Georgia State University
A3914-01
Animal Welfare Assurance

I, James A. Weyhenmeyer, as named Institutional Official for animal care and use at Georgia State 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 and/or the National Science Foundation (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:

1. College of Arts and Sciences,
2. J. Mack Robinson College of Business
3. College of Education and Human Development
4. Honors College
5. Institute for Biomedical Sciences
6. Byrdine F. Lewis School of Nursing and Health Professions
7. College of Law
8. Andrew Young School of Policy Studies
9. Office of Research
10. School of Public Health
11. Language Research Center
12. Collab Tech
13. Georgia State University Research Foundation, Inc.

- All of the above listed components are physically located on the University Campus in Atlanta, Georgia.
- There are no off campus satellite facilities and/or other covered components.

B. The following are other institution(s), or branches and components of another institution:

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, and 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).

E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (sub-award) 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 the PHS Policy are as follows:

As indicated above, there are direct and open lines of communication between the IACUC and the Institutional Official (IO) and between the Veterinarian and the IO.
B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

1. **Name:** Michael W. Hart

**Qualifications**
- Degrees: DVM, Texas A&M University, 1994; MS; Diplomate of the American College of Laboratory Animal Medicine
- Training or experience in laboratory animal medicine or in the use of the species at the institution: Pursuant to obtaining his Doctor of Veterinary Medicine Degree, Dr. Hart practiced small animal medicine and surgery in a private veterinary practice (1994-1996). Dr. Hart received a Master of Science degree in Basic Medical Science in 1998 commensurate with his completion of a laboratory animal residency program at the University of Alabama at Birmingham (1996 – 1998). He has served as a laboratory animal veterinarian since completing his residency (1999 – present). Dr. Hart became a Diplomate of the American College of Laboratory Animal Medicine (ACLAM) in 2002.

**Authority:** Dr. Hart has direct program authority and responsibility for the Institution's animal care and use program including access to all animals. Dr. Hart also serves as a voting member on the IACUC.

**Time contributed to program:** Dr. Hart is a full-time employee who dedicates one hundred percent of his time to the animal care and use program. He provides veterinary care in conjunction with Dr. Wilkes.

2. **Name:** Amelia Carolis Wilkes

**Qualifications**
- Degrees: DVM, University of Tennessee, 2010; Diplomate of the American College of Laboratory Animal Medicine
- Training or experience in laboratory animal medicine or in the use of the species at the institution: Pursuant to obtaining her Doctor of Veterinary Medicine degree, Dr. Wilkes participated in a veterinary internship in a small animal medicine and surgery specialty practice (2010-2011). Dr. Wilkes completed a laboratory animal residency program at Emory University (2011 – 2013) and a primate veterinary fellowship at the Yerkes National Primate Research Center, Emory University (2013 – 2014). She has served as a laboratory animal veterinarian since completing her residency/fellowship (2014 – present). Dr. Wilkes became a Diplomate of the American College of Laboratory Animal Medicine (ACLAM) in 2015.

**Responsibilities:** Dr. Wilkes has access to all GSU animal facilities and animals. Specific responsibilities are as follows:
- Clinical Laboratory Animal Veterinarian
- Serves as the Clinical Laboratory Animal Veterinarian for the University
- Directs all aspects of the animal resources program in conjunction with the University Veterinarian
• Provides preventative medical and veterinary care for animals used in research and teaching programs
• Develops, conducts, and/or facilitates training workshops for investigators (surgical techniques and principals; biomethodology wet labs for hamsters, mice, and rats)
• Provides veterinary consultations for IACUC protocols
• Serves as a voting member on the IACUC

**Time contributed to program:** Dr. Wilkes is a full-time employee who dedicates one hundred percent of her time to the animal care and use program. She provides veterinary care in conjunction with Dr. Hart.

C. The IACUC at this Institution is properly appointed according to 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 President, as Chief Executive Officer (C.E.O.), has delegated to the Institutional Official the authority to appoint the members of the IACUC. In accordance with the Health Research Extension Act of 1985, this delegation of authority is specific and is in writing. The IACUC consists of at least five members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Part VIII is a list of 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 as a basis for evaluation.** The IACUC procedures for conducting semiannual program reviews are as follows:

   • The IACUC will meet at least once every six months to review the Institutional Program for Humane Care and Use of Animals.

   • The IACUC uses the Guide and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review.

   • To facilitate the evaluation, the IACUC will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website.

   • The evaluation will include, but not necessarily be limited to, a review of the following:

     a. Institutional and Individual Responsibilities;
     b. IACUC Membership and Functions;
     c. IACUC Member Experience and Training;
     d. IACUC Records and Reporting Requirements;
     e. Husbandry and Veterinary Care (all aspects);
     f. Personnel Qualifications (Experience and Training);
     g. Occupational Health and Safety;
     h. Emergency and Disaster Planning.
     i. Security (personal and facility);
     j. The Institution's PHS Assurance
• If program deficiencies are noted during the review, they will be categorized as significant or minor and the IACUC will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals.

• IACUC subcommittees may be used to conduct all or part of the program reviews. However, no member will be involuntarily excluded from participating in any portion of the reviews.

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

• At least once every six months at least two voting members of the IACUC will inspect all of the institute’s animal facilities and animal surgical areas.

• The areas inspected include, but are not necessary limited to the following: Any and all buildings, rooms, areas, enclosures, vehicles and equipment, including satellite facilities, used for animal confinement, transportation, maintenance, breeding, or experiments inclusive of surgical manipulation.

• The IACUC uses the Guide and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review.

• To facilitate the evaluation, the IACUC will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website.

• If deficiencies are noted during the inspection, they will be categorized as significant or minor and the IACUC will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel.

• No IACUC member will be involuntarily excluded from participating in any portion of the inspections.

• All animal facilities, even those that house or involve only non-USDA covered species, will be inspected by the IACUC in the above described manner.

3. Prepare reports of the IACUC evaluations according to PHS Policy IV.B.3. and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:

• Individual IACUC members will convey their observations to the IACUC Chairperson, or his or her designee, who, in turn, will draft the reports using the sample OLAW Semiannual Report to the Institutional Official format from the OLAW website.
• The reports will contain a description of the nature and extent of the institution's adherence to the Guide and the PHS Policy.

• The reports will identify specifically any IACUC approved departures from the provisions of the Guide and the PHS Policy, and state the reasons for each departure. If there are no departures, the reports will so state.

• Approved departures must be approved as part of a protocol, protocol amendment, or other written document, using either Full Committee Review (FCR) or Designated Member Review (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, i.e., the IACUC will develop a reasonable plan and schedule for discontinuing the departure or for having the departure properly reviewed and approved.

• The reports will distinguish significant deficiencies from minor deficiencies. A significant deficiency is one that is or may be a threat to the health and safety of the animals.

• If program or facility deficiencies are noted, the reports will contain a reasonable and specific plan and schedule for correcting each deficiency.

• The report will identify all relevant facilities as being accredited by AAALAC International.

• Copies of the draft reports will be reviewed, revised as appropriate, and approved by the Committee.

• The final reports will be 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.

