

SAVANNAH STATE UNIVERSITY UNIVERSITY SYSTEM OF GEORGIA SAVANNAH, GEORGIA 31404 (Animal Welfare Assurance # A 4216-01) ANIMAL WELFARE ASSURANCE In accordance with the PHS Policy for Humane Care and Use of Laboratory Animals

I, Dr. Chellu S. Chetty, as named Institutional Official (IO) for animal care and use at Savannah State University (SSU), hereinafter referred to as the institution, by means of this document, provide assurance that this Institution will comply with the with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS 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 PHS, HHS, and/or NSF. 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:
 - Savannah State University
 - The Biology, Chemistry, Environmental Science, Forensic Science and Marine Science Programs in the College of Sciences and Technology (COST)
 - The Behavior Analysis Program in the College of Liberal Arts and Social Sciences (CLASS).
- B. The following are institution(s), or branches and components of another institution:
 - None

II. INSTITUTIONAL COMMITMENT

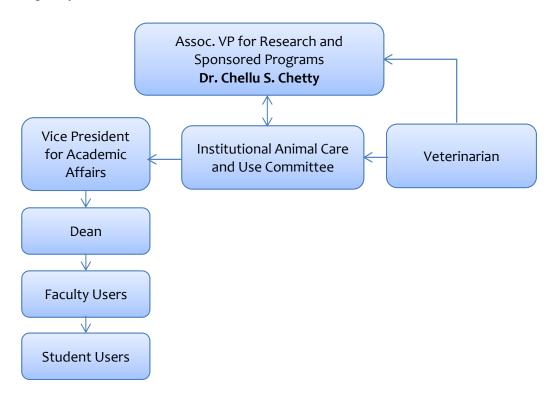
- A. This institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- B. This institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and 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 will 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").
- 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 as follows:



- B. The qualifications, authority, and percent of time contributed by the veterinarian who will participate in the program are:
 - 1. Name: Dr. Lesley Y. Mailler, D.V.M.
 - a. Qualifications
 - Doctor of Veterinary Medicine, University of Georgia, School of Veterinary Medicine
 - Bachelor of Science in Equine Science, University of Georgia, College of Agriculture

- Associate of Science in Liberal Arts, Armstrong Atlantic State University
- Training or experience in laboratory animal medicine or in the use of the species at the institution:
 - o Fifteen (15) years of experience in small and large animal care including experience in surgery of small animals, exotics and personnel management.
- b. Authority: Dr. Mailler has actively participated as a consulting veterinarian and will continue to participate in the program. She has delegated program authority and responsibility for the Institution's animal care and use program including access to all animals.
- c. Time Contributed to Program: Dr. Lesley Y. Mailler will visit this institution semi-annually and will exert 2% effort of equivalent time (six hours during a semi-annual inspection or a total of 12 hours each year) to inspect and evaluate the animal facility at this institution. In addition, she will also visit the institution, if and when necessary.
- 2. Name: Dr. Pamela L. Fandrich, D.V.M.
 - a. Qualifications
 - Doctor of Veterinary Medicine, University of Georgia, School of Veterinary Medicine
 - Bachelor of Science in Biology, Armstrong State College
 - Member of several professional societies including American and Georgia Veterinary Medical Associations.
 - Training or experience in laboratory animal medicine or in the use of the species at the institution:
 - Sixteen (16) years of experience in small animal care and surgery with an extensive background in veterinary technology, surgical procedures, animal anatomy, and physiology.
 - b. Responsibilities: Dr. Fandrich will provide adequate veterinary care of research animals in the event of Dr. Mailler's absence. She will visit this institution semi-annually and will exert 2% effort of equivalent time (six hours during a semi-annual inspection or a total of 12 hours each year) to inspect and evaluate the animal facility at this institution. In addition, she will also visit the institution, if and when necessary.
- 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 six 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, their names, degrees, profession, titles, or specialties and institutional affiliations of the IACUC chairperson and members.

