Animal Welfare Assurance for Domestic Institutions

I, Michael P. Eriksen, as named Interim 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, 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:

1. College of Arts and Sciences*,
2. College of Education and Human Development*,
3. Institute for Biomedical Sciences*
4. Byrdine F. Lewis School of Nursing and Health Professions*,
5. School of Public Health*,
6. Language Research Center**, and
7. Georgia State University Research Foundation, Inc. *
   - *These above listed components are physically located on the University Campus in Atlanta, Georgia.
   - **These above listed components are other covered components in the Atlanta Metro area.
   - 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:
   - N/A

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, Eighth Edition (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 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 Carlois 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 an alternate to the Attending Veterinarian 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 IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Attached in Section VIII below 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 6 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 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); and
  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 6 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 one voting member of the IACUC will inspect all the institute’s non-USDA covered species animal facilities, laboratories where live animals are taken and animal surgical areas and at least once every six months at least two voting members of the IACUC will inspect all the institute’s USDA covered species animal facilities, laboratories where live animals are taken and animal surgical areas.

• The areas inspected include, but are not necessarily limited to, the following: Any and all buildings, rooms, areas, enclosures, vehicles and equipment, 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 Facility Inspection 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.
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 and/or comments 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. Deviation from a must statement in the Guide, without IACUC approval, is a noncompliance that will be reported to OLAW through the IO.

- 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 involving the care and use of animals at the Institution to the IO, IACUC Chair, Institutional Veterinarians, and/or any member of the IACUC or the IACUC Staff. They may also report concerns anonymously via the “Report Compliance Issues” link on the IACUC and University Research Services & Administration web pages. These processes follow, and are in compliance with, applicable whistleblower policies, which include nondiscrimination against the concerned/reporting party.
Retaliation against the complainant(s) is prohibited by university policy and federal/state laws.

- 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 applicable institutional website(s).

- If necessary, the IACUC Chair may appoint a subcommittee to interview personnel involved and gather additional information. In any case, the information obtained, and the 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, the USDA and AAALAC International. Reports to the IO may be either via meeting minutes, semiannual report of IACUC evaluations, or separate document. Reports to OLAW, the USDA and AAALAC will be in writing and through the IO. Preliminary reports to the IO, OLAW and the USDA 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, animal facilities and personnel training are discussed and developed by the IACUC.

- The IACUC’s recommendations are included in the IACUC meeting minutes or in a report of the IACUC’s evaluations or in 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:

- All animal use protocols submitted to the IACUC are reviewed in the same manner regardless of the funding source and regardless of whether the activity is a research or a teaching proposal.

- All IACUC protocols (new or three year de novo renewals) are submitted via an electronic protocol management system iMedRIS (Integrated Medical Research Information System) aka iRIS (Integrated Research Information System).

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

- Veterinary and member review is then conducted on the submitted protocol.

- A formal written veterinary consult is required of all protocols, regardless of the level of pain and distress. The veterinary consult is done in concert with the IACUC Chair assigned reviewer(s) prior to submission for IACUC review and approval. The veterinarian completes the “Veterinary Consult Review Form” using the electronic protocol management system iRIS for written documentation. Once the veterinary consult and the reviews are completed, the investigator is notified via an email from iRIS indicating he/she must respond to the comments made by the veterinarian and/or the reviewer(s). The investigator must either accept and incorporate the suggestions made by the
veterinarian and/or the reviewer(s) or provide an explanation as to why the suggestion(s) were not accepted and incorporated into the protocol. The revised protocol, along with the corresponding Veterinary Consult and reviewer(s) comments, are available to the IACUC members via iRIS.

• Prior to full committee review, each IACUC member will be provided with written descriptions of activities (protocols) that involve the care and use of animals. Every member of the IACUC always has full access to all protocols and all documentation associated with any given protocol via the iRIS electronic system.

• Full Committee Review (FCR) is conducted in person or in combination with a teleconference (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”).

• Reviews are conducted with the goal of having the protocol approved at the monthly convened meeting.