• Following completion of each evaluation, the completed report will be submitted to the Institutional Official in a timely manner—generally within 30 days.

• Deficiencies will be tracked by the IACUC Office Staff to ensure that they are appropriately resolved.

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

• Any individual may report concerns to the IO, IACUC Chair, Institutional Veterinarians, or any member of the IACUC. They may also report concerns anonymously via the "Report Compliance Issues" link on the IACUC and University Research Services & Administration web pages.

• Notices are posted 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. These instructions are also posted on an applicable institutional web-site.

- If necessary, the IACUC Chair may appoint a subcommittee to interview personnel involved and gather additional information. In any case, the information obtained and suggested interventions will be presented at an IACUC meeting for discussion by the full Committee.

- Reported concerns and all associated IACUC actions will be recorded in the IACUC meeting minutes.

- The IACUC will report such actions in writing to the IO and, as warranted, to OLAW and AAALAC International. 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.

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

- Recommendations regarding any aspects of the institution's animal program or animal facilities are discussed and developed by the IACUC.

- The IACUC's recommendations are included in the IACUC Meeting minutes or a report of the IACUC's evaluations or a separate letter to relevant personnel. Such documents are reviewed and approved by the IACUC and then submitted to the IO.

6. Review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals according to PHS Policy IV.C.1-3. The IACUC procedures for protocol review are as follows:

Submission, Pre-review, & Distribution

- IACUC protocols, new or three year renewals), are submitted via an electronic protocol management system (iMedRIS).

- A pre-review of the protocol is conducted by the IACUC Office staff for missing information or clarification of stated information.

- Veterinary review is then conducted on the submitted protocol.

- IACUC members are notified via email of any new protocols that are to be reviewed. New protocols, those received after September 1, 2015 can be accessed via the electronic protocol management system. Amendments to protocols approved after September 1, 2015 are also accessed via the electronic protocol management system. Amendments to protocols submitted prior to
September 1, 2015 are located in the IACUC Office and are available via email attachment.

- New protocols are available via the electronic protocol management system. Protocols submitted prior to September 1, 2015 are located in the IACUC Office and are available via email attachments.

- No animal work may begin before the full committee has been given the opportunity to review the protocol and call for a full-committee review and before the protocol has been approved by (1) the majority of a quorum of the members or (2) the designated reviewer in the absence of a call for full committee review. It is acknowledged that neither the PHS Policy nor the Animal Welfare Regulations recognize "provisional" or "interim" approval of any animal study proposal.

**IACUC Review**

- 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.

- The IACUC may invite consultants to assist in reviewing complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also members of the IACUC.

- 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.

- In order to approve proposed protocols or proposed significant changes in ongoing protocols, the IACUC will conduct a review of those components related to the care and use of animals and determine that 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 insofar 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 will 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 will be 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 will be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

d. The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.

e. Medical care for animals will be available and provided as necessary by a qualified veterinarian.

f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.

g. Methods of euthanasia used will be 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.

- Prior to committee 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.

**Full-Committee Review (FCR)**

- 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.

- Full Committee Review is conducted in person or in combination with a teleconference.

- After the Full Committee has reviewed the protocol; the Chair (or Vice Chair) calls for the vote. A show of hands indicates “yes”, “no” or abstention.

- The possible outcomes of FCR are as follows:
  a. Approval
  b. Require Modifications to secure approval
  c. Approval Withheld

- Review of 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 all the applicable procedures delineated in the PHS Policy and elsewhere in Part III.D.6 of this Assurance.
b. DMR if approved unanimously by all members at the meeting at which the required modifications are delineated AND if the entire current IACUC has previously approved, in advance and 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.

If DMR is used, the approval date is the date the approval letter is generated for the final revised protocol after it has been approved by the designated reviewer(s). However, the approval date may not be more than 30 days after the DMR approved the final revised protocol.

Minor modifications of an administrative nature, i.e., typographical or grammatical errors, required signatures, etc. may be confirmed and conducted by IACUC administrative/support personnel.

Designated-Member Review (DMR)

- Generally, the FCR method will be used for new protocols. However, should a situation warrant it, the protocol will be distributed to all IACUC members to allow all members the opportunity to call for FCR.

- Records of polling of members to obtain concurrence to use the DMR method, or concurrence by silent assent after three full working days, and approval of protocols via DMR are maintained and recorded in the minutes of the next convened IACUC meeting.

- If full-committee review (FCR) is not requested, at least one member of the IACUC, designated by the chairperson or vice chairperson and qualified to conduct the review, will 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 the use of the designated-member review (DMR) method may not be subject to any other conditions.

- After all required modifications are made, a final revised protocol, i.e., an identical document with all required modifications included, is submitted to all designated reviewers for review and approval.

- If multiple designated reviewers are used their decisions must be unanimous; if not, the protocol will be referred to FCR.

- The possible outcomes of DMR are as follows:
  a. approval,
b. require modifications in (to secure approval) or
c. request FCR of the protocol.

Special or Expedited Reviews

- There are no alternate processes or procedures for special or expedited reviews.

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 according to PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

- Other than the specific exceptions delineated in OLAW Guidance, Notice NOT-OD-14-126, August 26, 2014 and as delineated below and in IACUC approved policies, review and approval of significant changes is in accordance with the DMR process unless FCR is requested by an IACUC member. See Paragraph III.D.6., above for details of the DMR and FCR review processes.

- Significant changes include changes that have, or have the potential to have, a negative impact on animal welfare. In addition, some changes or activities that may not have a direct impact on animal welfare are also considered to be significant.

- Examples of changes considered to be significant include, but are not limited to, changes:

  a. in the objectives of a study;
  b. from non-survival to survival surgery;
  c. resulting in greater discomfort or in a greater degree of invasiveness;
  d. in the housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
  e. in the species;
  f. in Principal Investigator;
  g. that impact personnel safety;
  h. in anesthetic agent(s) or the use or withholding of analgesics;
  i. in the method of euthanasia;
  j. in the duration, frequency, or number of procedures performed on an animal;
  k. in approximate number of animals used

1Changes of less than 10% in the approximate number of animals used of mice of the genus Mus and rats of the genus Rattus that are bred for use in research only may, at the IACUC’s discretion, be considered minor (not significant). These changes are, however, documented.

- Review and approval of items a. – g. must be by FCR or DMR. See Part III.D.6. above.

- Review and approval of items h. – j. may also be handled administratively in consultation with a Georgia State University veterinarian who is authorized by the IACUC and as described in an IACUC approved written policy(ies) that is compliant with OLAW Guidance, Notice NOT-OD-14-126, August 26, 2014. Such policies will
include specific evaluation criteria, e.g., published drug formularies, AVMA Guidelines for the Euthanasia of Animals, allowable blood draw data/charts, etc. Such policies will also address possible negative impacts on animal welfare.

- Review and approval of item k. may also be handled administratively, but without requiring additional veterinary consultation, as described in IACUC approved written policies that are compliant with OLAW Guidance, Notice NOT-OD-14-126, August 26, 2014. Such policies will address the rational for the original number of animals used, approved study objectives, the rational for the additional animals, and possible negative impacts on animal welfare.