D. The IACUC will

1. Review at least once every six months this institution's program for humane care and use of animals, the Semiannual Program and Facility Review Checklist

(http://grants.nih.gov/grants/olaw/sampledoc/cheklist.htm) as a basis for evaluation of: 1) IACUC Membership and Functions, 2) IACUC Records and Reporting Requirements, 3) Veterinary care, 4) Personnel Qualifications and Training, and 5) Occupational Health and Safety of Personnel. The IACUC procedures for conducting semiannual program reviews are as follows:

- The IACUC will meet at least twice a year. The chair will call for the meeting and set the agenda. Each time the committee meets; it will also make an evaluation of the animal facility and procedures of animal care and use. A report will be prepared and will be discussed in the committee and recommendations (if any) will be addressed up in a letter and the same will be forwarded to the investigator and a copy to the institution's official signing of the animal assurance.
- The committee will also review grant applications (involving animal use) prepared for submission to NIH and other funding agencies using the following criteria: a) Rationale and purpose of the proposed use of animals; b) Justification of the species and number of animals requested; c) Availability or appropriateness of the use of less-invasive procedures, other species, isolated organ preparation, cell or tissue culture, or computer simulation; d) Adequacy of training and experience of personnel in the procedures used; e) Unusual housing and husbandry requirements; f) Appropriate sedation, analgesia, and anesthesia; g) Unnecessary duplication of experiments h) Conduct of multiple major operative procedures; i) Criteria and process for timely intervention, removal of animals from a study, or euthanasia if painful or stressful outcomes are anticipated; j) Postprocedure care; k) Method of euthanasia or disposition of animal; and l) Safety of working environment for personnel. The faculty investigators will submit copies of the proposals to the IO who in turn will request the IACUC to make an evaluation regarding the proposed facility and procedure for animal use. The IACUC recommendations will be forwarded to the respective investigators with a copy to the Institutional Official. A copy of this report will be filed in the office of Sponsored Research Administration.
- 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. Semiannual Program and Facility Review Checklist (http://grants.nih.gov/grants/olaw/sampledoc/cheklist.htm) as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:
 - Assessment of the living conditions of animals appropriate for the species and contribution to their health and comfort.
 - Inspection of the housing, feeding, and non-medical care of the animals directed by the veterinarian or other scientist trained and experienced in the proper care handling, and use of the species being maintained or studied.
 - Evaluation of preventive medicine, animal procurement and transport on: a) animal vendors, b) procedures for lawful animal procurement, evaluation of animals and transport, c) procedures for quarantine and stabilization, d) policies on separation by species, source and health status, e) policies for isolation of sick animals, e) program of surveillance, diagnosis, treatment and control of disease, f) availability of diagnostic resources for preventive health program, and g) provision for emergency, weekend and holiday veterinary care.
 - Review of the procedures for surgery: a) procedures for monitoring surgical anesthesia

and analgesia, b) pre-surgical plan (e.g. identify space, supplies, conduct pre-op exam, define post-op care), c) appropriate training or experience of personnel in surgery and anesthesia, d) major procedures distinguished from minor, e) use of effective aseptic procedures for survival surgery, f) implemented procedures for use of surgical facility, g) implemented procedures for using/scavenging volatile anesthetics, h) effective procedures for sterilizing instruments and monitoring expiration dates on sterile packs, and i) documentation of post-operative monitoring and care.

- Evaluation of processes to avoid or minimize discomfort, distress and pain to the animals, consistent with the sound research design in the guidelines for avoiding unnecessary pain and distress; assessment and categorization of pain [a) guidelines for assessment and categorization of pain, b) IACUC guidelines for avoiding unnecessary pain and distress, c) appropriate anesthetics, analgesics, tranquilizers used for each species, d) special precautions for the use of paralytics and e) veterinary input in the choice of drugs].
- Review of the methods of euthanasia on: a) compliance with current AVMA Panel on Euthanasia unless approved by the IACUC, b) guidance provided on appropriate methods for each species, and d) training available for personnel in humane methods of euthanasia.
- Evaluation of drug storage and control including: a) safe, secure, storage arrangement, b) record keeping meets regulations, and c) procedures exist for ensuring drugs are within expiration date.
- Review of the training program for personnel and the occupational health safety program.
- 3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy at IV.B.3. and submit the reports to Institutional Official (IO). The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:

As described below the departures will be identified from the nature and extent of institutional adherence to the "Guide" for the care and use of laboratory animals and the Public Health Science Policy along with the reasons for each departure. These will be included in the report to the Institutional Official along with any minority views.

