I, R. Larry Dooley, as named Institutional Official for animal care and use at Clemson University, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

I. APPLICABILITY OF ASSURANCE

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS. This Assurance covers only those facilities and components listed below.

A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:
   Clemson University

B. The following are other institution(s), or branches and components of another institution:
   None

II. INSTITUTIONAL COMMITMENT

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 ensures 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 according to the Guide for the Care and Use of Laboratory Animals (Guide). The Guide for the Care and Use of Agricultural Animals in Research and Teaching (Ag Guide) is used as a supplement to the Guide.
E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

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 identified in a diagram that is appended as an attachment entitled Organizational Chart for the Animal Health Program and Institutional Animal Care and Use Committee (IACUC).

Clemson University has developed an institutional policy outlining the responsibilities and authority of the Attending Veterinarian. It can be accessed by clicking on the following link. http://media.clemson.edu/research/sponsored-programs/policies/attending-vet%20.pdf

B. The qualifications, authority, and percent of time contributed by the veterinarians who participate in the program are identified below.

Name: John Parrish, Attending Veterinarian & University Veterinarian.
Qualifications:
- Degrees. DVM in 1981 from Auburn University and Ph.D. in 1993 from the University of Alabama at Birmingham.
- Training/experience. Dr. Parrish is licensed in South Carolina and is a Diplomate in the American College of Laboratory Animal Medicine (ACLAM). He has twenty-five years of experience with a variety of laboratory animal species in military, commercial, and academic settings.

Authority: Dr. Parrish has direct program authority and responsibility for the Institution’s entire animal care and use program including access to all animals. He reports directly to the IO.

Time Committed to the Program: Full time employee – 100%

Name: Julie Helm, Field Veterinarian, at the Clemson University, Livestock Poultry Health Department-Animal Health Programs, Office of the State Veterinarian, Columbia, South Carolina.
Qualifications:
- Degrees: DVM
- Training/experience: Dr. Helm is a Diplomate of the American College of Poultry Veterinarians (ACPV) She is a Poultry Veterinarian for Clemson University Livestock Poultry Health Programs and coordinates the National Poultry
Improvement Program for SC since 1996. Dr. Helm is licensed in South Carolina.

**Authority:** Dr. Helm serves as a consultant and has delegated program authority and responsibility for the Poultry farm. Dr. Helm conducts semi-annual inspections and oversees the health programs for the University’s poultry research farm.

**Time Contributed to Program:** 5%

**Name:** Jeff Nordin, Contract Veterinarian for EDISTO Research and Education Center (EREC) in Blackville, S.C.

**Qualifications:**
- **Degrees:** DVM (University of Georgia Veterinary School in 1987)
- **Training/experience:** Dr. Nordin is licensed in South Carolina. He has been in private practice for 25 years working with cattle. He practices in Saluda, SC and acts as a contract veterinarian providing quarterly visits and emergency services as needed.

**Authority:** In coordination and consultation with Dr. Parrish, Dr. Nordin has delegated program authority for the Edisto facility and provides routine and emergency veterinary services as needed.

**Time Contributed to the Program:** Contract – 5%

The Attending Veterinarian also maintains a list of local veterinarians approved to provide veterinary services to the various Clemson farms. Provision of services must be pre-approved by the attending veterinarian or his designee.

Dr. Margaret Champion provides backup veterinary services for the Godley-Snell Research Center. Dr. Champion is a 1982 graduate of the University of Florida School of Veterinary Medicine and is the Director of the Veterinary Technician Training Program at Tri-County Technical College in nearby Pendleton, SC.

Veterinarians employed by the South Carolina Office of the State Veterinarian may be consulted for review of vaccination, preventive medicine, parasite control, SOP, certification and other disease management or control programs.

The University of Georgia Veterinary Hospital in Athens, Georgia is available for consultation and in-patient care.

C. The Institutional Animal Care and Use Committee (IACUC) at this Institution is properly appointed in accordance with the PHS Policy IV.A.3.a and is qualified through the experience and expertise of its members to oversee the institution’s animal care and use program and facilities. The IACUC consists of at least five members appointed by the President of Clemson University and its membership meets the composition requirements set forth in the PHS Policy at IV.A.3.b. Clemson University has developed an institutional policy outlining the responsibilities and
authority of the IACUC. It can be accessed at: http://media.clemson.edu/research/sponsored-programs/policies/iacuc-responsibilities.pdf

Attached is a list of the IACUC membership including the Chairperson and members of the IACUC and their names, degrees, profession, titles or 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 for the Care and Use of Laboratory Animals* as a basis for evaluation. The IACUC procedures for conducting the semiannual program reviews are as follows: The Animal Care and Use Program is initially evaluated by a subcommittee appointed by the IACUC chair. The findings are reviewed with the IACUC at a convened quorum of the voting members. Discussion and deliberation ensues to produce the final report. The OLAW Sample Semiannual Program Review and Facility Inspection Checklist is used to ensure the program’s overall effectiveness. *The Guide for the Care and Use of Agricultural Animals in Research and Teaching* is utilized when appropriate.

2. Inspect at least once every six months all of the institution's animal facilities including satellite facilities(s), using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows: Site/facility inspections and program evaluations are organized and coordinated by the IACUC Administrator in the Office of Research Compliance (ORC). The inspection group conducting the inspection and evaluation of facilities includes at least a veterinarian and one or more voting members of the IACUC.