- All such aforementioned policies related to administrative review will be adopted by formal action by the IACUC.

- All authorizations of individuals by the IACUC to handle changes administratively is specific (by name or positional title and change(s) authorized to handle) and in writing.

- All such aforementioned policies and authorization of individuals related to administrative review may be approved for a maximum of 36 months only. That is, all such policies expire no later than the three-year anniversary of the IACUC approval.

- If the IACUC wishes to continue the procedures/policies and/or authorizations beyond the expiration date, prior to expiration of the policy, the existing or a new policy must be reviewed and adopted by formal action by the IACUC.

- All approved significant changes to previously approved ongoing activities will be documented in the associated protocol file.

- If additional personnel are to be added a Personnel Amendment Form must be submitted. All personnel to be added must have completed all required training and be enrolled in the Medical Monitoring Program. The Personnel Amendment must be approved by the IACUC Chair prior to new personnel working on approved IACUC protocols.

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

- The IACUC Office or the electronic protocol management system sends the PI notice in writing informing them of the status of the protocol following review. The PI will be notified whether the protocol or the amendment has been approved, requires modification to secure approval or approval has been withheld.

- If the IACUC’s decision is to require modifications to secure approval, the required modifications are delineated in the written notification.
• If approval is withheld, the notice will include the reasons that it was withheld and the PI may respond to the IACUC in person and/or in writing.

• The Institutional Official may contact the IACUC Compliance Officer regarding the status of any submitted or approved IACUC protocol at any time. The Institutional Official is notified by receiving a copy of the PI’s notification letter and/or a copy of the IACUC meeting minutes.

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 at least once every 3 years according to PHS Policy IV.C.1.-.5. The IACUC procedures for conducting continuing reviews are as follows:

Post-approval Monitoring

• Ongoing activities are monitored continuously by the animal care and use staff.

• Post approval monitoring currently includes: program evaluations, reviews of protocols, reporting noncompliance, ensuring that individuals who work with animals are appropriately trained and qualified, and addressing concerns involving the care and use of animals at the institution.

• The veterinarians along with the animal care and technical staff, add another important level of program supervision including daily observation of animals by trained animal care personnel and communication to the veterinary staff for follow-up, facility monitoring by facility maintenance personnel, post-operative care by trained personnel, evaluation of outcomes of animal procedures by investigators and staff, hands-on training in animal procedures, and appropriate reporting of incidents involving occupational health and safety.

• In addition, post-approval monitoring of research studies can be conducted to identify possible weaknesses and elicit process improvements. This strategy also serves to increase investigator awareness of regulatory requirements and improve the ethical conduct of research. This monitoring may be protocol oriented or investigator-oriented.

  a. A protocol is randomly selected for observation to maintain consistency and evaluate procedures that have been submitted and approved as part of the IACUC process.

  b. An Investigator is monitored based on known or suspected information regarding how procedures are conducted. Results can subsequently lead to monitoring of all active protocols approved for that investigator.

Continuing / Periodic Review

• USDA Regulated Species – For those species covered under the AWA, the PI submits an IACUC Protocol Continuation or Cancellation Form (e.g. annual review form) to the IACUC on an annual basis. Review of this Form along with the protocol is done by a voting member or members of the committee.
- Non-USDA Regulated Species – require only triennial review.

- Annual protocol reviews are recorded in the IACUC meeting minutes. The IACUC meeting minutes are reviewed and approved by the Committee.

- All 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 the activities will continue beyond the expiration date, a new protocol must be submitted, reviewed, and approved as described above in Paragraph III.D.6., prior to expiration of the original or preceding protocol.

10. Be authorized to suspend an activity involving animals according to PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:

- The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the approved protocol, applicable provisions of the Animal Welfare Act, the Guide, the institution's Assurance, or IV.C.1.a.-g. of the PHS Policy.

- The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.

- If the IACUC suspends an activity involving animals, or any other institutional intervention results in the temporary or permanent suspension of an activity due to noncompliance with the approved protocol, the Policy, Animal Welfare Act, the Guide, or the institution's Assurance, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation in writing to OLAW, USDA (if applicable) and AAALAC-Int'l. Preliminary reports may be made verbally.

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

1. Administration/management.

- An advanced practice nurse associated with the GSU School of Nursing serves as the program administrator for the Medical Monitoring Program for Vertebrate Animal Exposure.

- The purpose of the Medical Monitoring Program for Vertebrate Animal Exposure (MMPVAE) is to prevent, monitor, and reduce diseases transmitted from animals to humans (zoonotic diseases) and mitigate adverse reactions from exposure to laboratory animals (e.g. allergies). In addition, educational programs have been established to educate personnel about zoonotic diseases, personal hygiene, and other related issues.
• The MMPVAE has been developed in accordance with the Occupational Health and Safety in the Care and Use of Research Animals document prepared by the National Research Council (NRC), the Guide for the Care and Use of Laboratory Animals (Institute of Laboratory Animal Resources [ILAR]), and the Biosafety in Microbiological and Biomedical Laboratories, CDC•NIH.

2. Scope.

• All faculty, staff, students and visiting researchers who are in direct physical contact with one or more animals used for research or a classroom project at the University are required to be enrolled in the MMPVAE. Also included are all members of the IACUC and physical plant staff and others having responsibility in the animal facilities.

• It is the responsibility of the Principal Investigators, managers, and supervisors to ensure that all individuals working with vertebrate animals under their direction are enrolled in the MMPVAE.

3. Health Histories and Evaluations.

• An advanced practice nurse associated with the GSU School of Nursing serves as the Program Administrator (0.5 FTE) for the Medical Monitoring Program for Vertebrate Animal Exposure (MMPVAE).

• Specific services provided include, but are not limited to, distributing MMPVAE informational materials to enrollees, managing the enrollee database, performing a risk assessment based on the Enrollment Questionnaire, and distributing reminders to enrollees about services coming due (e.g. repeat TB testing).

• The Medical Service Provider offers professional medical support services for the MMPVAE. The MSP will provide physical examinations; administer appropriate tests, procedures, and/or immunizations. Treatment for animal related illnesses or injuries are under the purview of the Office of Safety and Risk Management.

• To enroll in the program a form must be submitted on an annual basis. This form is also used to submit a change in exposure (e.g. working with non-human primates when previously only working with mice).

• The completed questionnaire is reviewed by the MSP (specifically the advanced practice nurse) as a critical component of the risk assessment process (e.g. to identify existing conditions that may influence the health of persons with animal contact and, in certain cases, the existence of human disease that could adversely affect the health of certain species of animals).

• Subsequent to the conduct of the risk assessment, the advanced practice nurse notifies enrollees of any recommended and/or required medical procedures (e.g. TB testing, immunizations, respiratory fit testing, and the like). In addition, based upon the answers provided on the questionnaire, the advanced practice nurse may contact the enrollee to request a meeting to discuss a relevant issue(s). Certain medical screenings must be repeated on a periodic basis and program
participants are sent reminders when such services are due. Expenses for medical services provided are borne by the university, not the program participant.

