meeting in order to facilitate approval of protocols. In this situation, the full committee grants approval for the protocol. Protocols can also be reviewed by the designated review system appointed by the Chair, who has the authority to approve the protocol, require modifications to secure approval, or request full committee review. For additional information on protocols, amendments, change in personnel, etc. contact the Institutional Animal Care and Use Committee.
Training in Animal Care and Use
Qualifications of investigators and the students and staff working with them are assessed by the Institutional Animal Care and Use Committee during review of protocols. Assessment of training is also monitored by University Research Services. Training of individuals in the appropriate research animal techniques is provided in several ways. All faculty, staff and students working with animals are required to complete the online training on animal care and use. The course modules explain the function of the Institutional Animal Care and Use Committee, federal and state laws as well as institutional policies governing the use of animals in biomedical research and the occupational health program for the care and use of animals. All individuals listed on an approved animal protocol must complete the required training modules before animals can be ordered.

Animal Resources
Sources of Research Animals
All animals used in this institution are purchased from commercial suppliers and dealers. SU maintains a list of approved animal vendors, and all vertebrate animals must be ordered through the listed vendors. To have a new vendor listed, please contact University Research Services. No vertebrate animals may enter any Salisbury University animal facility or lab without an IACUC approved protocol. Orders from approved vendors must be processed through the University Research Services.

Animal Purchasing
All animal-based research must be approved by the Institutional Animal Care and Use Committee. To assure this, all investigators will be asked to provide the identification number of the approved protocol (protocol number) at the time they are placing orders for animals. Investigators must make sure that the protocol number used is correct for the procedure and species to be used. All personnel listed on an approved protocol must complete the online animal care and use training modules before animals will be ordered. The number of animals purchased will be debited from the approved number of animals in the protocol. Once the approved number is reached, the protocol must be amended to request additional animals. Animals are delivered to Salisbury University at a central receiving dock. After arriving, animals are checked for accuracy and condition and then transported to the proper animal facility for housing. Any animals arriving without an Animal Resources purchase order number will not be delivered.

Veterinary Medical Services
In accordance with the generally-accepted tenet that comfortable, healthy, genetically and nutritionally appropriate animals kept under optimal environmental conditions are more likely to yield fruitful research results and in compliance with the various laws and accreditations under which Salisbury University operates, veterinary medical services are available as the need arises. When an investigator, research staff member, fellow, student, technician or any other person associated with institutional animal use believes an animal is abnormal, sick, in
discomfort, or otherwise requiring aid, a call for veterinary care should be initiated. It is essential that clinical calls be initiated by the investigator, student, fellow or technician at the earliest sign of any abnormality. **Animal care is the responsibility of the principal investigator. The veterinary staff is available for consultation and advice if problems arise.**

**Occupational Health and Safety**

Salisbury University is concerned about the safety and welfare of its faculty, staff and students. We are committed to alerting individuals to potential work-related health risks and counseling them on methods to avoid workplace hazards. All faculty, staff, students and fellows are responsible for compliance with appropriate safety and health standards as issued by Salisbury University. Faculty, staff, students and fellows are to follow safe work practices and report all unsafe conditions. Faculty and supervisors must train employees, fellows and students to develop and maintain safe work practices. Faculty and supervisors must frequently inspect the workplace to ascertain unsafe conditions. Faculty and supervisors should be aware that Salisbury University has policies addressing disciplinary action for failure to comply with safety policies. Principal investigators are responsible for ensuring that all individuals working under their supervision have a safe working environment and are educated of the potential hazards associated with their jobs.

