

MEDICAL UNIVERSITY OF SOUTH CAROLINA
Assurance of Compliance with Public Health Service
Policy on Humane Care and Use of Laboratory Animals

Assurance #A3428-01

Medical University of South Carolina (MUSC), hereinafter referred to as Institution, hereby gives assurance that it will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

I. APPLICABILITY

This Assurance is applicable to all research, research training, experimentation, biological testing, and related activities, hereinafter referred to as activities, involving live, vertebrate animals supported by the Public Health Service (PHS) and conducted at this institution, or at another institution as a consequence of the subgranting or subcontracting of a PHS-conducted or supported activity by this institution.

“Institution” includes the following branches and major components of the Medical University of South Carolina: Medical University of South Carolina, Medical University Hospital Authority, MUSC Foundation, Foundation for Research Development.

II. INSTITUTIONAL POLICY

A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.

B. This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."

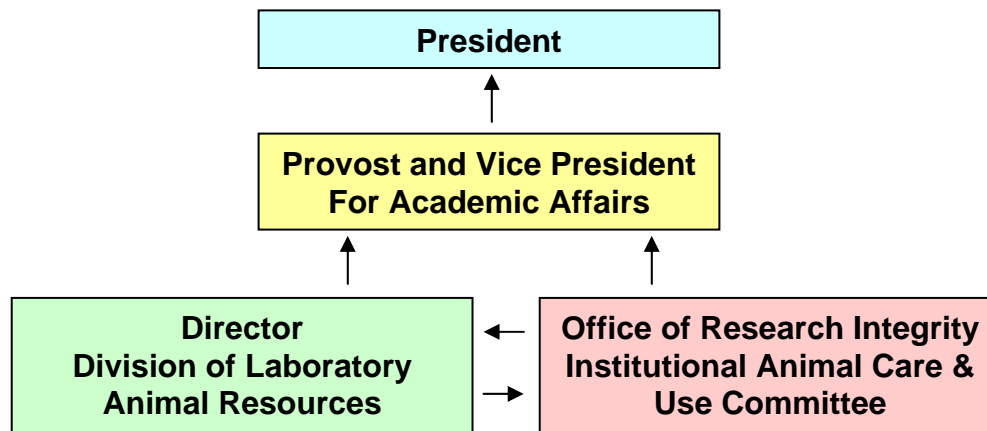
C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this institution will make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance as well as all other applicable laws and regulations pertaining to animal care and use.

D. This Institution has established and will maintain a program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals (Guide).

III. INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE

A. The lines of authority and responsibility for administering the program and ensuring compliance with this Policy are:

- John R. Raymond, M.D.
Provost and Vice President for Academic Affairs
(Institutional Official)
*Stephen M. Lanier, Ph.D.
Associate Provost for Research
has signature authority and may serve as alternate Institutional Official in Dr. Raymond's absence
- M. Michael Swindle, D.V.M.
Director, Division of Laboratory Animal Resources
(Institutional Veterinarian)



B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are:

All of the veterinarians have academic appointments in the Department of Comparative Medicine (DCM). Their service appointment is in the Division of Laboratory Animal Resources (DLAR).

M. Michael Swindle, D.V.M. is Director of DLAR, Professor and Chairman of the DCM and Professor, Department of Surgery. He is a Diplomate of ACLAM and ECLAM. As Director, DLAR, he is administratively responsible for the institutional animal care and use program for all vertebrate animals. He is a full-time employee of MUSC and 100% of his time is devoted to the program in lab animal medicine, including administration, teaching and collaborative research. He has had 38 years of experience.

Kathy Laber-Laird, D.V.M., M.S. is a Professor in DCM. She is course director for DLAR training courses and serves as veterinary director of the VA Animal Research

Facility and Administrative Vice Chairman of DLAR. She is a Diplomate of ACLAM and has had 23 years of experience. She has a 5/8:3/8 VA:MUSC appointment.