- Many of the medical services are provided by the advanced practice nurse on the GSU campus. In addition to the services provided by the advanced practice nurse, medical services may also be provided by an occupational health physician group.

- The enrollee can choose to waive recommended but not required medical procedures. The MSP will maintain permanent medical records for each vertebrate animal user. Confirmation of services provided and results of authorized procedures under the auspices of the MMPVAE will be maintained by the advanced practice nurse.


- Hazard identification and risk assessment are a cooperative effort involving the advanced practice nurse, the occupational health physician group, the Biosafety Committee, the Radiation Protection Committee, the IACUC, the Attending Veterinarian, and the scientists conducting animal research.

- As a component of enrolling in the MMPVAE, individuals are required to complete a Health History Questionnaire which displays assigned reading materials commensurate with answers provided on the questionnaire, inserts the enrollee into the occupational health and safety program database, and generates auto-reminders about services due (e.g., TB testing, respirator fit testing, need to complete the questionnaire for annual reassessment, etc.).

- The aforementioned assigned reading materials provide important information about inherent risks involving a laboratory animal environment to include laboratory animal allergies, relevant zoonotic diseases, personal hygiene, bites and scratches, lifting injuries, and the like.

- The advance practice nurse reviews the completed questionnaire and notifies enrollees of any recommended and/or required medical procedures (e.g. TB testing, immunizations, respiratory fit testing, etc.). In addition, based upon the answers provided on the questionnaire, the advance practice nurse may contact the enrollee to request a meeting to discuss a relevant issue(s).

- The use of hazardous materials, such as isotopes, toxic chemicals, biological agents, etc. in animals is allowed only after a thorough review by the IACUC, IBC, and/or Radiation Protection Committee, as appropriate, with subsequent provisions being established which must be followed. The IACUC protocol inquires about the use of such materials and assures that the appropriate approvals are in place prior to the IACUC protocol being approved.

- Studies involving hazardous materials are conducted under the direction of a Principal Investigator who is responsible for ensuring the safety of the operation, and for following established policies and procedures for the use of these materials. The DAR and the PI and his/her research laboratory members must and
do work closely in this respect to assure that the appropriate signage, training, and procedures are in place and that all relevant personnel are informed of such.

- Proper training of personnel is an important component by which risk is minimized. DAR employees are required to read and follow SOPs related to the various animal care and use and associated procedures in which they engage. Similarly, all individuals working with primates are required to read the SOPs on an annual basis. Further, the IACUC reviews the training and experience of all personnel working with animals as a component of an IACUC-approved protocol.

- The DAR provides training related to appropriate animal handling and restraint in an effort to minimize the occurrence of injuries and exposures to disease.

5. Procedures in Place to Alleviate Hazards and Minimize Risks.

- The Division of Animal Resources (DAR) provides training related to appropriate animal handling and restraint in an effort to minimize the occurrence of injuries and exposures to disease.

- The MMPVAE enrollees are placed into one or more categories (see below) with regard to animal contact and/or exposure.

- Placement into a particular category(ies) constitutes the basis for the medical procedures which are recommended or required. Additional services may be recommended and/or required by the advance practice nurse subsequent to the review of the completed questionnaire.

- In addition, should the enrollee be working with a biological, chemical, and/or radiological hazard then other recommendations and/or requirements may apply as determined by the appropriate oversight committees/individuals (e.g. Institutional Biosafety Committee, Radiation Protection Committee, chemical safety officers).

The categories are as follows:

1. Rodents, rabbits, ferrets, birds
2. Nonhuman primates
3. Fish, reptiles, amphibians
4. Animal contact limited to environmental exposure (e.g. physical plant staff, IACUC members, others who may enter animal facility but not contact animals)

- Category 1 participants are those who anticipate handling only rodents, rabbits, ferrets, birds and/or their tissues, body fluids or wastes.

Tetanus Immunization (recommended) - Immunization with tetanus toxoid is updated according to recommendations of the Public Health Service Immunization Practices Advisory Committee (IPAC) of the Centers for Disease Control and Prevention (CDC). Booster doses may be administered every ten (10) years or as needed during any of the following:
a. following the report of an injury
b. as needed

Protocol-Specific Hazards - The use of hazardous materials, such as isotopes, toxic chemicals, biological agents, etc. in animals is allowed only after a thorough review by the IACUC, IBC, and/or Radiation Protection Committee, as appropriate, with subsequent provisions being established which must be followed.

- **Category 2** participants are those who anticipate handling only nonhuman primates and/or their tissues, body fluids or wastes. Note that participants entering the nonhuman primate housing areas (even if no animal contact is made) are designated as category 2 participants.

  **Tetanus Immunization** (recommended See Category 1 description above)

  **Hepatitis-A Vaccination Program** (recommended) - If an employee handles nonhuman primate blood, body fluids or tissues as a work requirement in research related activities, the MMPVAE recommends immunization against Hepatitis-A virus. Hepatitis is primarily transmitted through non-human primate fecal material.

  **Hepatitis-B Vaccination Program** (recommended) - If an employee handles nonhuman primate blood, body fluids or tissues as a work requirement in research related activities, the MMPVAE recommends immunization against Hepatitis-B virus.

  **Tuberculosis screening** (required) - Tuberculosis is a zoonotic disease that can be devastating in any nonhuman primate colony. Due to the inherent risks, special precautions must be taken for those individuals working with nonhuman primates. Participation in the TB screening program is mandatory.

  **Rubeola (Measles)** (required) - This is a zoonotic disease that can affect nonhuman primates and often causes a fatal pneumonia in nonhuman primates. Participation in the measles program is mandatory.

  **Protocol-Specific Hazards** (See Category 1 description above)

- **Category 3** participants are those who anticipate handling only fish, amphibians, or reptiles and/or their tissues, body fluids or wastes.

  **Tetanus Immunization** (recommended See Category 1 description above)

  **Protocol-Specific Hazards** (see above)

- **Category 4** participants are those in which animal contact is limited to environmental exposure (e.g. physical plant staff, IACUC members, others who may enter animal facility but not contact animals).

  **Tetanus Immunization** (recommended See Category 1 description above)

  **Protocol-Specific Hazards** (See Category 1 description above)
- **Laboratory Animal Allergies** - Animal care staff and others who handle laboratory animals may be sensitized to animal dander or other proteins. Individuals at risk of developing allergies or experiencing the onset of existing allergic reactions include those with preexisting allergies, asthma, seasonal rhinitis or eczema. Preventing exposure to the allergies may require the use of personal protective equipment such as gowns, gloves, and respiratory protection. Allergic reactions to animals are among the most common conditions that adversely affect the health of workers involved in the care and use of animals in research.

- **Latex Allergies** - Latex allergy is a reaction to certain proteins found in natural rubber latex, a product manufactured from the milky fluid that comes from the rubber tree. If you have a latex allergy, your body mistakes latex for a harmful substance. Latex allergy may cause a variety of allergic reactions to include sneezing or a runny nose and may cause a more severe reaction known as anaphylaxis which is a potentially life-threatening condition. The MSP may determine if you have a latex allergy or if you are at risk of developing a latex allergy.