All individuals (faculty, staff, fellows and students) who are exposed to animals, living or dead tissues, body fluids, wastes, bedding, their living quarters or equipment involved in the care and use of animals are required to participate in the Animal Exposure Surveillance Program (AESP). Details of the AESP are provided in the AESP handbook. The AESP allows Salisbury University to monitor a person’s level of risk in handling animals, offer appropriate prophylactic protection from diseases associated with animal handling, assess current health status, and monitor health during employment or training at Salisbury University. People with impaired immune function may be at increased risk from hazards associated with animal care and use. Moreover, a large number of workplace chemicals, physical and biologic agents can damage the reproductive systems of both male and female workers, resulting in infertility, spontaneous abortion, developmental impairment or death in an embryo, fetus or child. These risks are also discussed during AESP enrollment. Principal investigators and departmental administrators are responsible for forwarding the names of faculty, postdoctoral fellows, and students with exposure to animals, body fluids, waste, bedding or equipment involved in the care and use of animals to Student Health Services.

**Laboratory Hazards**

While this is not intended to be a complete list, the following information is provided to highlight hazards common to most laboratory environments as well as specific hazards involving the use of animals. Precautions, treatments, and procedures for reporting any incidence that may occur is also provided.
Physical Hazards

Bites and Scratches
All animals are capable of inflicting bites and scratches. Small animals, such as rodents and rabbits usually deliver relatively minor wounds. Larger species like cats, dogs and nonhuman primates can inflict severe wounds. All bite and scratch wounds can become infected by the normal bacterial flora of the animal's mouth or toenails, or by bacterial flora from the individual's skin. To prevent bites and scratches use proper animal handling techniques. Protective garments, such as gloves, gauntlets and long-sleeved laboratory coats limit injury to the hands and restraining devices. In case of a bite or scratch from a laboratory or wild animal, immediately wash the wound with plenty of soap and water, contact your supervisor immediately so appropriate medical measures and diagnostic procedures can be performed.

Splashes
In case of a splash or exposure to potentially infectious material involving your eyes, nose or mouth, flush the site with water for fifteen minutes, and proceed to the Student Health Services.

Wet floors
Wet floors are a prominent physical hazard in animal areas. Do your part in promptly reporting or eliminating wet floor surfaces. If it is necessary to walk across wet floors, use extreme caution. Proper non-slip shoes or protective boots are recommended for environments that consistently have wet floor surfaces. When possible, post wet floor signs to alert coworkers and visitors of this hazard.

High Pressure Water and Steam
High pressure water and steam are physical hazards for animal handlers who utilize equipment such as autoclaves, power washers, and cage washers. Avoid skin contact with high-pressure water and steam. When unloading an autoclave, verify that the pressure is at zero prior to opening the door. Slowly crack open the door and allow the steam to gradually escape. Allow materials in the autoclave to cool for at least 10 minutes prior to removal and use heat resistant gloves as necessary.

Electricity
Electricity is an important physical hazard in the care and use of animals. Salisbury University Policy prohibits use of extension cords, unless an emergency situation is declared by administration. Use caution with power equipment, radios and other electrical devices, particularly in areas with wet floors, and water or steam sources.

Biological Hazards

Laboratory Animal Allergies
Allergic reactions to animals are among the most common conditions that adversely affect the health of people laboratory workers eventually develop occupationally related asthma, and related symptoms of coughing, wheezing, and shortness of breath, which can persist for
months or years after exposure ceases. Rats, mice, guinea pigs, rabbits and cats are probably among the most important inducers of allergies in laboratory animal workers. Allergens present in the urine, saliva, fur, dander, bedding and other unknown sources are aerosolized during handling of the animals, clipping hair, cage changing, dumping bedding and cleaning the animal rooms. Personal protective equipment such as laboratory coats, gloves, face masks, respiratory equipment, biosafety cabinets and dump stations reduce the risk of developing allergies. Individuals who are already sensitized, for example due to allergies to domestic cats, are in the highest risk category. Laboratory animal workers should undergo screening to identify those at risk and participate in the monitoring program. If you develop symptoms of job related animal allergies contact your supervisor and Student Health.

Allergies are an important risk associated with animals. If you feel you may suffer from an allergy to the animals you work with, report to your supervisor and to the Occupational Health Services for your campus to obtain appropriate treatment. Allergies can usually be managed by a combination of medical management and workplace strategies. It’s important to consult with Student Health Services to determine the cause of your allergy in order to manage it effectively.