Alison C. Smith, D.V.M., is a Professor in DCM and Department of Medicine, Division of Cardiology. She serves as Clinical Director and is responsible for oversight of the clinical activities, the surgical unit and post surgical care programs. She is a Diplomate of ACLAM and has had 23 years of experience. She is a full time employee of MUSC and performs administration, teaching and collaborative research.

Sarah Bingel, V.M.D., Ph.D. is an Associate Professor DCM and Pathology and serves as a diagnostic pathologist with 40 years of experience. She is a full time employee of MUSC who will be retiring in 2008.

Kristi L. Helke, D.V.M., Ph.D., is an Assistant Professor in DCM and the Department of Pathology. She is a full time employee who provides pathology and diagnostic service. She is Board Eligible for the American College of Veterinary Pathologists and has 7 years of experience.

DLAR has responsibility for and provides care for all warm blooded vertebrate animals at MUSC. No investigator-managed satellite facilities for these species exist or will be approved without notification to the PHS.

Investigators' laboratories provide care for fish, amphibians, reptiles and invertebrates. These laboratories are inspected as part of the semiannual inspection by the IACUC and must also provide a written SOP for husbandry for approval by the IACUC at the time of submission of a protocol.

DLAR provides the centralized surgical laboratories and fluoroscopic imaging laboratories for MUSC. For rabbits and large animals, major survival surgery may be performed only in the DLAR facilities as part of the DLAR program. Minor surgery involving topical procedures or subcutaneous implants of a minor nature may be performed in other facilities with IACUC approval.

DLAR personnel provide the post-surgical care program for these species at MUSC. They also provide technical services and collaborative research interactions.

C. This Institution has established an Institutional Animal Care and Use Committee (IACUC), which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy at IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, position titles, specialties and institutional affiliations.

D. The IACUC will:

1. Review at least once every six months the institution's program for humane care and use of animals, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual program evaluations are:

The following aspects of the program are reviewed: IACUC membership and functions; IACUC records and reports; veterinary care, personnel qualifications and training; and, occupational health and safety of personnel. The current Self-Study for Accreditation by AAALAC, International is also reviewed as part of the program evaluation. This Self-Study, which is updated semi-annually by the DLAR Director, follows the outline of the Guide and provides a complete description of the Institution's program for the care and use of laboratory animals. The document is distributed to all Committee members prior to the meeting at which the semi-annual report is reviewed.

2. Inspect at least once every six months all of the institution's animal facilities, including satellite facilities, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are:

A subcommittee of the IACUC, composed of at least two members, semi-annually inspects all animal facilities using the Guide for the Care and Use of Laboratory Animals (Guide) and the USDA Animal Welfare Regulations, 9 CFR Chapter 1, subchapter A, as applicable as a basis for evaluation. Review of the facilities includes animal housing and support areas; cagewash; aseptic surgery; and procedures areas, non-survival surgeries on large animals, laboratories, and rodent survival surgeries. All laboratories at MUSC are included in the inspection, including those which house animals >12 hours and/or perform surgical procedures. In addition, DLAR veterinarians or the IACUC may make unannounced inspections of any laboratory separate from the semiannual inspections. No Committee member wishing to participate in any evaluation is excluded.

3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy at IV.B.3. and submit the reports to the Institutional Official. The IACUC process for developing reports and submitting them to the IO is:

The report contains a description of the nature and extent of the institution's adherence to the Guide and the PHS Policy. If program or facility deficiencies are identified during the course of the IACUC's review and inspection, they are classified by the IACUC as significant or minor, and a reasonable and specific plan and schedule is developed for the correction of each deficiency. Final reports of the semi-annual evaluations/inspections are considered full committee actions. In accordance with USDA requirements, the reports are reviewed and signed by a majority of the IACUC members and include any minority IACUC views. Any failure to adhere to the plan and schedule which results in a significant deficiency remaining uncorrected is reported within 15 business days

by the IACUC, through the IO, to the Animal and Plant Health Inspection Service (APHIS) and any Federal agency funding that activity.