- **Bites and scratches** - Most animals are capable of inflicting bites and/or or scratches. Proper animal handling will serve to minimize the occurrence of bites and/or scratches, the use of the appropriate PPE will assist in this objective.

- **Personal Protective Equipment (PPE)** - The Medical Monitoring Program for Vertebrate Animal Users is designed to help protect individuals from the risk of possible infection by animal-associated organisms or other agents associated with animal research. However, it is up to the individual to take proper precautions in the handling of animals. In doing so, the use of personal protective equipment (PPE) is critical. The PPE provides a physical barrier to potentially hazardous materials associated with animals. The institution shall provide, at no cost, appropriate PPE. The appropriate PPE to be utilized is based upon a risk assessment and takes into consideration the animal species utilized, the types of procedures being conducted, and the individual conducting the activity (e.g., the presence of laboratory animal allergies may require the use of additional PPE). The institution is also responsible for cleaning, laundering, disposal and replacement of PPE at no cost. Failure to use appropriate PPE may increase the chance of being exposed to potentially hazardous materials from animal contact. Therefore, the use of proper PPE is required.

- **Personal Hygiene** - There are a number of personal hygiene issues that apply to all workers who are exposed to animals. There must be no eating, drinking, or applying of cosmetics in areas where animals are housed. All work surfaces must be decontaminated daily and after any animal-related spills or contacts. Laboratory coats must be worn over street clothes or employees can change into special designated clothing when working with animals. Personal protective equipment must be used appropriately. Very importantly, thorough hand washing must be done after handling the animals and prior to leaving the laboratory.

6. **Immunizations.**
• **Tetanus** - Tetanus is caused by a toxin produced by bacteria that is frequently found on surfaces contaminated by dirt and/or the feces of some animals. The organism can gain entrance into the body through bite wounds, puncture wounds caused by sharp objects, or contamination of other deep wounds. Failure to be vaccinated against tetanus could result in severe illness or death.

Immunization with tetanus toxoid is updated according to recommendations of the Public Health Service Immunization Practices Advisory Committee (IPAC) of the Centers for Disease Control and Prevention (CDC). Booster doses may be administered every ten (10) years or as needed during any of the following:
  a. following the report of an injury
  b. as needed

• **Hepatitis A Virus** - Individuals who may have occupational exposure to human or nonhuman primate (NHP) fecal material or fecally-contaminated materials while working on animal research will be offered the Hepatitis A vaccination. Failure to be vaccinated against HAV could result in severe illness such as liver disease. The vaccine is safe and effective in protecting the individual against the potentially deadly virus.

• **Hepatitis B Virus**
  Individuals who may have occupational exposure to human or nonhuman primate (NHP) blood, tissue or other potentially infectious materials while working on animal research, will be offered the Hepatitis B vaccination. Failure to be vaccinated against HBV could result in severe illness such as liver disease. The vaccine is safe and effective in protecting the individual against the deadly virus.

• **Measles**
  Measles is best known for causing a rash in childhood, but measles can affect other parts of the body and sometimes occurs in adults. Vaccination has significantly reduced the number of cases in the United States, although isolated outbreaks continue to occur.

  There are two types of measles, each caused by a different virus. Although both produce a rash and fever, they are really different diseases:

  The rubeola virus causes "red measles," also known as "hard measles" or just "measles." Although most people recover without problems, rubeola can lead to pneumonia or inflammation of the brain (encephalitis).

  The rubella virus causes "German measles," also known as "three-day measles." This is usually a milder disease than red measles. However, this virus can cause significant birth defects if an infected pregnant woman passes the virus to her unborn child.

  Both the rubeola and rubella viruses are spread through the respiratory route. This means they are contagious through coughing and sneezing. In fact, the rubeola virus is one of the most contagious viruses known to man. As a result, it can spread rapidly in a susceptible population. Infected people carry the virus in their respiratory tract before they get sick, so they can spread the disease without being
aware of it. If people are immune to the virus (either through vaccination or by having had measles in the past), they cannot get the disease caused by that virus. For example, someone who had rubella as a child would not be able to get the disease again. Remember that rubella and rubeola are different viruses. An infection with one of these viruses does not protect against infection with the other. Like man, non-human primates (e.g. monkeys and apes) are also susceptible to both types of measles. If a non-human primate becomes infected with measles, it is usually because a human has passed the infection to the non-human primate.

Since students, faculty, and health care and other workers in colleges and other post-high school educational institutions are at increased risk of acquiring measles and mumps, they should receive two doses of Measles, Mumps, and Rubella (MMR) vaccine or provide other evidence of measles immunity (physician diagnosis or laboratory evidence).

Personnel working with NHP are required to have proof of MMR vaccination or have a measles titer assayed. Personnel will be required to have a MMR vaccination booster if their titer assay is below the required level.

A personal history of measles is NOT acceptable as proof of immunity. Acceptable evidence of measles immunity includes:

- A positive serologic test for antibody
- A physician diagnosis of disease
- Birth before 1957
- Written documentation of vaccination*

*Please note that MMR vaccination consists of two doses separated by at least 28 days. Since 2%-5% of persons do not develop measles immunity after the first dose of vaccine, the second dose is to provide another chance to develop measles immunity for persons who did not respond to the first dose. There is no evidence that adverse reactions are increased when MMR is given to a person who is already immune to one or more of the components of the vaccine.

Individuals who have not provided acceptable evidence of measles immunity will be:

- denied access to facilities housing NHPs; or
- required to wear additional PPE to protect the NHP from possible exposure and will have limited access within the animal facility.

- Also, See Section 5 above.

7. Precautions taken during pregnancy, illness or decreased immunocompetence.

- Impaired Immune System - Individuals with an impaired immune system, due to medication or disease, may be at a significantly greater risk of contracting an infectious disease from the animals with which they work. Such individuals should contact their personal physician and specify that they work with laboratory animals. One can also discuss this issue with the advance practice nurse associated with the MMPVAE who may, in turn, refer the enrollee to an occupational health physician.
• Health Precautions for Pregnant Personnel Working with Animals - Pregnant employees or those planning to become pregnant should contact their obstetrician/gynecologist immediately and specify that they work with laboratory animals. The particular species and types of activities involved (e.g. work with a particular infectious agent, chemical hazard, inhalant anesthetic, radioisotope, etc.) should be discussed so that one becomes educated about the associated risks and precautionary measures. One can also discuss this issue with the advance practice nurse associated with the MMPVAE who may, in turn, refer the enrollee to an occupational health physician.

8. Provisions for personnel who are not involved in animal care and/or use but nevertheless need to enter areas where animals are housed or used.

• Such individuals complete a "Visitor Access Form." There is a separate form dedicated to the Petit Science Center and Natural Science Center Animal Facilities which do not house non-human primates as opposed to the Language Research Center Animal Facilities which do house non-human primates. Each form provides relevant information pertaining to risks/hazards as well as procedures to follow while in the animal facility.

9. Availability and procedures for treatment of bites, scratches, illness or injury.

• First aid kits are maintained in each vivarium and are maintained by the Division of Animal Resources management staff.