Any member wishing to participate may do so. Any location where animals are housed for more than 12 hours is inspected by the IACUC. (AWAR §2.31, c, 2 and PHS Policy (III, B). The inspection report is reviewed and approved by a majority of a quorum of the committee at a convened meeting of the IACUC, and any minority views are included in the report to the Institutional Official.

The committee uses OLAWs Sample Semiannual Program and Facility Review Checklist, the NIH eighth edition of the *Guide for the Care and Use of Laboratory Animals* and the *Occupational Health and Safety in the Care and Use of Research Animals* as the basis for the evaluation and inspection of all laboratory animal facilities and programs. *The Guide for the Care and Use of Agricultural Animals in Research and Teaching* is utilized when appropriate.

3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy IV.B.3. and submit the reports to the Institutional Official (IO). The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows: The IACUC prepares written reports of the semi-annual evaluations which outline significant and minor deficiencies, as well as a reasonable and specific plan and timeline for correcting all deficiencies. The semiannual IACUC report also includes the nature and
extent of Clemson’s adherence to the Guide and all departures from the Guide are specifically named with reasons for the departure specified. The semiannual IACUC report on the evaluation of the entire animal care and use program and inspection of all animal facilities is approved at a convened meeting of the IACUC. Approval of the report requires signatures from a majority of a quorum of the IACUC. The report, including any minority views, is submitted to the Institutional Official. The Institutional Official acknowledges in writing receipt and review of the semi-annual report.

Any failure to adhere to the plan and schedule that results in a significant deficiency which remains uncorrected shall be reported in writing within 15 business days by the IACUC, through the Institutional Official, to 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 as follows: The IACUC posts procedures for reporting any deficiencies, or concerns regarding animal use and care in conspicuous locations throughout the campus and satellite facilities, as well as the IACUC/ORC website. A procedure and a form for reporting animal concerns can be obtained from the IACUC website or the ORC office. Any IACUC member or person from the ORC receiving oral or electronic notification of an animal concern may complete an animal concern form and submit it to the IACUC Administrator. The ORC has developed a checklist for evaluating animal concerns that is used to ensure consistency of review. The process clearly states that no employee, committee member, laboratory personnel or student shall be discriminated against or be subject to any reprisal for reporting violations in good faith. The information regarding reporting of concerns is also provided as part of the required mandatory animal care and use training.

Concerns about the treatment of animals or protocol noncompliance are reported to the IACUC. Reports may be made anonymously. The IACUC Chair, ORC Director and Attending Veterinarian review the complaint/concern immediately to determine if it is an accident/non-event/administrative issue, a potential concern, or an emergency situation as outlined in the IACUC Bylaws.

If it is determined to be an accident/non-event/administrative issue a discussion of the issue is added to the agenda of the next regularly scheduled IACUC meeting.

If it is determined to be an actual or potential animal concern then an IACUC subcommittee is appointed by the Chair/designee to investigate the situation. Animals are evaluated by the Attending Veterinarian or designee to document health status, and take any actions needed to secure the health and welfare of any animals involved in the concern. The subcommittee report is filed with the IACUC Chair, copy of the draft report is provided to the individuals involved in the investigation and the report is added to the agenda for the next regularly scheduled IACUC meeting.

If it is determined that the animal concern is an emergency, then immediate action is taken by the Attending Veterinarian or designee to place the animals under the
authority of the Veterinarian's care with written documentation submitted to the Chair. IACUC members are notified of the emergency and the Chair appoints a subcommittee to investigate the situation. An emergency IACUC meeting is called as soon as the subcommittee has findings to report and a quorum can be constituted.

The IACUC determines what action will be taken and immediately notifies the Principal Investigator of such action. Following review and evaluation of the report, the IACUC takes all actions consistent with federal regulations to assure animal well-being and compliance. The IACUC makes recommendations to the IO. The IO determines appropriate corrective actions and communicates those findings to the IACUC and/or to others the O deems appropriate. If the IACUC suspends or terminates an activity, the IO, in consultation with the IACUC, reviews the reasons for suspension/termination, then takes appropriate corrective action, and then reports the suspension/termination and corrective action with a full explanation to appropriate agencies (e.g., USDA-APHIS, OLAW, AAALAC), and any agency funding that activity. Please see Section III.D.10 for additional information regarding suspension of an activity.

5. Make written recommendations to the IO, regarding any aspect of the Institution’s animal program, facilities, or personnel training. The procedures for making recommendations to the IO are as follows: The Committee may recommend to the IO changes and improvements to the animal program or facilities necessary to maintain a high quality animal research program and to maintain compliance with all regulations. The IACUC Administrator prepares reports of the IACUC semiannual reviews and program reviews as well as any recommendations as set forth in the PHS Policy at IV.B.3. These reports and recommendations are forwarded to the Institutional Official.

6. Review and approve, require modifications (to secure approval), or withhold approval of those activities related to the care and use of animals as set forth in the PHS Policy IV.C.1-3. The IACUC procedures for protocol review are as follows: The IACUC meets monthly. The IACUC reviews all teaching, research and testing activities involving live vertebrates animals.