• For protocols that do not go to full committee review, at least one member of the IACUC, designated by the chairperson or vice chairperson and qualified to conduct the review, along with a veterinarian, 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) and the veterinarian 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.

• As necessary, requests for modification will be sent back to the PI for revision of the protocol. Upon receipt of the revised protocol, if multiple designated reviewers are used (two), their decision to approve must be unanimous; if not, the protocol will be referred to the PI for further revision or for 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.

• Generally, the GSU IACUC uses the FCR method for all new protocols (includes de novo renewals) apart from Breeding only protocols, which are usually reviewed by DMR.

• However, should a situation warrant it, the DMR process may be used for any new IACUC protocol. In such a case, the protocol is available to all IACUC members via iRIS to allow all members the opportunity to call for FCR.

• When the IACUC requires modifications (to secure approval) of a protocol, such modifications are reviewed as follows:
  o FCR or DMR following the procedures delineated in the PHS Policy and elsewhere in Part III.D.6 of this Assurance above.
  o DMR if approved unanimously by all members at the meeting at which the required modifications are delineated AND if the entire current Committee 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. On an annual basis all IACUC members sign the following agreement: "I agree that if the Designated Member Review is approved unanimously by all members at the meeting at which the required
modification(s) are delineated that the quorum of members present at the convened meeting may decide by unanimous vote to use Designated Member Review subsequent to Full Committee Review when modification is needed to secure approval. However, as a member of the IACUC I may, at any time request to see the revised protocol and/or request Full Committee review of the protocol.”

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

- No member may participate in the IACUC review or approval of a protocol in which the member has a conflicting interest (e.g., in which an individual has competing interests or loyalties 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, 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:

- Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.

- 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.

- 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.

- 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.

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

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

• After full committee review, the vote is called, and the following motions can be made:
  o Approve as submitted; or
  o Return to Principal Investigator for revision and then return to IACUC for designated member review unless Full Committee Review is called; or
  o Return to Principal Investigator for revision and then return to IACUC for Full Committee Review; or
  o Approval withheld.

• A majority of the quorum present is always required for a vote to be valid.

• No animal work may begin before the full committee has been given the opportunity to review the protocol and call for FCR and before the protocol has been approved by (1) the majority of a quorum of the members or (2) the designated reviewer(s) 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”, “conditional” or “interim” approval of any animal study proposal.

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:

• Per PHS Policy IV.C., the IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

  o Review and approval of significant changes is in accordance with the DMR process unless FCR is requested by an IACUC member. See above for details of the DMR and FCR review processes. Examples of changes considered to be significant include, but are not limited to changes:
    • in the objectives of a study;
    • from non-survival to survival surgery;
    • resulting in greater pain, distress, or degree of invasiveness;
    • in the species;
    • in Principal Investigator;
    • in the method of euthanasia;
    • housing and or use of animals in a location that is not part of the animal program overseen by the IACUC; and
    • changes that impact personnel safety,

• Some significant changes to an IACUC protocol may be handled through the IACUC approved Veterinary Verification and Consultation (VVC) process according to the IACUC reviewed and approved guideline in consultation with a veterinarian authorized by the
IACUC. This IACUC approved guideline is in keeping with guidance provided by the PHS Policy on Humane Care and Use of Laboratory Animals (Policy) (IV.C.1.) and Animal Welfare Regulations (9 CFR 2.31 (d) (1) (i)-(iv)) and the Office of Laboratory Animal Welfare (NIH Guide Notice NOT-OD-14-126). The VVC process includes all Division of Animal Resources (DAR) veterinarians. The veterinarian is not conducting Designated Member Review (DMR) but is serving as a subject matter expert to verify that compliance with the IACUC-reviewed and approved policy is appropriate for the animals in this circumstance. The consultation with the veterinarian is documented. The veterinarian has the authority to request IACUC review (via DMR or Full Committee Review) of the proposed changes for any reason and must request such IACUC review for any changes which do not meet the parameters of this policy. Significant changes eligible for administrative review with VVC include*:

- changes in anesthesia, analgesia, sedation, or experimental substances;
- changes in euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals including those approved with conditions, as long as the conditions are met; and
- changes in the duration, frequency, type, or number of procedures performed on an animal.