• In the event of bites, scratches, illness or injury:

Accident/injury posters are conspicuously posted in all animal facilities which provide relevant instruction as summarized below. Further, these posters are discussed during the animal facility orientation process as it pertains to all new animal users.

Faculty and Staff*: For non-life-threatening events, faculty and staff are directed to a physician via the university worker's compensation program. For life-threatening events, faculty and staff are instructed to dial 404-413-3333 for the Georgia State University Police, or 911. The faculty and staff are advised that the police can stay with them until the ambulance arrives and can help to direct the ambulance to the appropriate location.

Students*: For non-life-threatening events, students are instructed to seek assistance at the Student Health Clinic on the university campus. For life-threatening events, students are instructed to dial 404-413-3333 for the Georgia State University Police, or 911. The students are advised that the police can stay with them until the ambulance arrives and can help to direct the ambulance to the appropriate location.

*For any accident/injuries/exposures involving rhesus macaques, all are treated as potentially life-threatening and individuals with such a exposure are transported to
the Emory Hospital. All individuals working with rhesus macaques carry a B-virus exposure card which is presented to the Emory Hospital staff.

10. Procedures/program for reporting and tracking injuries and illnesses.

- Principal Investigators and Managers/Supervisors must ensure that individuals are trained to promptly report any illnesses, needle stick, bite or scratch wounds, or splashes that might result from animal contact to:
  
  a. the Principal Investigators and
  b. Managers/Supervisors as well as
  c. the Occupational Health and Safety Program Administrator (OHSPA, aka Assistant Director of Environmental Programs).

Step 1 - report to supervisor
Step 2 - supervisor fills out lab accident report form
Step 3 - seek medical attention (can be done before step 2 if emergency)
Step 4 - if it is a workers comp claim, supervisor will be prompted to fill out workers comp forms

- Any necessary medical services would then be determined and authorization for treatment would be issued if recommended by the physician.

11. Other Pertinent Information Regarding the OH&S Program.

**Herpes B Virus of Macaque Monkeys**

- B Virus naturally occurs in macaque monkeys. While relatively benign in its natural host, the alphaherpesvirus can cause rapidly ascending encephalomyelitis (inflammation of the brain) with a fatality rate of approximately 80% if spread to humans (through bites, scratches, splashes, or needle-stick injuries). B virus directly affects the central nervous system of infected human and nonhuman primates.

- In the macaque host, B virus causes mild symptoms that are similar to that of herpes simplex virus 1 (cause of common cold sores) in humans. These symptoms can include oral or genital lesions, but virus can be shed in the absence of lesions as well. If infected, the macaque monkey remains infected for the duration of its lifetime and is a potential source of the virus for humans. All macaque monkeys maintained by GSU are serologically negative for B virus (screened annually) but, as false negatives can occur and due to the severity of infection if acquired by a human, they are treated as if they are infected.

- Georgia State University National B Virus Resource Laboratory provides diagnostic assays for both nonhuman primates and humans suspected to be infected with B virus. Service is provided on a 24/7 and on an emergency basis 365 days/year. Diagnostic testing services are offered for injury (exposure) related human and nonhuman primate samples as well as for routine screening. B virus zoonosis can be effectively managed with early detection of this deadly agent in cases of zoonotic infection. Early detection can translate into prevention of
morbidity and mortality as a result of an inadvertent exposure to this uniquely pathogenic herpesvirus.

- Individuals charged with working with macaque monkeys will be required to read and follow standard operating procedures designed to prevent potential exposure to this virus. Further, these standard operating procedures outline steps that must be followed in the event of a potential exposure.

**Tuberculosis (TB)**

- Tuberculosis is caused by a bacterial organism and is capable of producing serious disease in both people and nonhuman primates. Tuberculosis typically attacks the lungs but can also affect other parts of the body. It is typically transmitted via the air by coughing and sneezing. An active TB infection can spread to other people. A latent infection cannot spread to other people, but it can turn active and become contagious.

- The Division of Animal Resources periodically tests the nonhuman primates for the presence of TB. Similarly, people who have contact with nonhuman primates (NHPs) must receive a semi-annual tuberculin skin test and/or an annual chest x-ray as clinically indicated. Once the individual is cleared with their initial chest x-ray, the individual may request an Annual Tuberculosis Screening Questionnaire to be used instead of the annual chest x-ray.

- Individuals who have not completed their semi-annual tuberculin skin test or Annual Tuberculosis Screening Questionnaire will be:
  
a. denied access to facilities housing NHPs; or
b. required to wear additional PPE to protect the NHP from possible exposure and will have limited access within the animal facility.

- The MMPVAE program sends reminders as to when individuals need their semi-annual tuberculin skin test and/or Annual Tuberculosis Screening Questionnaire. Testing is done with the Mantoux (PPD) technique that measures hypersensitivity to tuberculin. The appearance of inflammation at the site of injection is measured to indicate past or present tuberculosis infection. Individuals who have tested "positive" in the past are required to have one baseline chest x-ray and then annual symptom review. Chest x-rays will not be performed annually, but only if indicated based on the clinical presentation. At any time, if any employee has symptoms of TB (persistent cough, low grade fevers, unexplained weight loss, night sweats) further evaluation must be done.

- Individuals with a previous positive skin test for tuberculosis should provide a certificate from the attending doctor (giving the circumstances of the positive test result, and indicating any treatment prescribed, and its duration) to the MSP. If the individual has ever been diagnosed with tuberculosis, this individual must present a written certification, signed by the attending doctor, proving that the individual was adequately treated. The certificate must include dates and types of medications taken for the MSP to review. Contact the MMPVAE advance practice nurse for more information.
• If the chest x-ray is read as negative (clear) subsequent annual chest x-rays are not routinely needed unless:

   a. symptoms develop that could be attributed to TB; or
   b. the individual has not completed and submitted an Annual Tuberculosis Screening Questionnaire (Appendix B) to the MSP for review

• All vaccines may be given on the same day as a TB skin test, or any time after a TB skin test is applied. However, if MMR has been given, and one or more days have elapsed, Advisory Committee on Immunization Practices recommend waiting 4-6 weeks before giving a routine TB skin test. No information on the effect of varicella or other live injected vaccines on a TB skin test is available. Until such information is available, it is prudent to apply rules for spacing measles vaccine and TB skin testing to these vaccines. There is no evidence that inactivated vaccines interfere with PPD response.

**Oral Herpes Simplex (Cold Sores)**

• Humans who suffer periodically from cold sores represent a serious threat to some species of NHPs. The virus that causes the disease is lethal to some NHPs. People with active cold sore lesions should avoid contact with NHPs until their lesions have healed. It is the responsibility of the Midlevel or Senior Level Employee to decide if a "no contact" order should be given to the vertebrate animal user with cold sores if he or she is working with NHPs. This "no contact" order should not adversely affect the employee's terms or conditions of employment.

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:

1. **IACUC Members**

   • IACUC members receive training from both internal and external training programs.

   • New IACUC members participate in an orientation session in which the GSU IACUC Policies and Procedures are reviewed.