- Individual IACUC members convey his/her observations to the IACUC Chairperson, or designee, who, in turn, drafts reports using the Semiannual Report to the Institutional Official.
- The report contains changes to the institution's program for animal care and use, a description of the nature and extent of the institution's adherence to the Guide and the PHS Policy.
- The report specifically details any IACUC approved departures from the provisions of the Guide and the PHS Policy, and states the reasons for each departure. The reports note when no departures from the Guide and PHS Policy occur. Approved departures for the Guide and PHS Policy are approved as a part of a protocol, protocol amendment, or other written document, using either FCR or DMR as delineated below in Section III.D.6.
- Departures from the provisions of the Guide that are not IACUC approved are considered deficiencies and addressed as such. To address such departures the IACUC will develop a reasonable plan and schedule for discontinuing the departure or for having the departure properly reviewed and approved.

- The reports distinguish significant from minor deficiencies. If program or facility deficiencies are noted, reports contain a reasonable and specific plan and schedule for correcting each deficiency. Copies of the draft reports are reviewed then revised as appropriate and approved by the Committee.
- The final reports are signed by a majority of the IACUC members and will include any minority opinions. If there are no minority opinions, the reports will so state.
- The completed reports are submitted to the Institutional Official in a timely manner following the evaluation.
- Deficiencies identified in institution's animal care and use will be tracked by the Institutional Official to ensure that they are appropriately resolved.

All research protocols related to animals will be reviewed by the IACUC at its regular meeting. However, in cases where a research protocol had to be reviewed in between the times the IACUC will convene an emergency meeting for discussion and approval/disapproval of the proposed research protocols. As routine practice, none of the SSU faculty will deviate in the established research protocols as related to animal care and use. The time line of research activities will be adjusted in such a way as to accommodate the addition and variety of instances requiring new protocols. Such additions will occur only after a scheduled meeting of the IACUC.

Both significant and minor deficiencies (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html) which may be a threat to the health or safety of animals will be identified and categorized (significant or minor) in the Semiannual Program and Facility Review Checklist (http://grants.nih.gov/grants/olaw/sampledoc/cheklist.htm). The plan for correction of each deficiency and a schedule for accomplishing the correction will be included in the semiannual program and facility review report.

The IACUC Chair will copy the IO on the letter to the investigator delineating the identified deficiencies and the recommended corrective actions.

- 1. For Significant Deficiencies or Continuous Minor Deficiencies: Deficiencies are deemed serious if they can or do affect the health, safety or well-being of animals or personnel. If the IACUC determines that the deficiencies identified represents serious or continuing noncompliance with federal regulations, the IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of that activity provided by the principal investigator and approved by the Committee.
- 2. Minor Deficiencies: Deficiencies are deemed minor if they do not affect the health, safety or well-being of animals or personnel. If the IACUC determines that the identified deficiency/problem represents a minor deficiency with federal regulations and/or IACUC requirements or determinations it may, in consideration of the nature of the research study and the reported problem take one or more of the following actions: a) Elect to make corrective action only, b) Provide a verbal and/or written listing of the deficiency to the investigator and require a corrective action plan at a regular meeting of the IACUC and recording this incident in the IACUC minutes, c) Provide a written listing of the deficiency

to the investigator and requiring a corrective action plan within a specified time period. The letter may or may not be copied to the investigator's department chair depending on the IACUC's decision on the sanction.

- 4. Review concerns involving the care and use of animals at the institution. The IACUC procedures for reviewing concerns are as follows:
 - Using the attached checklists to identify the deficiencies in the program and/ or facility during the course of the IACUC's review and inspection and classification of each concern as either significant or minor,
 - Developing a schedule with reasonable and specific plans to correct each deficiency,
 - Any individual may report concerns to the Institutional Official (IO), IACUC Chair, Veterinarian or any member of the IACUC.
 - Notices are located in the animal facilities advising individuals how and where to report animal welfare concerns and stating that any individual who, in good faith, reports an animal welfare concern will be protected against reprisals.
 - There will not be any threat of reprisals against those reporting perceived mistreatment or compliance. The IACUC will review, and if warranted, investigate concerns about the care and use of animals at the facility resulting from these complaints. Procedures to handle these concerns by IACUC will include:
 - a) Determination of the substance of a complaint to be investigated further,
 - b) Explanation of violations and/or alleged nature of complaint as well as the purpose of the investigation or the manner in which it will be conducted,
 - c) Conduct of interviews4 and inspection of facilities,
 - d) Review of animal receiving records, housing and health records, billings, memos and other written materials if necessary, and
 - e) Provision of the results of the investigation to all parties involved, including the President.
 - All reported concerns are brought to the attention of the full Committee.
 - If necessary the IACUC Chair convenes a meeting to discuss, investigate, and address any reported concern.
 - Reported concerns and all associated IACUC actions are recorded in the IACUC meeting
 minutes. The Committee reports such actions, in writing, to the IO and, as warranted, to
 OLAW. Reports to the IO may be either via meeting minutes, semiannual report of
 IACUC evaluations, or separate document. Reports to OLAW will be in writing and
 through the IO. Preliminary reports to both the IO and OLAW may be made verbally.