A. The Principal Investigator (PI) consults with Attending Veterinarian regarding veterinary care procedures and potential for pain and distress prior to submitting the Animal Use Protocol (AUP) to the IACUC Administrator in the Office of Research Compliance (ORC). The Attending Veterinarian assigns the pain category and reviews with the PI the methods for analgesia, anesthesia and euthanasia. The IACUC Administrator performs an administrative review of the AUP submitted to include the review of the protocol and, if applicable, the grant proposal. If needed, the IACUC Administrator provides the PI with a listing of information or sections of the application that need to be modified before it can be sent to the Chair. The IACUC Administrator sends the AUP to the Chair who determines the type of review (Full Committee or Designated Review) and assigns the reviewers. To expedite functions, if the Chair is not available, the Vice-Chair may make the assignments. The IACUC Administrator sends a communication to the IACUC members regarding the protocol, type of review and the names of the Primary and Secondary reviewers. Any Committee member may
request anytime in writing or subject to recording in the official minutes of a called meeting that a Designated Review be changed to a Full Committee Review prior to approval. While this request may be made initially verbally, such requests are submitted in writing to the IACUC Chair and the IACUC Administrator.

B. Full Committee Review. The Principal Investigator submits a completed AUP to the IACUC Administrator. Protocols receive Full Committee Review if the protocol includes the following:

- Major survival surgical procedure(s)
- Multiple survival surgeries
- Exceptions to recommendations in the ILAR Guide or Ag Guide
- Euthanasia methods that are not consistent with the AVMA Guidelines
- Studies where death is the experimental endpoint
- Experiments which involve any of the following
  - Burn studies
  - Head/spinal trauma
- Potential for more than minimal or transient pain, distress or discomfort not relieved by drugs
- Any procedure involving non-human primates, dogs or cats

When projects are funded, the AUP and the proposal are reviewed for congruency by the IACUC Administrator. An agenda listing all proposed activities to be reviewed along with written descriptions of all these activities involving the care and use of animals is provided to all IACUC members prior to the scheduled meeting. The names of respective primary and secondary reviewers on protocols requiring Full committee Review will be provided with the agenda.

Protocols assigned to Full Committee Review are assigned a Primary and Secondary Reviewer. If a member of the IACUC has been identified as having a conflict of interest, that member may not participate in the IACUC review or approval of the project, other than to provide information requested by the IACUC. The protocols are circulated to all members using a controlled access server. The Secondary Reviewer and other members shall post comments on the General Reviewers Form. The Primary Reviewer shall review the submission as well as the comments from the IACUC members on the General Reviewers Form. The Primary Reviewer contacts the PI to resolve any potential modifications and clarifications needed. The Primary Reviewer strives to ensure all items identified for correction are corrected before the IACUC meeting during which the protocol is discussed.

The Primary Reviewers completes the Initial Reviewer form within seven (7) calendar days of posting but not before the general review period has ended (i.e. 5 calendar days). If required, final review comments and recommendations are written in a language to allow direct posting to an e-mail that either the Primary Reviewer or the Chair sends to the PI. Minor changes agreed to by the PI and the Primary Reviewer
may be corrected in the submissions by the IACUC Administrator or the Primary Reviewer. Significant or extensive modifications will be made by the PI and submitted to the IACUC office as a revised protocol (AUP). The Primary Reviewer, Secondary Reviewer or the Chair presents the protocol during the convened meeting of the IACUC and recommends an action which includes, approval, modifications required to secure approval or withhold approval. Approval requires the approval vote of a majority of the quorum present. Members with conflicts of interest may not vote.

Clemson University has adopted the use of Designated Member Review (DMR) subsequent to Full Committee Review (FCR). This process is described on the next page.

The IACUC notifies the investigator in writing of its decision to approve, require modifications in order to secure approval or withhold approval. If the AUP is not approved as is, the investigator receives written notification stating the reasons, and outlining modifications required to receive approval. The IACUC Administrator prepares the approval letter for the Chair’s signature. A copy of the signed correspondence and a copy of the approved AUP are sent to the PI within one week. Copies are maintained in the protocol file in the ORC.

C. Designated Review. Submissions that do not require Full Committee Review may be assigned to Designated Review. (This process is sometimes referred to as Expedited Review.) The Chair is responsible for appointing the Designated Reviewer. Submissions for Designated Review are processed as described for Full Committee Review with the exception that a Secondary Reviewer is not assigned. If there are no calls for Full Committee Review within five (5) calendar days, the Designated Reviewer can approve the protocol or require modification to secure approval. Protocols that the Designated Reviewer cannot approve will be reviewed by Full Committee. If a member requests a Full Committee Review, a Secondary Reviewer is assigned and the activity is reviewed in accord with Full Committee Review procedures.

Procedures for the Designated Reviewer with regard to reviewing the IACUC members’ general comments and completing the form are the same as described under Full Committee Review. Should the Designated Reviewer decide not to address general reviewer(s) comments, the Designated Reviewer will inform the other reviewer(s) of the decision before final approval is given to allow a member or members of the IACUC the opportunity to call for Full Committee Review.

Minor changes agreed to by the PI and the Designated Reviewer may be corrected in the submissions by the IACUC Administrator or the Designated Reviewer. Significant or extensive modifications will be made by the PI and submitted to the designated Reviewer and the IACUC Administrator as a revised protocol (AUP).