The following practices may help to reduce your exposure to animal allergens:

1) When possible, perform animal manipulations in a ventilated hood or a biosafety cabinet. If this is not possible, a dust mask or surgical mask may be helpful.
2) When you’re not working in a hood or cabinet, make sure that the animal room or other work area is adequately ventilated and that all the air handling equipment in the room is in good order. If there is doubt, your supervisor can ask facilities to measure the number of air changes in the room.
3) Don’t wear your street clothes when working with animals. Wear protective clothing. Reduce your skin contact with animals by wearing gloves, sleeve covers and long-sleeved lab coats.
4) Wash your hands frequently. Wash hands, face and neck before leaving the work area.
5) Avoid touching your hands to your face while working with animals and animal equipment.
6) Use hair nets or wash your hair on leaving the facility. Allergens in the hair will result in significant exposure to others and may be carried home resulting in prolonged exposure.

Keep cages and your work area clean.

Blood borne pathogens
Common exposure routes for infectious agents are inhalation of aerosolized agents, splash of infectious materials to the skin or mucous membranes, or exposure via needle sticks, cuts and other sharps injuries. Any exposure to potentially infectious materials should be reported via the incident reporting protocol previously outlined. Exposure to the mucous membranes should receive on-site first aid by flushing with copious amounts of running water. Exposure to the skin should receive on-site first aid by washing the affected area with soap and water. After on-site first aid, proceed to Student Health Services.

The highest risk of infection from blood borne pathogens occurs from needles and sharps. Sharps are defined as any item that can puncture human skin or a red trash bag. Needles and
sharps are never to be discarded directly into the general waste stream or red trash bags. All needles and sharps must be discarded directly into approved sharps containers. Approved sharps containers must be placed in all areas where sharps may be utilized or generated. Filled sharps containers must be properly secured prior to disposal, and are disposed in red bags or biohazard boxes lined with red bags, as appropriate for your building. Hand washing is the most effective way to prevent infections to you and coworkers. All animal areas should be equipped with a hand sink that is stocked with liquid soap and paper towels. Wash your hands often, using soap and water. All potentially infectious materials and all contaminated equipment or apparatus should be decontaminated before being washed, stored or discarded. Autoclaving is the preferred method for decontamination and sterilization.

**Containment of Potentially infectious material**
The containment of infectious agents is performed according to the applicable Biosafety level: *Biosafety Level I* generally involves agents of no known or minimal potential hazard to laboratory personnel and the environment. *Biosafety Level II* includes all Biosafety Level I practices plus partial containment equipment such as biological safety cabinets, protective barriers such as lab coats, gloves, and face protection, and limited access to the laboratory. Biosafety Level II work involves agents of moderate potential hazard to personnel and the environment. *Biosafety Level III* is designated for research utilizing indigenous or exotic agents that may cause serious or potentially lethal disease as a result of exposure by the aerosol route.

**Zoonotic Diseases**
Zoonotic diseases are those diseases of animals capable of infecting humans. Salisbury University requires all students and faculty to complete online training modules in zoonotic diseases. Additionally, faculty should provide students with specific information related to species utilized by their labs. A number of zoonotic diseases are a potential hazard in institutions conducting animal based research. Such diseases are rare in rodents, rabbits, cats and dogs raised indoors for research purposes. There is a higher possibility of contracting a zoonotic disease from random source cats, dogs, farm animals, nonhuman primates and animals obtained from the wild (e.g. wild rats, prairie dogs, woodchucks). Humans may also become infected with agents introduced into animals for research purposes. All such biohazardous material must be registered in the Salisbury University Biological Inventory (see research registrations below) in addition to having an approved IACUC protocol (See protocol submissions above). In case of injury or unexplained illness associated with such animal use, inform the medical personnel treating you of the possibility of infection with that agent.