In cases where there is sufficient evidence of serious noncompliance, the IO in consultation with the IACUC will impose sanctions on an investigator found responsible for mistreatment of animals or violation of assurance of compliance.

To minimize or avoid any public complaints and reports of noncompliance, the veterinarian and investigators will work together to prevent or correct problems and will have such conversations with, or letters to, members of the IACUC, the veterinarian or the president.

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 will include:

- Identifying the deficiencies from the evaluation of the semiannual program and facility by **all** members of IACUC, and
- Making specific recommendations to meet the requirements of the guidelines established for appropriate animal care and treatment.
- 6. In accord with the PHS Policy IV.C.1-3, the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals. The IACUC procedures for protocol review are as follows:
 - Protocols proposing to use live vertebrate animals in research, testing, or education are submitted electronically to the IACUC Chair in a pdf format. The application undergoes pre-review and is then subject to either Designated-Member Review (DMR) or Full-Committee review (FCR).
 - The IACUC Chair or designee pre-reviews the application for completeness or obvious concerns. The Veterinarian may pre-review the application to ensure that proposed procedures necessitating analgesia or anesthesia are adequately addressed.
 - The IACUC Chair of protocols for review notifies IACUC members via email.
 - Following any pre-review, the IACUC Chair sends the protocol via email to all members. The Chair may identify members to serve as designated reviewers (if DMR is the method of use) or primary reviewers for FCR.
 - No member may participate in the IACUC review or approval of a protocol in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.
 - Prior to the review, each IACUC member will be provided with written descriptions of activities (protocols) that involve the care and use of animals and any member of the IACUC may obtain, upon request, full committee review of those protocols.
 - If FCR is requested, approval of those protocols may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present.
 - The possible outcomes on FCR include one of the following: 1) approve; 2) require modifications prior to approval; 3) withhold approval.
 - Required Modifications Subsequent to FCR. When the IACUC requires modifications (to secure approval), of a protocol, such modifications are reviewed as follows:
 - a) FCR or DMR following the all applicable procedures as delineated in the PHS Policy and elsewhere in Part III.D.6 of this Assurance.

 Or
 - b) DMR, if approved unanimously by all members at the meeting, at which the required modifications are developed, is delineated. If all IACUC members have agreed in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.
 - Generally, for initial protocol reviews, the FCR method is used. However, should a

situation warrant, the IACUC may use the DMR method. In such instances, the protocol will be distributed to all IACUC members to allow members the opportunity to call for FCR. Records of members polled to obtain concurrence to use DMR, or concurrence by silent assent after five (5) working days and approval of protocols via DMR, are maintained and recorded in the minutes of the next convened IACUC meeting. If any member during polling or within five (5) working days believes the protocol should go before a full committee, then its review is deferred to the next full committee IACUC meeting.

- If FCR is not requested, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, may be assigned to review those protocols and have the authority to approve, require modifications in (to secure approval) or request FCR of those protocols.
- Other IACUC members may provide the designated reviewer(s) with comments and/or suggestions for the reviewer's consideration only. That is, concurrence to use the designated-member review (DMR) method may not be conditioned.
- If multiple designated reviewers are used, after all required modifications are made, a final revised protocol, i.e., an identical document with all required modifications included, is submitted to all of the designated reviewers for review and approval.
- If multiple designated reviewers are used, their decisions must be unanimous; if not, the protocol will be referred for FCR.
- Outcomes of DMR are 1) approval; 2) request additional information from the PI for approval; or 3) refer for FCR.
- There are no alternate processes or procedures for special or expedited reviews.
- In order to approve proposed protocols or proposed significant changes in ongoing protocols, the IACUC conducts a review [by FCR or DMR] of those components related to the care and use of animals and determines if the proposed protocols are in accordance with the PHS Policy. In making this determination, the IACUC will confirm that the protocol will be conducted in accordance with the Animal Welfare Act as it applies to the activity, and that the protocol is consistent with the *Guide* unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the protocol conforms to the institution's PHS Assurance and meets the following requirements:
 - a) Procedures with animals avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
 - b) Procedures that may cause more than momentary or slight pain or distress to the animals are performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
 - c) Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved are painlessly killed at the end of the procedure or, if appropriate, during the procedure.
 - d) The living conditions of animals are appropriate for their species and contribute to their health and comfort. A veterinarian directs the housing, feeding, and nonmedical care of the animals or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.
 - e) Medical care for animals is available and provided as necessary by a qualified veterinarian.
 - f) Personnel conducting procedures on the species being maintained or studied are

appropriately qualified and trained in those procedures.