After posting of the protocol on the secure drive, after review by the IACUC members, after approval by the Reviewer, and if a Full Committee Review is not requested, then the approval letter is signed by the IACUC Chair. Such notification is then sent to the
Principal Investigator. The IACUC Administrator prepares the official correspondence for the Chair's signature. A copy of the signed correspondence and a copy of the approved AUP are sent to the PI within one week and a copy maintained in the protocol file.

In accordance with USDA and PHS guidance (NOT-OD-09-035) the Clemson University's IACUC stipulates the following procedure for use of Designated Member Review (DMR) subsequent to Full Committee Review (FCR) when substantive information is lacking from a protocol.

As indicated by the signatures of the IACUC members on 5/13/09, CU Policy #17 states that a quorum of members at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification of an animal use protocol (AUP) is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised AUP and/or request FCR of the AUP. When this procedure is issued, the AUP approval date is the date that the designated member approves the study.

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 as follows:

Final determination of whether changes to an existing AUP can be made via amendment or submission of a new AUP is left to the discretion of the IACUC Chair and the ORC. The procedures described in the above sections for Designated and Full Committee review and approval of new protocols is used for review and approval of proposed significant changes.

Minor charges submitted as an amendment may be administratively approved by the Chair or the Attending Veterinarian. If it is judged by the IACUC Chair, in consultation with the Office of Research Compliance, that the changes in questions should be reviewed by a larger body, the amendment can then be submitted for either Designated or Full Committee Review. The IACUC Administrator may approve amendments for addition/deletion of qualified personnel after verification of training and MSP enrollment.

8. Notify investigators and the Institution in writing of its decision to approve, seek modifications in order to secure IACUC 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.4. The IACUC procedures to notify investigators and the institution of its decisions regarding protocol review are as follows: The PI is informed in writing regarding the IACUC actions to approve a new protocol, require modifications in order to secure approval or withhold approval.

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 IV.C.1.-5. at least once every three years.
The IACUC procedures for conducting continuing reviews are as follows. Ninety days prior to the anniversary date of an approved protocol, the IACUC Administrator informs the Principal Investigator that the annual review is due. An annual review form must be completed and returned in sufficient time to assure review and approval before the anniversary date of the approval. PIs are encouraged to submit the annual review form at least two weeks prior to the anniversary date of the approved protocol. Reminders are forwarded to the PI at 90, 60 and 30 days prior to the anniversary date of original approval.

If no response has been received two weeks prior to the anniversary of the approval date, the IACUC Administrator sends a final reminder. If the annual review has not been received by the anniversary date, the IACUC takes action to ensure animal care and use is in compliance with federal law.

Completed annual review forms are assigned to Designated Review, as described in III.D.6. The Designated Review is usually conducted by the Chair or his/her designee and the Attending Veterinarian. If any member requests a Full Committee Review, the Chair assigns a Secondary Reviewer and notifies all IACUC members that the annual review will be a Full Committee Review. All annual reviews approved by the Attending Veterinarian and the Chair are posted on the secure drive.

Animal Use Protocols are approved for three (3) years with at least annual continuing review. 90, 60 and 30 days before the 3-year anniversary of the original approval, the IACUC Administrator informs the PI in writing that the protocol will expire on the anniversary date and submission of a new protocol for review and approval before the anniversary date is required for continuation of the animal activities. Triennial reviews are conducted as new protocol reviews – Submission of a new protocol is required and the protocol review is conducted as described in III.D.6, using the criteria and procedures for review as specified in IV. C. of the PHS policy.

Additional post approval monitoring includes the following methods: Facility Inspections; Veterinary or IACUC observation of selected procedures; Observation of animal care by animal care technicians, veterinary staff, IACUC staff and IACUC members; External regulatory and accreditation visits by USDA and AAALAC; Facility monitoring by facility personnel; Reporting of incidents involving occupational health and safety; Evaluation of animal outcomes by investigators and staff.

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 as follows: The IACUC has the authority to suspend any activity it previously approved if it determines that the activity is not being conducted in accordance with the Animal Welfare Act, the Guide, the PHS Assurance, Ag Guide, or Clemson University policies. An activity may be suspended only after review at a convened meeting of a quorum of the IACUC and a suspensor is approved by a majority of the quorum present. If the IACUC suspends
an activity, the IO, in consultation with the IACUC, reviews the reasons for suspension, takes appropriate corrective action, and reports the suspension and corrective action with a full explanation to appropriate agencies (e.g. USDA/APHIS, OLAW and AAALAC International), and any agency funding that activity. The PI of any activity that has been suspended by the IACUC may appeal that action and request another review based on the correction of misinformation or additional information not available at the time of the initial review.

The risk-based occupational health and safety program for personnel working in laboratory or agricultural animal facilities or have frequent contact with animals is as follows:

The Medical Surveillance Program (MSP) is a component of the Occupational Health and Safety program at Clemson University and is administered through the Joseph F. Sullivan Center by a registered nurse who holds a Master's degree in Public Health. The Medical Surveillance Program collaborates with the Research Safety Department (RS), the Environmental Safety Department (ES), IACUC and the Institutional Biosafety Committee (IBC) to provide a comprehensive occupational health and safety program for personnel with increased risk due to animal exposure.