**Chemical Hazards**
Material Safety Data Sheets (MSDS) are fact sheets that summarize information about the hazards, handling procedures, emergency first aid and required protective equipment regarding each substance. Health, Safety and Environment has MSDS sheets for all substances used at Salisbury. Should you have a concern or question about any substance in your workplace,
discuss the situation with your supervisor. If the supervisor is unable to answer your questions, contact Health, Safety and Environment.

Labeling
All containers must have a label of the common name in English to identify the contents.

Cleaning agents
Cleaning agents are a common form of chemical utilized by animal handlers. All cleaning agents must be stored in labeled and tightly capped containers at all times. Consult the product label or the MSDS for appropriate protective equipment when handling cleaning agents. Always wear a face shield and gloves when handling and dispensing concentrated cleaners.

Corrosives and Flammables
Corrosive materials are the most common form of toxic substances found in a typical laboratory and are frequently used in animal facilities. These include strong acids, strong bases and oxidizing agents. When handling corrosive substances ensure that skin, face and eyes are protected by clothing, laboratory coats, aprons, and eyewear and/or face shields. Flammable materials are clearly labeled as such on the product label. All flammable materials not in immediate use should be stored in an approved flammable materials storage cabinet. Existing approved cabinets have doors which positively latch. Newly acquired flammable material storage cabinets must have doors which self-close and self-latch.

Anesthetic agents
Anesthetic agents have long been associated with health hazards. Chronic exposure to these agents may have possible effects on the liver, kidney, nervous system and reproductive system. Engineering controls, such as systems that scavenge waste gases from the source are the best methods to control these hazards.

Excess chemicals
Excess chemicals should be disposed of through the Salisbury Hazardous Material Disposal Program. Call the standard waste stream or in the biohazardous waste stream. Excess chemicals should not be labeled as “waste”. The Department of Health, Safety and Environment makes the determination of what is hazardous waste.
In the event of a spill of a hazardous material which is chemical in nature:
A. Identify all materials by common name.
B. Estimate how much is spilled.
C. Evaluate the degree of danger to patients, staff or visitors.
D. Evaluate the degree of danger to equipment or property.
Immediately call the emergency number for your campus.
If your skin or eyes are exposed to a chemical, flush the affected area with large amounts of running water. After on-site first aid, proceed to the Occupational Injury Clinic for your campus.

Research Registration Programs
In order to control and monitor biological hazards in the work environment, Salisbury University has established the Salisbury University Biological Inventory in accordance with federal regulations and guidelines. It is the responsibility of the principal investigator to assure that individuals working with the registered agents and materials are appropriately trained and that the protocols are conducted in compliance with Salisbury University policies.

Registration of Research with Pathogenic and/or Oncogenic Material
It is the responsibility of each principal investigator to register with Health, Safety and Environment all potential biohazardous agents and materials presently in use for investigative research and for all agents maintained in stock culture collections for research and/or teaching purposes.

Registration of Research with Recombinant DNA
All principal investigators conducting recombinant DNA research are required to register such protocols with the Department of Health, Safety and Environment and the Institutional Biosafety Committee. Research involving recombinant DNA requires strict adherence to the most current NIH guidelines.

Incident and Injury Reporting
It is the policy of Salisbury University that all incidents which result in an injury to faculty, staff or students be appropriately documented and reported. In the event of a work-related incident the following should be contacted:

Medical Emergency
If the accident or injury is life threatening, or if the injured individual believes his or her injury is of an emergent nature, call the emergency number for your campus:

Emergencies
All faculty, staff and students should be aware of the emergency protocols for their campus. In the event of fire or other emergency: Part of the emergency response protocols for Salisbury University includes hazard-warning signage. This yellow placard is required to be posted at the entrances to all laboratories and research areas to indicate the hazards contained therein. These yellow warning placards must contain the names and emergency telephone numbers of two individuals who are familiar with the hazards contained within the area. Emergency responders may refuse to enter a placarded area prior to discussing the hazards contained therein with the emergency contact individuals. It is the responsibility of the principal investigator or the area supervisor to include the emergency contact information on the yellow placards. If your area does not have the proper warning signage at its entrances, contact Environmental Health and Safety.