   • Other aspects of training include:

     b. Roles & Responsibilities of Reviewers of protocols;
     c. Roles & Responsibilities of the Designated Reviewers;
     d. AALAS Training requirements;
e. Overview of the IACUC Protocol Application and required training of researchers/staff;
f. Roles and responsibilities of the IACUC Chair,
g. Roles & Responsibilities of the University Veterinarian; and
h. Roles & Responsibilities of the IACUC Compliance Officer.

• Each IACUC member is provided access to the following resources:
  a. The PHS Policy for the Humane Care and Use of Laboratory Animals;
  b. The National Research Council (NRC) Guide for the Care and Use of Laboratory Animals;
  c. The ARENA/OLAW IACUC Guidebook;
  d. The current AVMA Guidelines on Euthanasia; and
  e. A copy of the current [most recent OLAW approved] GSU Assurance.

• In addition, relevant training topics and literature applicable to laboratory animal use and the IACUC are discussed at the IACUC meetings on a regular basis.

• When possible, IACUC members attend one or more of the following training opportunities: IACUC 101, IACUC 201, IACUC Advanced, the PRIM&R-ARENA conference, SCAW/OLAW workshops and other similar conferences and/or webinars addressing IACUC-relevant issues.

2. Animal Care and Use Personnel

• The Georgia State University PHS Assurance is available on the IACUC webpage. Personnel involved in animal care and/or use are notified of the document’s location during the Animal Facility Orientation.

• The completion and documentation of all training, including procedure-specific training, species-specific housing methods, husbandry procedures, and handling techniques is required prior to approval of the animal protocol by the Institutional Animal Care and Use Committee.

• In addition, research staff members performing experimental manipulation, including anesthesia and surgery, must be deemed competent, through training or experience, to accomplish such procedures humanely and in a scientifically acceptable fashion.

• Training or instruction in research and testing methods that minimize the number of animals required to obtain valid results and minimize animal distress is also provided.

• Professional staff whose work involves hazardous biological, chemical, or physical agents has training or experience to assess potential dangers and select and oversee the implementation of appropriate safeguards.

• Targeted individuals for training include the Principal Investigator, co-investigators, instructors, staff, students and others working with animals in association with a protocol.
• Georgia State University requires training for all personnel listed on a protocol
even those not having direct animal exposure. Individuals in this category must
complete the online training module “Working with the IACUC” and “Ethical
Decision-Making in Animal Research” prior to being listed on an approved IACUC
protocol.

• GSU uses the AALAS Learning Library as the primary online training resource.
Training/instruction is available 24 hours a day with the AALAS Learning Library.
The online training is free. The online training modules must be repeated at three-
year intervals.

• Each investigator, student, staff member, etc. listed on an animal use protocol
must take and pass the relevant modules of online training. At the time of
completion of a module, AALAS provides the IACUC Office with the title of the
module, the completion date, and the name of the person who completed the
session.

• Onsite hands-on workshops have also been developed and are presented by the
Division of Animal Resources under the direction of the Attending Veterinarian.

• Prior to approval of any protocol, investigators and their listed staff must have
completed and passed the exams of the online training modules listed below.
Additional training mandated by the IACUC (e.g. in the event of any
noncompliance report), may be required as well. In addition, individual training is
conducted periodically at the request of any investigator, student, or staff member.

• The Institution is responsible for training its staff to meet the performance
requirements cited in paragraph IV.C.1.a.- g. of the PHS Policy, as well as other
requirements delineated in 9 CFR, Part 2, Subpart C, Section 2.32(c).

• Specifically, as applicable, training and instruction of personnel include guidance
in at least the following areas:

  1. Humane methods of animal maintenance and experimentation, including:

     a. The basic needs of each species of animal;
     b. Proper handling and care for the various species of animals used;
     c. Proper pre-procedural and post-procedural care of animals; and
     d. Aseptic surgical methods and procedures;
     e. Inhalation anesthesia methods;
     f. Post-procedure care of mice and rats -minimizing pain and d and distress
        and pain management.

  2. The concept, availability, ethics and use of research or testing methods that
     limit the use of animals or minimize animal distress;

  3. Proper use of anesthetics, analgesics, and tranquilizers for any species of
     animals used by the facility;
5. Proper methods of euthanasia, including:
   a. The need for euthanasia
   b. AVMA Guidelines for the Euthanasia
   c. Methods of euthanasia
   d. Verification of death

5. Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act;

6. Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information:
   a. On appropriate methods of animal care and use;
   b. On alternatives to the use of live animals in research;
   c. That could prevent unintended and unnecessary duplication of research involving animals; and
   d. Regarding the intent and requirements of the Animal Welfare Act and USDA-APHIS Regulations.

   - In addition, targeted individuals must attend an animal facility orientation meeting. These orientations are offered on a monthly basis by the Division of Animal Resources. The orientation is not required for established users of the animal facility. Rather, the targeted individuals are those new to the GSU animal facilities.

   - All animal users enroll in the Medical Monitoring Program for Vertebrate Animal Exposure (MMPVAE) on an annual basis. This program is described in Section E above.

IV. Institutional Program Evaluation and Accreditation

A. 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 reevaluated by the IACUC at least once every six months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to 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 PHS Policy and 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.

B. This Institution is Category 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. Recordkeeping Requirements

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

1. A copy of this Assurance and any modifications made to it, 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 granted or withheld

4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official

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. 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

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 noncompliance with the PHS Policy
2. Any serious deviations from the provisions of the Guide

3. Any suspension of an activity by the IACUC

C. Reports filed under VI.A. and VI.B. above should include any minority views filed by members of the IACUC.
### VII. Institutional Endorsement and PHS Approval

#### A. Authorized Institutional Official

<table>
<thead>
<tr>
<th>Name: James A. Weyhenmeyer, PhD</th>
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<tbody>
<tr>
<td>Title: Vice President for Research and Economic Development</td>
</tr>
<tr>
<td>Name of Institution: Georgia State University</td>
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<tr>
<td>Address: (street, city, state, country, postal code)</td>
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<td>Atlanta, GA 30303-3999</td>
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<tr>
<td>Phone: 404-413-3517</td>
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<tr>
<td>Fax: 404-413-3518</td>
</tr>
<tr>
<td>E-mail: <a href="mailto:jweyhenmeyer@gsu.edu">jweyhenmeyer@gsu.edu</a></td>
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</table>

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.