**Control and Prevention strategies**

All students, faculty and staff who have contact with animals used in research, teaching or demonstration (which include handling, cleaning, feeding, exposure to unfixed tissues, or exposure to animal waste or bodily fluids) are included in the Occupational Health and Safety Program and must enroll in the CU Medical Surveillance Program. Principal investigators and animal facility supervisors are responsible for ensuring that all employees, staff, students, and volunteers exposed to animals, enroll in the MSP and receive zoonotic training prior to animal exposure.

Students whose only contact with animals will be observation in a teaching exercise will not normally be required to enroll in the program, but are provided zoonotic training appropriate for their exposures.

**Procedures for hazard identification and risk assessment** at Clemson’s Animal Care and Use Program include a wide range of participants (students, faculty and staff), animals (farm, lab and wildlife) and exposure settings (field studies, labs, and agricultural production). There is also diversity in age, education, and cultural background among individuals and within groups (students, faculty, and staff), so medical surveillance needs vary greatly and are customized to meet each requirement. All teaching, research and farm activities are covered by protocols, so risk assessment and potential hazard identification is accomplished prior to protocol approval and updated as needed with any new job assignment or protocol changes to implement safeguards.

The IACUC Administrator ensures that all personnel listed on an IACUC protocol have completed the CU mandatory training modules on CITI: “Basic Course for Research Investigators, Students and Animal Care Staff” and the Medical Surveillance Program (MSP)
and Zoonotic Disease training course. Enrollment in MSP includes completion of an Occupational Health History form and a Client Profile which identifies prior occupational exposures, current and past medical conditions, immune status, pregnancy, allergies, immunization history, and current medications. Also, depending on the evaluation of the risk assessment, a Hepatitis B Declination form and/or a Respirator Questionnaire may also be required. The forms are available in the mandatory “MSP Enrollment” module at www.citiprogram.org. Once completed, the forms are forwarded to the Occupational Health Nurse for risk assessment. The process includes the selection of appropriate biosafety levels, engineering controls, microbiological practices safety equipment, facility standards, training, and medical surveillance practices. Our goal is to prevent illness or injury by reducing risk to the lowest possible level.

If an individual named on a protocol has not previously enrolled in the Medical Surveillance Program or completed the mandatory CITI training, approval is withheld until all requirements are met.

All records of participants in the Medical Surveillance Program are maintained by the Occupational Health Nurse at the Joseph F. Sullivan Center in Edwards Hall.

Risk assessment is performed by the CU Occupational Health Nurse (OHN) in consultation with the veterinary staff, instructors, facility managers, RS and ES staff, IACUC and IBC, plus the personnel themselves. Risk assessment for animal activities is based on the physical and biological hazards characteristic of species; the frequency, intensity, and duration of exposure; the use of hazardous materials; the person's own occupational health history and susceptibility, and the occupational illness and injury experience of the particular animal facility.

Work with live vertebrate animals that involve biological agents (BSL2 and greater, human blood/bodily fluids/cell lines, CDC select agents and toxins), recombinant DNA, and hazardous chemicals that are highly toxic, mutagenic, teratogenic, carcinogenic (confirmed or suspected), explosive or Schedule I or II drugs, need IBC approval before IACUC approval is granted.

The IACUC works closely with the Institutional Biosafety Committee (IBC) to ensure that proper initial and continuing review have been conducted regarding the use of these agents in animals. All areas and/or equipment involved in the use of potentially harmful or hazardous agents are identified regarding the nature of the hazards, authorized personnel to work on the project and required PPE.

The Assistant Vice President for Research Compliance and the Occupational Health Nurse both regularly attend the IACUC and IBC meetings and the Attending Veterinarian serves on both the IACUC and the IBC. All animals and animal waste associated with hazardous materials are handled according to the requirements of the IACUC and Research Safety (RS). Signs with the universal symbol for biohazardous and/or chemical agents are posted on the door.

Facilities, equipment and monitoring vary depending on the complexity of the research where animals are used. The centralized animal facility, Godley-Snell Research Center (GRSC),
offers housing space for small and large laboratory animals. This well-developed research center offers a surgical facility complete with two large surgery suites, nursing station, sterile preparation area, hand washing room, recovery room, surgical preparation room as well as radiology; therefore; the need to transport animals outside of the facilities exposing the public to potential animal allergens rarely occurs. Anesthetic delivery and monitoring equipment are available to various animal species. This 22,000 sq. ft. facility also offers a 1000 sq. ft. biocontainment suite that meets CDC animal biosafety level 3 criteria. The BSL3 suite is appropriately identified; entry is restricted and enforced with an electronic card access system.

Personnel training on matters of occupational health and safety are provided in the mandatory MSP/zoonotic training is provided by one of four methods, depending upon the size and needs of the group, the nature of the hazard, and the degree of exposure:

1) Various species specific courses are offered online through www.citiprogram.org.
2) PowerPoint Presentation by the OHN for groups or classes
3) Personal instruction by the OHN in the MSP office (required method for rabies and Hantavirus training)
4) Species-specific handouts developed for small groups or for classes with very specific exposures or needs.

The training programs contain both general and detailed species-specific zoonotic information. They also contain information regarding allergies, physical and biological hazards, special precautions for pregnancy, illness and injury reporting and treatment, the significance of immunosuppression, and the importance of frequent, thorough hand washing.