4. Review concerns involving the care and use of animals at the institution. The IACUC procedures for reviewing concerns are:

All concerns involving the care and use of laboratory animals are reported to and discussed at a convened meeting of the IACUC. Immediate action is taken by the Committee as necessary to resolve any issues that are or may be a threat to animal health or safety. Reporting of incidents or concerns about the care and use of laboratory animals may be performed anonymously via several pathways. Incidents may be reported to DLAR veterinarians, the IACUC or an anonymous hotline. All concerns are investigated and reported to the IACUC for potential action. All incidents and actions taken are reported through the IACUC to the IO and OLAW if necessary. It is institutional policy that persons are free to report incidents or concerns without fear of reprisal.

5. Make written recommendations to Institutional Official, regarding any aspect of the institution's animal program, facilities, or personnel training. The procedures for making recommendations to the IO are:

The semiannual report of the IACUC is sent to the IO. The report includes any deficiency and plan for correction. In addition, DLAR makes a facility and incident report to the IACUC at every convened meeting. Minutes of all meetings are sent to the IO. If the deficiency requires institutional funding or action for correction, the IO is responsible for ensuring that the deficiencies are corrected.

6. Review and approve, require modifications in (to secure approval), or withhold approval of those activities related to the care and use of animals as set forth in the PHS Policy at IV.C. The IACUC procedures for protocol review are:

All applications proposing the use of vertebrate animals are submitted to the Office of Research Integrity (ORI). This Office provides administrative oversight and staffing for the IACUC.

The IACUC meets monthly to review all proposals requiring full Committee review.

Regardless of the source of funding, all proposed projects involving the use of vertebrate animals are reviewed and approved by the IACUC to ensure that the projects will be conducted in accordance with the PHS Policy. This includes teaching proposals and proposals involving contract work. In making this determination, the IACUC must confirm that the research project will be conducted in accordance with the Animal Welfare Act insofar as it applies to the research project, and that the research is consistent with the Guide unless acceptable justification for a departure is presented. Further, the IACUC must determine that the project conforms to the institution's Assurance and meets all of the PHS Policy requirements.

All proposed projects involving the use of vertebrate animals are reviewed by the IACUC using a designated reviewer system. All members of the IACUC

receive a copy of the Vertebrate Animal Review Application (VARA). The IACUC Chair or Vice-Chair (or their designee) appoints a designated reviewer who will be assigned should no Committee member request full Committee review. The Committee is given a designated time frame to indicate which method of review is preferred. If any member feels that a protocol should go before the full committee, then its review must be deferred to the next full IACUC meeting. If no member requests full-committee review, the designated reviewer and a DLAR veterinarian act on behalf of the IACUC to approve the protocol, request additional information from the Principal Investigator (PI) to approve it, or refer it for full review. Members may share comments with the designated reviewers. A list of all protocols that were approved by designated review is provided at the next convened meeting of the IACUC.

If full committee review is requested, approval may be granted only after review at a convened meeting with a quorum of the IACUC, and with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of a research project in which the member has a conflicting interest except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the quorum.

Regarding the disposition of a protocol submitted for review by the full committee review method, the IACUC may make the following determinations:

- Approval
- Require modifications (to secure approval) when it is determined that no major revisions or clarifications are the required. The IACUC Chair or other designated reviewer(s) is assigned to review the PI's response and is empowered by the IACUC to approve the protocol without further review by the full committee. Any member of the Committee can request review of the PI's response. The PI must meet all conditions arising from the IACUC's review before final approval can be granted.
- Table the protocol with a request for additional substantive information or significant revision of the protocol. When a protocol is tabled, full committee review is required before further action can be taken.
- Withholding of approval

When the designated review method is used, the only options are the following:

- Approval
- Referral to full committee for review
- Requirement of modifications to secure approval

7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy at IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are:

All proposed significant changes to previously approved protocols are reviewed by the IACUC using a designated reviewer system. All members of the IACUC receive a copy of the applicable amendment form and any supporting

documentation. When the amendment form and any supporting documentation is sent out to IACUC members, the IACUC Chair or Vice-Chair (or their designee) appoints a designated reviewer who will be assigned should no Committee member request full Committee review. The Committee is given a designated time frame to indicate which method of review is preferred. If any member feels that a proposed significant change should go before the full committee, then its review must be deferred to the next full IACUC meeting. If no member requests full-committee review, the designated reviewer and a DLAR veterinarian act on behalf of the IACUC to approve the proposed significant change, request additional information from the PI to approve it, or refer it for full review. Members may share comments with the designated reviewers. A list of all proposed significant changes that were approved by designated review is provided at the next convened meeting of the IACUC.