* Anything that falls outside of the IACUC-approved policies/documents is ineligible for VVC, and VVC may not be used to add a new procedure if it is a significant change that was not previously approved on the protocol.

- A significant change (submitted via an Amendment Form), such as adding a new rodent strain and increasing animal numbers can be handled administratively (via the IACUC Guideline “Administrative Review and Approval of Non-Procedural Requests”) after review by the veterinarian and the IACUC Chair. The veterinarian and/or the IACUC Chair both have the authority to request IACUC review (via DMR or FCR) of the proposed changes for any reason and must request such IACUC review for any changes which do not meet the parameters of this policy. Changes 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 documented.

- 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 for Vertebrate Animal Exposure. The Personnel Amendment must be approved by the IACUC Office staff prior to new personnel working on approved IACUC protocols.

- If a grant, sponsor or other funding is to be added, an Amendment Form must be submitted. The Amendment Form is approved by the IACUC Office Staff after appropriate grant/protocol congruency is performed.

- Change in the title of an approved protocol.

- Investigators may use fewer animals than approved. This does not require IACUC approval, notification, consultation, or administrative handling.

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 PI receives notice, via email, from the iRIS electronic protocol management system 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(s) in (to secure approval) or approval has been withheld.

• If approval is withheld, the notice will include the reasons that it was withheld, and the PI may respond to the IACUC in writing.

• The Institutional Official may contact the IACUC office regarding the status of any submitted or approved IACUC protocol at any time. The Institutional Official is notified by receiving a copy of the IACUC meeting minutes twice a year, in conjunction with the annual report of the IACUC to the IO.

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:

• Continuing / Periodic Review
  o 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 and approval of this Form is done by a voting member or members of the committee. See Part III.D.6., above for details of the DMR and FCR review processes.
    ▪ Annual protocol reviews are recorded in the IACUC meeting minutes. The IACUC meeting minutes are reviewed and approved by the Committee.
  o Non-USDA Regulated Species – require only triennial review.
  o All protocols are approved for a maximum of 36 months. All protocols expire no later than the three-year anniversary of the initial IACUC approval.
    ▪ If the activities are to 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 proceeding protocol.

• 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.
  o In addition, post-approval monitoring of research studies is 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 protocol will be randomly selected for observation to maintain consistency and evaluate procedures that have been submitted and approved as part of the IACUC process; or
    ▪ 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.
- the authority and responsibility of the IACUC is not contravened by the PAM program, institutional compliance officials, or other mechanism established to monitor animal care and use.

- Ongoing activities are also monitored on a daily basis as part of routine husbandry activities by the animal care and use staff and daily observation by the veterinarians and/or veterinary care staff. These individuals add an important level of program supervision including daily observation of animals by trained animal care personnel and communication to the veterinary staff for follow-up, along with 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.

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 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 due to noncompliance with 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 to OLAW, AAALAC, the USDA, and the granting agency as applicable.

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:

- The purpose of the Medical Monitoring Program for Vertebrate Animal Exposure (MMPVAE aka the occupational health and safety program) 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). Educational programs have been established to educate personnel about zoonotic diseases, personal hygiene, and other related issues.

  - The MMPVAE was 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.

  - 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.

- A Nurse Practitioner (NP) associated with the GSU School of Nursing serves as the Program Administrator for the MMPVAE. This individual is responsible for the day to day operation of the program.
The NP reviews the Risk Assessment and Health History Questionnaire submitted by participants and serves as the first line of medical risk assessment.

- A certified occupational health medical services provider (MSP) is contracted to provide a collaborative healthcare team for referral for services when deemed necessary by the NP or if she is unable to provide services onsite.
  - Individuals specifically associated with the ABSL3-TB Vivarium and Lab are participants in the MMPVAE. However, Emory University Hospital serves as the MSP. Emory University Hospital is located in Atlanta.

- Services provided by the NP include Tuberculosis screening, vaccination history review, respirator mask fit testing, allergy management and support to the compliance and safety committees.