- g) Methods of euthanasia used are consistent with the current recommendations of the American Veterinary Medical Association (AVMA) guidelines on euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.
- 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 the proposed significant changes in ongoing research projects will include:
 - Review and approval of significant changes are handled in the same manner as new protocols. See Paragraph III. Section D.6. above.
 - Prior to the review of protocols at a convened meeting, **all** IACUC members will be provided with full details of significant changes to the research projects and the rationale provided by the faculty investigators for specific deviations from the institutional program as well as policies on animal care and use. The IACUC, at the convened quorum-filled meeting, will either approve animal use in research if the submitted reasons are valid and are in accordance with applicable provisions of the *Animal Welfare Act*, the *Guide* and the *Institution's Assurance*, or disapprove the use of animals in research if there is a departure from the Institution's Policy and Assurance on Animal Welfare.

In case of "expedited review" of any proposed significant changes, **all** IACUC members will be provided with the **opportunity** to call for full review of the rationale provided by the faculty investigators before it is referred to the IACUC designated reviewer. The designated reviewer is authorized to approve (*but not to disapprove*) protocols if the rationale provided for specific deviations from the institutional program and policies on animal care and use is valid and is in accordance with applicable provision of the *Animal Welfare Act*, the *Guide* and the *Institution's Assurance*.

- Approving animal use in research, if the submitted reasons are valid and are in accordance with applicable provisions of the Animal Welfare Act, the Guide, the institution's Assurance or IV.C. of this policy, and
- IACUC requires investigators to notify the following kinds of significant changes and will monitor those protocols, which involve those changes: a) Change in objectives of a study; b) Change in degree of invasiveness of a procedure or discomfort to an animal; c) Change in species or in the approximate number of animals used; d) Change in personnel involved in animal procedures; e) Change in methods of euthanasia; and f) Change in duration, frequency or number of procedures performed on animal.
- 8. Notify investigators and the IO, 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 IV.C.4. The IACUC procedures to notify investigators and the institution of its decisions regarding protocol review are as follows:
 - If the IACUC determines that the investigator has adequately addressed all review criteria, based on the PHS Policy, the IACUC may approve the proposal and provide the investigator permission to perform the experiments or procedures as described.
 - If the proposal requires modifications, the IACUC determines that a proposal is approvable

contingent upon receipt of a very specific modification. If the modification represents significant departure, the IACUC will ask the investigator to revise the protocol to reflect the modifications imposed by the IACUC. If the proposal is missing substantive information necessary for the IACUC to make a judgment, or the IACUC requires extensive or multiple modifications, then the IACUC will require that the protocol be revised and resubmitted.

- If the IACUC determines that a proposal has not adequately addressed all of the requirements of the PHS Policy as applicable, the committee may withhold approval. A summary of the review along with the IACUC's decision will be sent to the investigator and a copy to the IO via email and mail. The Investigator is afforded the opportunity to respond either in person or in writing.
- 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.1-4 at least once every three years. The IACUC procedures for conducting continuing reviews are as follows:
 - The animal care staff, IACUC Chair and Veterinarian, performs post approval monitoring of animal research.
 - An evaluation of the compliance with applicable guidelines established for appropriate animal care and treatment, and
 - An assessment of any minority views filed by members of the committee.
 - Annual reviews Approved protocols for the use of USDA covered and non-USDA covered species are valid for a three-year period. The protocols are reviewed, by a member or members of the IACUC at least annually and renewed prior to years two (2) and three (3).
 - To maintain ongoing activities beyond the initial three-year approval period, a complete review of activities in new protocol submission by the IACUC is conducted just prior to the end of the three-year approval for specified protocol.
 - Protocols are approved for a maximum of 36 months. That is, all protocols expire no later than the three-year anniversary of the initial IACUC review.
 - If activities will continue beyond the expiration date, a new protocol must be submitted, reviewed, and approved as described in Paragraph III. Section D.6. above.
- 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:
 - Suspension of an activity or a project that violates the PHS Policy, Guide, Assurance, or Animal Welfare Regulations after review of the matter at a convened meeting including a quorum of the IACUC and with the suspension vote of a majority of the quorum of members present,
 - Notification of the investigator and the IO, Dr. Chellu S. Chetty, in writing statement of the reasons for its decision.
 - Individual authorized by this institution to verify IACUC approval of those sections of applications and proposals related to the care and use of animals is IO. He will take appropriate corrective action if any activity or project is recommended for suspension by IACUC, and report the action and the circumstances surrounding the suspension to

OLAW promptly.