If full committee review is requested, approval may be granted only after review at a convened meeting with a quorum of the IACUC, and with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of a proposed significant change in which the member has a conflicting interest except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the quorum.

Regarding the disposition of a protocol submitted for review by the full committee review method, the IACUC may make the following determinations:

- Approval
- Require modifications (to secure approval) when it is determined that no major revisions or clarifications are the required. The IACUC Chair or other designated reviewer(s) is assigned to review the PI's response and is empowered by the IACUC to approve the protocol without further review by the full committee. Any member of the Committee can request review of the PI's response. The PI must meet all conditions arising from the IACUC's review before final approval can be granted.
- Table the protocol with a request for additional substantive information or significant revision of the protocol. When a protocol is tabled, full committee review is required before further action can be taken.
- Withholding of approval

When the designated review method is used, the only options are the following:

- Approval
- Referral to full committee for review
- Requirement of modifications to secure approval

8. Notify investigators and the institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy at IV.C.4. The IACUC procedures to notify investigators and the institution of its decisions regarding protocol review are:

The IACUC notifies the PI in writing of its decision to approve or withhold approval, or of modifications required to secure approval. If the IACUC decides to withhold approval of an activity, it includes in its written notification a statement of the reasons for its decision and gives the PI an opportunity to respond in writing or the PI is asked to attend a convened meeting of the IACUC.

9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy at IV.C. 1-4 at least once every three years. The IACUC procedures for conducting continuing review are:

Continuing reviews of ongoing protocols are performed at intervals determined by the IACUC to be appropriate for the study, but no less often than once annually. Investigators are requested by the ORI staff to complete a Renewal Request Application where the investigator then assures that no changes have taken place since initial approval or notes that all significant changes have been submitted to the IACUC and approved prior to implementation. Responses are reviewed by an IACUC designee for assessment of the changes reported. Any changes to the approved activity that are deemed of sufficient magnitude to merit further consideration are presented to the IACUC. All of these dispositions are documented as official IACUC action.

Investigators are required to submit a new protocol at the time of triennial review. The IACUC conducts the triennial review of these protocols utilizing the same assessment criteria as new protocol submissions.

10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6. The IACUC procedures for suspending an ongoing activity are:

The IACUC or the Director, DLAR is authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6. The IACUC can suspend any activity at a convened meeting of a quorum with a vote of the majority of the quorum present. The action is reported to the IO who notifies OLAW with a full written explanation and a plan for correction of any issue. In the case of an immediate humane concern the Director, DLAR or Chairman, IACUC may suspend an activity until such time as the IACUC can convene and consider the issue. The IACUC is immediately notified if a suspension occurs and the suspension is subject to rapid review by the IACUC. The suspension must be sustained at a convened quorum of the IACUC, and with the approval vote of a majority of the quorum present.

E. The individuals authorized by this institution to verify IACUC approval of those sections of applications and proposals related to the care and use of animals are the IACUC Chair, the IACUC Vice-Chair, the IACUC Program Manager, the IACUC Administrator.

F. The occupational health and safety program for personnel who work in laboratory animal facilities or have frequent contact with animals is:

The Department of University Risk Management includes the following divisions: 1) Occupational Safety and Health; 2) Medical Risk Management; 3) Workers Compensation and Employee Health Services; 4) Insurance; 5) Radiation Safety. The Institution's program is described in the appropriate sections below and is in compliance with the Institute of Laboratory Animal Resources report, "Occupational Health and Safety in the Care and Use of Research Animals" and the CDC/NIH Report, "Biosafety in Microbiological and Biomedical Laboratories."