The CU Medical Surveillance Program provides training programs to students and employees regarding occupational health risks associated with direct animal contact (i.e. zoonotic diseases, allergens, immunosuppression, animal bites, scratches, biological hazards, physical hazards, as well as incidental risks (i.e. snakebites, rabid animal contact in the wild). They are taught to avoid contact with animals exhibiting unusual behavior or physical symptoms and to report these to the appropriate person, department, or agency.

In all forms of Clemson zoonotic training, personnel are taught to recognize the zoonotic illnesses they may encounter through animal or outdoor exposure. Accident prevention is discussed, and personnel are taught to notify their supervisors of illness, accidents, or bites, to obtain immediate medical treatment. Specific information is given regarding the procedures for obtaining care as a student or employee. Training and immunization records are maintained in the Medical Surveillance Program database and personnel are recalled for periodic training, testing, and immunizations.

Office of Research Safety (ORS) facilitates CU’s research by providing teaching and public service programs related to safety in research settings. These programs offer oversight and technical consultation on all research related safety issues.

Cautions and procedures regarding personal hygiene of personnel working with vertebrate animals include:
1. Enrollment in the Clemson University Medical Surveillance Program to assess needs and to provide appropriate immunizations and preventive measures for specific risks.

2. Proper management of animal health, with isolation, containment of high-risk animal experiments and exclusion from animal facilities those personnel having active infectious diseases that could potentially be hazardous to the animals.

3. Education and training is provided in the methods of monitoring and preventing exposure to health risks such as: appropriate personal hygiene, zoonoses, use of hazardous agents, potential for repetitive motion injuries and the proper handling and restraint of animals.

4. Appropriate personal protection apparel, equipment, and facilities are provided to those working with vertebrate animals. Outer garments worn in animal rooms should not be worn outside of the facility unless they are covered.

5. Personnel are excluded from animal facilities who have no need to use the facilities or who are unusually susceptible to animal-related illnesses.

6. Personnel are informed not to eat, drink, use tobacco products, apply cosmetics, or handle or apply contact lenses in rooms and laboratories where animals are housed or used.

7. Sinks are available in all laboratory animal rooms and procedural areas. Personnel are required to wash hands before leaving laboratory animal housing or procedural areas. Shower and locker rooms are available at all biomedical facilities and most other facilities.

All animal care personnel receive additional training and education regarding the potential hazards associated with animal experimentation involving hazards. Animal facility managers maintain Safety Data Sheets and chemical inventories, if applicable. If personnel are working with human body fluids or cell cultures including established cell lines, OSHA Bloodborne Pathogens Standard Training is required. If personnel are working with hazardous chemicals, Chemical Hygiene Training and Hazardous Waste Management Training is required. Required protective apparel is provided, and no unauthorized personnel are allowed to enter rooms containing hazardous materials.

There are currently no non-human primates at Clemson University.

Personal protection and safety precautions are outlined in the SOP "The Use of Personal Protective Equipment at the GSRC". This SOP is a component of the required training at GSRC, which is the central laboratory animal facility. The document contains what PPE is required for the protection of personnel, animals and research data under normal operations. Additional requirements for PPE may be necessary for specific use of biohazards or chemical hazards and will be described in the respective animal and IBC protocols and associated SOPs.
Physical exams are not given prior to employment, but a detailed medical health history is obtained at the time of MSP enrollment concerning medical evaluation and preventative medicine for personnel.

The occupational health nurse reviews these forms, and determines the appropriate level of medical surveillance for individuals who may be at increased risk to zoonotic disease or animal allergy, regardless of employment status. Personnel are contacted for needed follow-up which may include:

- immunizations, titers, or other tests
- additional training or personal guidance regarding zoonoses, safe work practices, or the need for protective equipment
- medical clearance and referral to Research Safety or Environmental Safety for additional training or fitting with protective equipment
- notification to the individual's department regarding enrollment, need for additional services, or need for employee accommodation.

Personnel are given tetanus information and are referred or given a Tetanus/diphtheria (Td) booster, if needed. Persons involved in trapping or handling potentially rabid animals are given a rabies pre-exposure series, titers, and boosters for the duration of exposure. They also receive extensive training on post-bite treatment procedures. Other prophylactic immunizations are offered when research with infectious diseases is being conducted for which effective vaccines are available. A declination form may be signed in lieu of vaccination.

Personnel in field studies involving potential Hantavirus exposure are medically evaluated and cleared for respirator use and referred to the industrial hygienist in ES for respirator fitting and fit-testing.

E-mail list serves are utilized by the Attending Veterinarian, RS and ES personnel, and the Occupational Health Nurse to keep abreast of national and local zoonotic outbreaks and to communicate this information to each other. The SC State Veterinarian is a Clemson employee who oversees the state wide programs in livestock and poultry health and Clemson's Animal Diagnostic Laboratory.

Students and employees are instructed to seek immediate medical treatment for any severe, unusual, or inappropriate illness (such as "flu" in the summer) and to advise health care providers of their animal exposures. Student illnesses and injuries are usually treated at Redfern Health Center on campus. Employee occupational illnesses and injuries are reported to supervisors, who then contact CompEndium Healthcare Services for referral under Worker's Compensation. Redfern Health Center is available on weekdays and an urgent care center, and hospital emergency room is available nearby. Distant University facilities utilize local healthcare facilities in their own area of the state. The Clemson Fire Department and EMS are located on campus.