E. SSU has the Occupational Safety and Health Administration (OSHA) guidelines and instructions/precautions on the use of hazardous agents. Mr. Randal Lowery is the Safety Compliance Coordinator who will give the personnel training in the OSHA. SSU research programs vary regarding the species used, the potential hazards presented, and the biological, chemical, or physical agents employed in research. Hence, its occupational health and safety program is based on an assessment of the risks and hazard identification present in its particular animal research and support program and will include the personnel working in laboratory animal facilities or have frequent contact with animals. All individuals that care for and use laboratory animals at the institution are required to participate in the OSHA program.

Animal care staff, research personnel, IACUC members, facility services individuals, custodial staff, police and safety, security, summer students, visiting faculty, the IO and others regularly exposed to hazards associated with the use of laboratory animals enroll in the OSHA program by completion of an initial risk assessment questionnaire distributed by the IO.

<u>Hazard Identification and Risk Assessment:</u> The OSHA program is based on the potential risk of exposure to biological and chemical hazards associated with the use of laboratory animals at SSU. The Animal Care Staff, Veterinarian, IACUC and IO, in concert with SSU Health and Safety are continuously engaged in risk assessment and the identification of hazards associated the use of laboratory animals at SSU. Adjustments to the OSHA Program are made as needed.

- 1. Ongoing hazard identification and risk assessment occurs through protocol reviews by the IACUC and evaluations of standard operating procedures in the animal facilities by the Veterinarian, Animal Care Staff, and IO.
- 2. Biological hazards identified include allergens from rodents (primarily urinary proteins and rat saliva). The potential infection of personnel using zebrafish with Mycobacterium marinum is also a biological hazard.
- 3. Potential chemical hazards include exposure to toxic compounds used in sanitation practices or experimental activities. Chemical hazards associated with the use of laboratory animals at SSU include sodium hypochlorite (bleach), chlorine dioxide (clidox), isoflurane, tricaine methanesulfonate (MS-222), carbon dioxide, oxygen/nitrogen gas mixtures, disinfectant containing isopropanol, and Alkyl (C12-16) dimethyl benzyl ammonium chloride (Odor Ban).
- 4. Major physical hazards identified include rodent bites, sharp items (such as broken glass, syringes, needles, and scalpel blades), compressed gas cylinders, ergonomically-based injuries from animal care and use tasks, autoclave units and other equipment.
- 5. Hazard identified and exposure risks due experimental procedures are determined from protocol reviews and post approval monitoring by the IACUC, Animal Care Staff, IO, and Health and Safety personnel.

The program requirements include the following: a pre-employment medical evaluation and history; immunization against tetanus (offered provided by Health Services at Savannah State University); detailed training on how to perform required procedures safely; instruction in personal hygiene, zoonosis, and precautions for pregnant women and others at risk;

protective clothing and devices; instruction in first-aid procedures appropriate to potential hazards; and access to medical attention for the treatment of animal bites, scratches, allergies and other job-related injuries or illnesses. They will be given training by Dr. Lesley Y. Mailler, Veterinarian and/or provided with computer-based media and videotapes regarding the animal related hazards (such as bites, scratches or allergies). The animal care personnel will use the personal protective items such as gloves, arm protectors, masks, shoe covers and protective clothing to avoid injuries. The occupational health and safety program for personnel who work in laboratory animal facilities or have frequent contact with animals will include:

- 1. provision of proof of an annual physical examination by a licensed physician which verifies a minimal standing or good health,
- 2. provision of proof of tuberculosis test (with x-ray evaluation if positive). Personnel who work in the laboratory and animal facility will be required to have an adult diphtheria-tetanus toxoid booster shot at 10-year intervals to reduce the risk from toxin exposure and wound contamination problems.
- 3. persons who contract diarrhea, the common cold, flu, liver disorders, zoonosis, pregnancy and immunosuppression disorders will be released from duty until released by a physician and submission of a supervisor's evaluation,
- 4. all injuries (bites, scratches, cuts etc.) will be reported to the Institutional Bio-hazard Officer immediately. SSU has made prior arrangements for appropriate emergency medical treatment at the Campus Health Services. Dr. Gary N. Harvey, the staff physician, is the designated attending physician,
- 5. personal hygiene procedures such as clean work clothing and prohibition of eating, drinking, and smoking around animals will be implemented, and
- 6. hazardous biological, chemical and physical agents will be stored in appropriate containers until they are disposed. Sunbelt Medical Services, Inc. 639 Vestal Rd. PO Box: 215, Sardis, GA 30456 will pick up the biohazard waste on a need basis.
- F. The total gross number of square feet in small animal facility (Room 153, Drew-Griffith Bldg.) is approximately 475 and the species of animals housed therein and the average daily inventory of animals, by species, in each facility is provided upon request from the OLAW. Two Bioclean Duo-Flo Unit from Lab Products Inc., are currently used to maintain the small animals. Since very few faculty members are involved in the use of animals especially, the maximum number of rats/mice housed at any given time will not exceed one hundred (100) per unit. The typical applications of this positive portable laminar flow clean room include:
 - 1. clean air housing of a two-sided rack of laboratory animals,
 - 2. laboratory animal clean air quarantine station,
 - 3. clean air storage application,
 - 4. filling and transfer operations,
 - 5. containment of harmful airborne dust particulate, and
 - 6. quality control inspection station. This self-contained mobile, modular unit has overhead, self-contained white fluorescent lighting diffused by patented, perforated acrylic ceiling tiles; greater than 100 foot-candles illumination on a plane 30 inches below ceiling with 24-hour timer with 15 minute adjustable settings. In July 2008, the entire Drew-Griffith

Building, where the animal facility is located, was completely renovated. The renovated animal facility has new floor, ceiling, light fixtures, tables, sinks etc.

The Facility and Species Inventory form provided by the OLAW will be used to evaluate the facility.

The total gross number of square feet in the animal facility, the species of animals housed and the average daily inventory of animals, by species, is provided in Section IX., the Facility and Species Inventory table.

G. The training or instruction available to new IACUC members, scientists, animal technicians, and other personnel involved in animal care, treatment, or use are as follows:

During the IACUC's semiannual meetings the Chair will discuss IACUC responsibilities including the time commitment for attending meetings, reviewing the program and protocols, and inspecting facilities. For the new members, the Chair will also conduct an education and training session with an orientation to the laws, regulations, standards, and policies. The members will be provided with the following background materials and resources and, if necessary, specific training to assist IACUC members in understanding and evaluating issues brought before the committee.

- 1) the PHS Policy for the Humane Care and Use of Laboratory Animals;
- 2) the current edition of the Guide for the Care and Use of Laboratory Animals,
- 3) the Animal Welfare Act and Animal Welfare Regulations;
- 4) the OLAW/ARENA IACUC Guidebook; and
- 5) a copy of the approved Animal Welfare Assurance

Savannah State University encourages and assists individuals (faculty, students and animal technician) involved in the care and use of animals to attend or participate in:

- a) conferences sponsored by Scientists Center for Animal Welfare,
- b) training program leading to certification in animal technology available from AALAS, and
- c) continuing training and education provided to all the members because it is important to keep abreast of the changes in the interpretation of these laws and regulations as well as the changes in veterinary science.

The individuals who do not attend these conferences will be trained in the humane practice of animal maintenance and experimentation such as species-specific housing methods, husbandry procedures, handling techniques and in testing methods that minimize the number of animals required to obtain valid results and minimize animal distress. The training programs include: a) taking selected courses in Veterinary Assistant Program offered by Savannah Technical Institute, Savannah, GA, b) the training at the Humane Society, Savannah, GA, and c) providing commercially available training materials that are appropriate for self-study.

1. The Veterinarian, Dr. Lesley Y. Mailler, Savannah, GA provides instruction in the humane practice of animal care and use; in-house training to students and staff will be given by research faculty members with prior experience in handling and caring of animals, and

2. Mr. Randal Lowery, Safety Compliance Coordinator will provide the Occupational Safety and Health Administration (OSHA) guidelines and instructions/precautions on the use of hazardous agents.