1. Occupational Health and Safety of Personnel

a. Hazard Identification and Risk Assessment

The Record of Circulation submitted to the Office of Research and Sponsored Programs for all research grants indicates the use of hazardous agents in projects involving the use of animals. If a hazardous agent use is proposed, the protocol is referred to either the Institutional Biosafety Committee (IBC) or the University Risk Management Office. DLAR is notified if such a protocol is used. Appropriate control measures are instituted depending on the protocol. These methods include environmental and personnel monitoring by the Radiation Safety Officer or the University Risk Management Office. The Director, DLAR is a member of the IBC and the Radiation Safety Council.

b. Personnel Training

- 1) When hazardous agents are used, personnel must be trained in the specific protocol for the agent. Each principal investigator must develop a biosafety plan which 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 hazardous agents. Special care is taken to advise at-risk populations. At-risk populations include, but are not limited to, immunocompromised individuals, those individuals who are pregnant, and individuals of child bearing age. It is also the responsibility of the laboratorian to inform their immediate supervisors of any change in their health status (such as pregnancy, taking medications resulting in reduced immunity, etc.). Laboratorians may also consult with Employee Health to seek guidance with respect to how best manage risk.
- 2) Lectures concerning zoonotic diseases and biohazards are included in the courses approved by DLAR. Personnel receive training for specific biohazardous protocols that are approved by the IBC. A mandatory OSHA course for all new university employees contains information on the possibility of diseases caused by exposure to animals. It includes information on allergies, bites and scratches, zoonotic diseases and exposure to biohazards. The existence of a program in Employee Health Services to address injuries, allergies and illnesses is explained. The DLAR SOPs and Investigator Handbooks contain basic information on biohazards and zoonosis. The information is available online on the DLAR website.

c. Personnel Hygiene and Protection

- 1) Personal Protective/Work Clothing Provided
Uniforms and lab coats are provided for DLAR personnel and laundered by the institution. Research staff members are provided with disposable outer clothing by DLAR. Staff members wear disposable gloves, gowns, face masks and shoe covers. Respirators are available if required.
- 2) Shower/locker rooms are provided in the Basic Science Bldg., Hollings Cancer Center and the Strom Thurmond Biomedical Research Building. Disposable outer clothing is discarded when leaving the facility.
- 3) Policies Regarding Eating, Drinking and Smoking in Animal Facilities
Eating and drinking areas are provided in employee lounges and offices. Eating, drinking and smoking are not allowed in research labs or animal housing areas. MUSC is a smoke-free facility; therefore, smoking must be done in designated outdoor areas.

2. Medical Evaluation and Preventive Medicine for Personnel

- a. An occupational health program is provided by Employee Health Services at MUSC. The program includes all personnel in DLAR, personnel working with biohazardous agents, and personnel with any contact with lab animals. The program includes:
 - A pre-employment physical and a physical thereafter is available upon request of personnel who believe they have a work related injury or illness. An annual physical which includes completing a risk-based assessment of the employee's duties is required.
 - Current immunization against diphtheria, tetanus, measles, hepatitis B and varicella.
 - Collection and preservation of frozen serum samples for reference values only if deemed necessary for biohazardous projects by the Institutional Biosafety Committee.
 - Personnel working with dogs, cats, and nonhuman primates have the option of taking prophylactic rabies vaccinations.
 - Personnel must receive an annual TB test.
 - Personnel working with pregnant sheep or fetal sheep must have a titer determination for Q Fever. Titers will be redetermined at least annually while actively working with sheep.
 - Any person suspecting an illness, allergy or health hazard due to their contact with lab animals or biohazards has the opportunity to address the question with the Biohazard Safety Committee and to have a physical examination by Employee Health Services.
Notices concerning the availability of the program are posted.
- b. Personnel involved with hazardous agents are included in the Occupational Health program as described above.