| Signature: | Date: 1/30/2016 |

#### B. PHS Approving Official *(to be completed by OLAW)*

<table>
<thead>
<tr>
<th>Name/Title:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office of Laboratory Animal Welfare (OLAW)</td>
</tr>
<tr>
<td>National Institutes of Health</td>
</tr>
<tr>
<td>6705 Rockledge Drive</td>
</tr>
<tr>
<td>RKL1, Suite 360, MSC 7982</td>
</tr>
<tr>
<td>Bethesda, MD USA 20892-7982 (FedEx Zip Code 20817)</td>
</tr>
<tr>
<td>Phone: +1 (301) 496-7163</td>
</tr>
<tr>
<td>Fax: +1 (301) 915-9465</td>
</tr>
</tbody>
</table>

| Signature: |
| Date: |

Assurance Number: 

| Effective Date: |
| Expiration Date: |
### VIII. Membership of the IACUC

Date: January 26, 2016

Name of Institution: Georgia State University

Assurance Number: A3914-01

<table>
<thead>
<tr>
<th>IACUC Chairperson</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: Christopher P. Ingalls</td>
</tr>
<tr>
<td>Title: Professor, Kinesiology and Health</td>
</tr>
<tr>
<td>Degree/Credentials: Ph.D., M.S.</td>
</tr>
<tr>
<td>Address: (street, city, state, zip code)</td>
</tr>
<tr>
<td>Sports Arena</td>
</tr>
<tr>
<td>125 Decatur St. SE</td>
</tr>
<tr>
<td>Atlanta, GA 30303</td>
</tr>
<tr>
<td>Email: <a href="mailto:cingalls@gsu.edu">cingalls@gsu.edu</a></td>
</tr>
<tr>
<td>Phone: 404-413-8377</td>
</tr>
<tr>
<td>Fax: 404-413-8053</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IACUC Roster</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Member/Code **</td>
</tr>
<tr>
<td>Degree/Credentials</td>
</tr>
<tr>
<td>Position Title ***</td>
</tr>
<tr>
<td>PHS Policy Membership Requirements ****</td>
</tr>
<tr>
<td>Christopher Ingalls</td>
</tr>
<tr>
<td>Ph.D., M.S.</td>
</tr>
<tr>
<td>Professor, Kinesiology and Health</td>
</tr>
<tr>
<td>Chair</td>
</tr>
<tr>
<td>Charles Menzel</td>
</tr>
<tr>
<td>Ph.D.</td>
</tr>
<tr>
<td>Senior Research Scientist, Language Research Center</td>
</tr>
<tr>
<td>Vice-Chair</td>
</tr>
<tr>
<td>Michael Hart</td>
</tr>
<tr>
<td>D.V.M., M.S.</td>
</tr>
<tr>
<td>University Veterinarian and Director Animal Resources</td>
</tr>
<tr>
<td>Veterinarian</td>
</tr>
<tr>
<td>Roberta Attanasio</td>
</tr>
<tr>
<td>Ph.D.</td>
</tr>
<tr>
<td>Associate Professor, Biology</td>
</tr>
<tr>
<td>Scientist</td>
</tr>
<tr>
<td>Kim Huhman</td>
</tr>
<tr>
<td>Ph.D.</td>
</tr>
<tr>
<td>Distinguished Professor, Neuroscience, Psychology</td>
</tr>
<tr>
<td>Alternate Scientist for Menzel &amp; Petrulis</td>
</tr>
<tr>
<td>Sang-Moo Kang</td>
</tr>
<tr>
<td>Ph.D.</td>
</tr>
<tr>
<td>Professor, Institute for Biomedical Sciences</td>
</tr>
<tr>
<td>Scientist</td>
</tr>
<tr>
<td>Jeffrey Otis</td>
</tr>
<tr>
<td>Ph.D.</td>
</tr>
<tr>
<td>Assistant Professor, Kinesiology and Health</td>
</tr>
<tr>
<td>Scientist</td>
</tr>
<tr>
<td>Aras Petrulis</td>
</tr>
<tr>
<td>Ph.D.</td>
</tr>
<tr>
<td>Associate Professor, Neuroscience, Psychology</td>
</tr>
<tr>
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</tr>
<tr>
<td>Richard Plemper</td>
</tr>
<tr>
<td>Ph.D.</td>
</tr>
<tr>
<td>Professor, Institute for Biomedical Sciences</td>
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<tr>
<td>Scientist</td>
</tr>
<tr>
<td>Cynthia Roberts</td>
</tr>
<tr>
<td>B.A.</td>
</tr>
<tr>
<td>President, Sentient Search Solutions</td>
</tr>
<tr>
<td>Non-scientist and Non-affiliated Member</td>
</tr>
<tr>
<td>Aaron Roseberry</td>
</tr>
<tr>
<td>Ph.D.</td>
</tr>
<tr>
<td>Assistant Professor, Biology</td>
</tr>
<tr>
<td>Alternate Scientist for Xue, Attanasio, Kang &amp; Plemper</td>
</tr>
<tr>
<td>Kay Lee Summerville</td>
</tr>
<tr>
<td>M.A.</td>
</tr>
<tr>
<td>Sr. Program Associate, (Adm.) Yerkes, Emory University</td>
</tr>
<tr>
<td>Non-affiliated Member</td>
</tr>
<tr>
<td>Constance Thalken</td>
</tr>
<tr>
<td>M.F.A.</td>
</tr>
<tr>
<td>Associate Professor, Photography</td>
</tr>
<tr>
<td>Non-scientist</td>
</tr>
<tr>
<td>Amelia Wilkes</td>
</tr>
<tr>
<td>DVM</td>
</tr>
<tr>
<td>Clinical Lab Animal Veterinarian</td>
</tr>
<tr>
<td>Veterinarian</td>
</tr>
<tr>
<td>Bingzhong Xue</td>
</tr>
<tr>
<td>Ph.D.</td>
</tr>
<tr>
<td>Associate Professor, Biology</td>
</tr>
<tr>
<td>Scientist</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.)

**IX. 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: Margaret &quot;Casey&quot; Kilcullen-Steiner</td>
</tr>
<tr>
<td>Title: Assistant Director, IACUC</td>
</tr>
<tr>
<td>Phone: 404-413-3508</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Contact #2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: Casey Marie Brinsfield</td>
</tr>
<tr>
<td>Title: IACUC/Biosafety Compliance Officer</td>
</tr>
<tr>
<td>Phone: 413-3649/413-3551</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>Natural Science Center Basement</td>
<td>4276</td>
<td>Mice</td>
<td>1700</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rats</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hamsters</td>
<td>930</td>
</tr>
<tr>
<td>Language Research Center Lanson Building B</td>
<td>2900</td>
<td>Chimpanzees</td>
<td>3</td>
</tr>
<tr>
<td>Language Research Center NASA Building E</td>
<td>8905</td>
<td>Rhesus Monkeys</td>
<td>7</td>
</tr>
<tr>
<td>Language Research Center Capuchin Building C</td>
<td>4914</td>
<td>Capuchin Monkeys</td>
<td>21</td>
</tr>
<tr>
<td>Petit Science Center 9th floor</td>
<td>19300</td>
<td>Mice</td>
<td>6400</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rats</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cotton Rats</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hamsters</td>
<td>570</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rabbits</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Zebra Finches</td>
<td>450</td>
</tr>
<tr>
<td>Petit Science Center 8th floor</td>
<td>583</td>
<td>Green Anole Lizards</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Green Tree Frogs</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td></td>
<td>African Clawed Frogs</td>
<td>2</td>
</tr>
<tr>
<td>Petit Science Center 6th floor</td>
<td>403</td>
<td>Mice</td>
<td>20</td>
</tr>
</tbody>
</table>

Unless otherwise indicated, mice and rats means mice of the genus *Mus* and rats of the genus *Rattus* that are purposely bred for research.