IV. INSTITUTIONAL PROGRAM EVALUATION AND ACCREDITATION

Savannah State University is Category 2 and is not accredited by AAALAC. 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 IV.B.3. of the PHS Policy. IACUC meetings are conducted in person, but members unable to attend may participate via a conference call. Materials needed to contribute to the IACUC meetings are sent via prior email to members participating via conference calling. Any use of telecommunications will be in accordance with NIH Notice NOT-OD-06-052 of March 24th, 2006, entitled Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals. 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 IACUC evaluations will be maintained by this institution and made available to the OLAW upon request. The report of the most recent evaluations (program review and facility inspection) is attached.

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 the 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 the IO.
- 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. This Institution's reporting period is January 1 December 31. The IACUC, through IO, Dr. Chellu S. Chetty, Associate Vice President for Research and Sponsored Programs, Savannah State University, will submit an annual report to OLAW on January 31st of each year. The 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), 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 dates that the IACUC conducted its semiannual evaluations of the institution's program and facilities (including satellite facilities) and submitted the evaluations to IO, Dr. Chellu S. Chetty, Associate Vice President for Research and Sponsored Programs.
- 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. of this document shall include any minority views filed by members of the IACUC.

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A.	Authorized	Savannah	State	University	Official

Name: Dr. Chellu S. Chetty

Title: Associate Vice President for Research and Sponsored Programs

Address: PO Box: 40289, Savannah State University, Savannah, GA 31404

Phone: 912-358-4277

Fax: 912-358-4780

E-Mail: chettyc@savannahstate.edu

Signature:

Date: 05/27/2016

B. PHS Approving Official

Name:

Title:

Address: 6705 Rockledge Drive-RKL1, Suite 360, MSC 7982, Bethesda, MD 20892-7982

Phone: 301-496-7163

Fax: 301-402-7065

E-Mail: <u>olawdoa@mail.nih.gov</u>

Signature:

Date:

C. Effective Date of Assurance:

D. Expiration Date of Assurance:

VIII. MEMBERSHIP OF THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

Date: Effective **01-12-2012**

NAME OF INSTITUTION: Savannah State University, Savannah, GA 31404

ASSURANCE NUMBER: A4216-01

Chairperson Name, Title, and Degree/Credentials		Business Address, Phone, Fax, and Email of Chairperson				
Name: Dr. Elissa T. Purnell		Address: PO Box: 20600, Department of Biology, Savannah State University, Savannah, GA 31404				
Title: Professor of Biology						
Degree/credentials: Ph.D.		Phone: 912-358-4447 F		Fax: 912-358-4950	Email: p	ournelle@savannahstate.edu
Name of Member*	Degree/Cr	edentials		Position Title		PHS Policy Membership Requirements**
Dr. Lesley N. Mailler	D.V.M	D.V.M		Veterinarian		Veterinarian
Dr. Johnny Johnson	Ph.D.		Assistant Professor of Biology Savannah State University		Scientist/Member	
Dr. Adegboye Adeyemo	Ph.D.		Professor of Chemistry & Minister, St. John's Baptist Church, Savannah, GA		Scientist/Member	
Mrs. Marilyn Felder	Associate Degree in Ministry		Associate Pastor, St. John's Baptist Church, Savannah, GA		Non-scientist/Member	
Mr. Horace Magwood	M.S.			Principal, Mercer Middle School, Savannah, GA		Non-affiliated Member

^{*} non voting members must be so identified

Scientist: a practicing scientist experienced in research involving animals.

Nonscientist: a member whose primary concerns are in a non-scientific areas (e.g. ethicist, lawyer, member of the clergy).

Non-affiliated member: a member who is not affiliated with the institution in any way other than as a member of the IACUC, and who is not a member of the immediate family of a person who is affiliated. 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 attending veterinarian may not be considered non-affiliated.

^{**}Veterinarian: a veterinarian with direct or delegated program responsibility.

IX: FACILITY AND SPECIES INVENTORY

DATE: 04/01/2015

NAME OF INSTITUTION: Savannah State University

ASSURANCE NUMBER: A 4216-01

Laboratory, Unit, or Building*	Gross Square Feet (including service areas)	Species Housed in Unit (Use complete common names)	Approx. Average Daily Inventory	
Room 153, Drew Griffith Building	475	C57BL mice	15	

^{*}Institutions may identify animal areas in any manner, e.g., initials, ID number, etc. However, the name and location must be provided to OLAW upon request.