3. Animal Experimentation Involving Biohazards

- a. The institution requires approval from the Institutional Biosafety Committee (IBC) or the University Safety Office prior to release of IACUC approval. Review includes qualifications and training of personnel involved in the projects.
 - b. Changes from standard husbandry practices are dictated from the appropriate Committee when the protocol is approved. Facility supervisors are responsible for overseeing adherence to protocols. If appropriate, the reviewing Committee performs unannounced inspections of the animal study and housing area, i.e. radiation safety, recombinant DNA.
 - c. When hazardous agents are used, the room is dedicated to the protocol.
 - d. Anesthetic gases are scavenged into a central system and with F-Air canisters. Rodent surgery using inhalant agents is performed in a fume hood or in areas with exhaust fans.
4. Facilities, Procedures, and Monitoring for Biohazards

- a. Showers and change facilities are provided in all of the major facilities. Personnel are required to change clothes when entering and leaving the facility. Shower and change facilities are provided.
- b. Personnel are required to take an OSHA course as part of employee orientation. Protective gloves, goggles, face masks and respirators are provided as required.
- c. Special facilities are provided for Class II agents. Rooms in various facilities are designated to perform studies with hazardous agents on an "as needed" basis. Individual laboratories may perform acute exposures on animals or tissues under the oversight of the Radiation Safety Officer and the Biohazards Safety Officer. Institutional policy has been that agents providing a greater hazard than Class II which require specialized facilities may not be used.

The availability of isolator cubicles provides the capability of performing experiments with Class II agents. The Hollings Cancer Center has been designated as a Class II facility. The Basic Sciences Building infectious disease facility on the second floor also designated as a Class II facility. Exhaust air is filtered.

- d. All of the above protocols are handled using disposable outer clothing and microisolator cages. Monitoring of the safety practices are overseen by the Radiation Safety Officer and the Biohazards Safety Officer.

G. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein and the average daily inventory of animals, by species, in each facility is provided in the attached table.

H. The training or instruction available to the IACUC, scientists, animal technicians, and other personnel involved in animal care, treatment, or use is:

1. IACUC

Upon appointment, members are provided educational materials including the MUSC Animal Assurance; PHS Policy on Humane Care and Use of Laboratory Animals; the Guide; IACUC Handbook; Report of the AVMA Panel on Euthanasia; Animal Welfare Act, Regulations and Standards; Public Responsibility in Medicine & Research (PRIM&R) Resources; IACUC Guidebook; and MUSC Investigator's Handbook. They are periodically provided additional information such as reprints of relevant journal articles and guidance updates. Members are provided the chance to attend OLAW and PRIM&R meetings. On the job training also occurs during facility walk through and observation of the protocol review process. All members complete online training currently required of PIs and other lab personnel. Supplementary training opportunities are identified and offered to members when available.

2. Animal Care Personnel

Animal caretakers receive on the job training during orientation. A training course is periodically held in-house and is mandatory for DLAR personnel. Many of DLAR caretakers currently are certified by AALAS. Personnel are offered the opportunity to attend a regional AALAS or Consortium for Comparative Medicine course annually. Personnel attend the Lab Animal Science class offered by DLAR in the College of Graduate Studies in the fall semester following initial employment.

3. Investigators and Research Technicians

A course titled "Laboratory Animal Science" is offered in the fall semester for technicians and investigators. Class attendance is maintained and certificates for classes attended are issued at the end of the course.

An annual animal training session, which is mandatory for all graduate students, is conducted by the College of Graduate Studies. Class attendance rosters are maintained.

A mandatory orientation for all new employees of the institution includes information on the necessity for obtaining all appropriate research protocol approvals prior to implementing research projects. It also includes information on the availability of training from DLAR.

All personnel identified on animal protocols are required to complete appropriate online modules supplied by the Laboratory Animal Training Association (LATA) or Collaborative Institutional Training Initiative (CITI).

DLAR maintains educational tapes and slide sets on various aspects of laboratory animal science which can be viewed by investigators and technicians. Sign-in sheets are maintained.