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

G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows: All personnel involved with animal research or teaching activities (investigators, instructors, technical personnel, students and temporary personnel) must complete mandatory training initially and a refresher IACUC course every five years. The IACUC utilizes an on-line “Animal Care and Use Training Program” and offers this program via the Collaborative Institutional Training Initiative (CITI). Certification of completion of the on-line training is required for all personnel involved in animal research and teaching activities at Clemson University. The on-line course is linked through the Research Compliance web site. Successful completion of the training course and exam is verified in a training database accessible to the IACUC Administrator. This training includes information on the Animal Welfare Act, humane treatment of animals, minimization of animal numbers, minimization of pain and distress, analgesia, role of the IACUC and occupational health and safety program. In addition to the on-line training program, all persons performing protocol specific procedures including, but not limited to, anesthesia, surgery and euthanasia must satisfactorily complete training programs supervised by the Attending Veterinarian.

All IACUC members are required to complete appropriate training. They are provided copies of the PHS Policy, the Guide for the Care and Use of Laboratory Animals, the Animal Welfare Act and the Animal Welfare Regulations, the OLAW/ARENA IACUC Guidebook and a copy of the approved Animal Welfare Assurance. Initially new members participate in an orientation with the IACUC Chair, which may include the on-line training programs, “Essentials for IACUC Members” or an equivalent program which may include, but not be limited to, an IACUC 101. Additional continuing education programs may be provided to IACUC members by attendance at local or national seminars or conferences. A retreat is organized once a year providing additional training.

IV. INSTITUTIONAL PROGRAM EVALUATION AND ACCREDITATION

All of this Institution’s programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past six months and will be re-evaluated by the IACUC at least once every six months thereafter, in accord with the PHS Policy IV.B.1-2. Reports have been and will continue to be prepared in accord with the PHS Policy IV.B.3. 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’s evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

This Institution is Category One (1)—accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). As noted above, reports of the IACUC’s
semiannual evaluations (program reviews and facility inspections) will be made available 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 semi-annual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official/Vice-President for Research.
   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 copied by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. REPORTING REQUIREMENTS

A. The Institutional reporting period is the calendar year (January 1 – December 31). The IACUC, through the Institutional Official, will submit an annual report to OLAW by January 31 of each year. The annual report will include:
   1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked)
   2. Any change in the description of the Institution’s program for animal care and use as described in this Assurance
   3. Any change in the IACUC membership
   4. 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 Institutional Official, the Vice President for Research.
   5. Any minority views filed by members of the IACUC

B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
1. Any serious or continuing non-compliance 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. of this document shall include any minority views filed by members of the IACUC.

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institutional Official

Name: Dr. R. Larry Dooley
Title: Vice President for Research
Address: 300 Brackett Hall, Clemson University, Clemson, SC 29634
Phone: 864-656-7701
Fax: 864-656-7700
E-mail: dooley@clemson.edu

Signature: [Signature]

Date: [4/18/14]

B. PHS Approving Official

Name:
Title:
Address:
Phone:
Fax:
E-mail:
Signature: [Signature]

Date: [ ]

C. Effective Date of Assurance:

D. Expiration Date of Assurance:
MEMBERSHIP OF THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

Date: April 17, 2014
Institution: Clemson University
Assurance Number: 3737-01

IACUC Chairperson Name, Title and Degree/Credentials

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Degree/Credentials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peter Skewes</td>
<td>Professor</td>
<td>PhD</td>
</tr>
</tbody>
</table>

Address: Office of Research Compliance
321 Calhoun Drive
Room 223, Brackett Hall
Clemson, South Carolina
29634-5704

E-mail: pskewes@clemson.edu
Phone: 864-656-4538
Fax: 864-656-4475

IACUC Roster

<table>
<thead>
<tr>
<th>Name</th>
<th>Degree/Credential</th>
<th>Position Title</th>
<th>PHS Policy Membership Requirements ***</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lisa Bain</td>
<td>PhD</td>
<td>Associate Professor</td>
<td>Scientist</td>
</tr>
<tr>
<td>Jennifer Groff</td>
<td>MS</td>
<td>Library Science</td>
<td>Nonscientist</td>
</tr>
<tr>
<td>Staci Johnson</td>
<td>MS</td>
<td>Science Instructor/Lab Coordinator/Safety Officer at nearby university</td>
<td>Nonaffiliated</td>
</tr>
<tr>
<td>Martine LaBerge</td>
<td>PhD</td>
<td>Professor</td>
<td>Scientist</td>
</tr>
<tr>
<td>John Parrish</td>
<td>DVM, PhD, DAACLAM</td>
<td>Attending Veterinarian</td>
<td>Veterinarian</td>
</tr>
<tr>
<td>Kimberly Paul</td>
<td>PhD</td>
<td>Assistant Professor</td>
<td>Scientist</td>
</tr>
<tr>
<td>Peter Skewes</td>
<td>PhD</td>
<td>Professor</td>
<td>Scientist-Chair</td>
</tr>
<tr>
<td>John Smink</td>
<td>MS</td>
<td>Facilities Manager</td>
<td>Scientist</td>
</tr>
<tr>
<td>John Whitcomb</td>
<td>PhD</td>
<td>Assistant Professor</td>
<td>Scientist – Vice Chair</td>
</tr>
<tr>
<td>William Mayo</td>
<td>MPH</td>
<td>Occupational Health Nurse</td>
<td>Ex Officio - nonvoting</td>
</tr>
</tbody>
</table>

* This information is mandatory.
** Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member...
must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

*** List specific position titles for all members, including nonaffiliated (e.g., banker, teacher, volunteer fireman; not "community member" or "retired").