DLAR periodically holds seminars on some aspects of lab animal science with outside speakers. Investigators and technicians are invited to attend. Sign-in sheets are maintained.

DLAR provides a manual for investigators which includes basic information on laws and regulations, animal ordering, animal use procedures and basic biological information.

DLAR veterinarians and technicians provide individualized training to investigators and technicians on an ongoing basis. DLAR also provides technical assistance and collaborative research. The IACUC may also identify individuals on protocols who require additional procedure-specific training. DLAR personnel report any problems with competence to the IACUC.

4. Reduction of Animals and Research Distress

Reduction of the numbers of animal used for each protocol is taught as a guiding concept in the DLAR courses. Environmental enrichment is provided for rabbits and large animals in their husbandry environment. Humane restraint slings are provided for swine. All protocols are reviewed with DLAR veterinarians to assure that appropriate means are used to alleviate pain and distress and that all procedures are designed to minimize animal pain or discomfort. The IACUC requires the investigator to provide a written description of the methods and sources used to determine that no alternatives were available for any protocol that may involve pain or distress. Any protocol that proposes unrelieved pain or distress must include appropriate scientific justification for withholding analgesia and requires full committee review and approval.

IV. INSTITUTIONAL STATUS

As specified in the PHS Policy at IV.A.2., as Category 1, all of this institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated and accredited by The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). All of this institution's programs and facilities (including satellite facilities) for activities involving animals have also been evaluated by the IACUC and will be reevaluated by the IACUC at least once every six months, in accord with IV.B.1. and 2. of the PHS Policy, and reports prepared in accord with IV.B.3. of the PHS Policy.

All IACUC semiannual reports will include a description of the nature and extent of this institution's adherence to the Guide. Any departures from the Guide will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC evaluations will be submitted to Dr. John Raymond, Provost and Vice President for Academic Affairs. Semiannual reports of the IACUC evaluations will be maintained by this institution and made available to the Office of Laboratory Animal Welfare (OLAW) upon request.

V. RECORD KEEPING REQUIREMENTS

A. This Institution will maintain for at least three years:

1. A copy of this Assurance and any modifications thereto, as approved by PHS.

2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations.
3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.
4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to Dr. John Raymond, Provost and Vice President for Academic Affairs.
5. Records of accrediting body determinations.

B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity.

C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. REPORTING REQUIREMENTS

A. At least once every 12 months, the IACUC, through Dr. John Raymond, Provost and Vice President for Academic Affairs, will report in writing to OLAW:

1. Any change in the status of the institution, any change in the description of the institution's program for animal care and use as described in this Assurance, or any changes in IACUC membership. If there are no changes to report, this institution will provide OLAW with written notification that there are no changes.
2. Notification of the dates that the IACUC conducted its semiannual evaluations of the institution's program and facilities (including satellite facilities) and submitted the evaluations to the IO.

B. The IACUC, through the Institutional Official, will provide the OLAW promptly with a full explanation of the circumstances and actions taken with respect to:

1. Any serious or continuing noncompliance with the PHS Policy.
2. Any serious deviations from the provisions of the Guide.
3. Any suspension of an activity by the IACUC.

C. Reports filed under VI.A. and VI.B. above shall include any minority views filed by members of the IACUC.

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institutional Official

Name: Dr. John Raymond, M.D.
Title: Provost and Vice President for Academic Affairs
Address: Room 213 Colcock Hall
179 Ashley Avenue
Charleston, SC 29425
Phone: (843) 792-3031
Fax: (843) 792-5110
Signature: _____
Date: March 26, 2008

B. PHS Approving Official

Name: Dr. Kim D. Taylor
Title: Senior Assurance Officer
Address: 6507 Rockledge Dr.
Bethesda, Maryland 20892-7982
Phone: (301) 402-4325
Fax: (301) 402-7065
Signature: _____

C. Effective Date of Assurance: April 8, 2008

D. Expiration Date of Assurance: April 30, 2012