**** PHS Policy Membership Requirements:

**Veterinarian**  
Veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals at the institution.

**Scientist**  
Practicing scientist experienced in research involving animals.

**Nonscientist**  
Member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).

**Nonaffiliated**  
Individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

[Note: all members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Non-voting members and alternate members must be so identified.]

**Other Key Contacts (optional)**

If there are other individuals within the Institution who may be contacted regarding this Assurance, please provide information below.

<table>
<thead>
<tr>
<th>Contact #1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: Tracy Arwood</td>
</tr>
<tr>
<td>Title: Assistant Vice President of Research Compliance &amp; Research Integrity Officer</td>
</tr>
<tr>
<td>Phone: 864-656-1525</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Contact #2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: Tina Pittman</td>
</tr>
<tr>
<td>Title: IACUC Administrator</td>
</tr>
<tr>
<td>Phone: 864-656-4538</td>
</tr>
</tbody>
</table>
X. Facility and Species Inventory

<table>
<thead>
<tr>
<th>Laboratory, Unit, or Building</th>
<th>Gross Square Feet [include service areas]</th>
<th>Species Housed [use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog]</th>
<th>Approximate Average Daily Inventory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic Animal Research Lab</td>
<td>4,478 sq. ft.</td>
<td>Fish</td>
<td>425</td>
</tr>
<tr>
<td>Aquatic Research Lab - Cherry Farm</td>
<td>2,430 sq. ft. and three acres with eight 0.1 acre ponds</td>
<td>Fish</td>
<td>600</td>
</tr>
<tr>
<td>BRC Greenhouse</td>
<td>1,800 sq. ft.</td>
<td>Fish</td>
<td>450</td>
</tr>
<tr>
<td>Brick Barn - Sheep Unit</td>
<td>9,984 sq. ft and 20 acres</td>
<td>Sheep</td>
<td>59</td>
</tr>
<tr>
<td>Calhoun Outdoor Lab - Aquaculture Facility</td>
<td>4,000 sq. ft. and 10 acres</td>
<td>Fish</td>
<td>200</td>
</tr>
<tr>
<td>Edisto Research and Education Center</td>
<td>6,472 sq. ft. and 775 acres</td>
<td>Cattle</td>
<td>500</td>
</tr>
<tr>
<td>Environmental Toxicology</td>
<td>5,911 sq ft</td>
<td>Fish</td>
<td>320</td>
</tr>
<tr>
<td>Equine Center</td>
<td>25,210 sq ft and 85 acres</td>
<td>Horse</td>
<td>53</td>
</tr>
<tr>
<td>Godley Snell Research Center</td>
<td>22,000 sq ft</td>
<td>Armadillo</td>
<td>&lt;1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cat</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mouse</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Raccoon</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rabbit</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rat</td>
<td>46</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sheep</td>
<td>&lt;1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Swine</td>
<td>&lt;1</td>
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<tr>
<td>Godley Snell Annex</td>
<td>1,769 sq ft</td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>Jordan Hall - Blob</td>
<td>1,239 sq ft</td>
<td>Fish</td>
<td>12</td>
</tr>
<tr>
<td>Institution</td>
<td>Area Description</td>
<td>Animal Type</td>
<td>Count</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>-------------------------------</td>
<td>-------------</td>
<td>-------</td>
</tr>
<tr>
<td>Jordan Hall - Childress/Chapman</td>
<td>1,239 sq ft</td>
<td>Fish</td>
<td>300</td>
</tr>
<tr>
<td>Lehotsky</td>
<td></td>
<td>Salamanders</td>
<td>&lt;1</td>
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<tr>
<td>Lehotsky - Rodgers</td>
<td></td>
<td>Fish</td>
<td>70</td>
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<tr>
<td>LaMaster Dairy</td>
<td>8,902 sq ft and 677 acres</td>
<td>Cattle</td>
<td>295</td>
</tr>
<tr>
<td>McAdams Greenhouse</td>
<td></td>
<td>Fish</td>
<td>20</td>
</tr>
<tr>
<td>Morgan Poultry Center</td>
<td>33,620 sq ft</td>
<td>Poultry</td>
<td>384</td>
</tr>
<tr>
<td>Simpson Research Center - Beef Unit</td>
<td>37,620 sq ft and 1131 acres</td>
<td>Cattle</td>
<td>695</td>
</tr>
<tr>
<td>Starkey Swine Center</td>
<td>30,398 sq ft</td>
<td>Swine</td>
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</tr>
<tr>
<td>Union County Aquaphonics</td>
<td>220 sq ft</td>
<td>Fish</td>
<td>30</td>
</tr>
</tbody>
</table>

*Institutions may identify animal areas (buildings/rooms) by a number or symbol in this submission to OLAW. However, the name and location must be provided to OLAW upon request.*