- Based upon the answers provided on the questionnaire, the NP will also provide physical examinations and/or counseling regarding participant health status and participation in an animal environment (example: pregnancy, vaccinations available etc.).

- An external physician with the MSP serves as the supervising physician for the NP and is available for consult as needed.

- Individuals identified as requiring participation in the MMPVAE must complete the Risk Assessment and Health History Questionnaire form on an annual basis to maintain animal facility access. This form is also used to submit a change in exposure (e.g. working with non-human primates when previously only working with mice). IACUC staff access the MMPVAE database to ensure enrollment has occurred prior to approval of all new protocols and Personnel Amendments. MMPVAE enrollment is also noted in the approved protocol under the “Personnel and Their Experience and Training” section.
  - There is no option of declination. Similarly, any human or animal safety measures that are required for participation in the animal activity are not subject to declination (e.g. those requiring annual N95 mask fit testing, TB testing and measles immunization, as it relates to those who work with NHPs, TB testing as it relates to those who work in the ABSL3 TB Vivarium and Lab, influenza immunization as it relates to those who work with flu-infected ferrets, annual blood borne pathogen training, etc.).
  - Recommendations that are made for health and safety that are not required by the protocol for participation may be declined.

- Others providing program input and assistance are as follows:
  - The Attending Veterinarian, to whom the NP reports, have regular communication regarding the program operation, program content, risk assessment, etc.
  - The Department of Insurance and Risk Management which manages safety training, right to know training, and the workers compensation program.
  - The Research and Environmental Safety Office which manages biological, chemical, radiological and environmental safety programs. Office staff include:
• The Biosafety Officers conduct biological risk assessments and provide input on facilities, practices and equipment for the safe use of biological materials in animals and animal facilities.

• The Radiation Safety Officer who provides input on facilities, practices and equipment for the safe use of radiological materials and radiation producing devices in animals and animal facilities.

• The Chemical Safety Officers conduct chemical risk assessments and provide input on facilities, practices and equipment for the safe use of chemicals in animals and animal facilities.

• The Division of Animal Resources veterinarians and Animal Healthcare Technicians provide training related to the appropriate animal handling and restraint in an effort to minimize the occurrence of injuries and exposures to disease.

• The IACUC evaluates the occupational health and safety program during its semiannual program review and assures all individuals associated with IACUC protocols are enrolled in the MMPVAE.

• The Institutional Biosafety Committee (IBC) reviews and provides guidance regarding any study involving infectious agents; microbial toxins; and recombinant or synthetic nucleic acid molecules related to the animal care and use program.
  
  o The NP contributes to this review process. Specifically, as it relates to all protocols involving animals under review by the IBC. The NP reviews the IBC protocol and makes recommendations in conjunction with the Biosafety Officer to the committee with respect to issues related to human health and safety. These recommendations are documented on a Biological Agent Reference Sheet (BARS).

• The Office of Legal Affairs attorneys, reviewed and approved the Risk Assessment and Health History Questionnaire, are consulted at other appropriate times to obtain necessary guidance related to program functions.

• The Radiation Protection Committee (RPC) reviews and provides guidance regarding any study involving radiation hazards related to the animal care and use program.

• The Laboratory Safety Committee (LSC) who reviews and provides guidance regarding any study involving chemical hazards related to the animal care and use program.

• Hazard identification and risk assessment are a cooperative effort involving the NP, 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 material 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, the need to complete the questionnaire for annual reassessment, etc.).
o The assigned reading material provides 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, etc.

o The NP reviews the completed questionnaire and notifies enrollees of any recommended and/or required medical procedures (e.g. TB testing, immunizations, respiratory fit testing, etc.). Based upon the answers provided on the questionnaire, the NP 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 requires the appropriate approvals are provided 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.

o 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. The IACUC reviews the training and experience of all personnel working with animals as a component of an IACUC-approved protocol.

• Procedures in Place to Alleviate Hazards and Minimize Risks.
  o The DAR provides training related to appropriate animal handling and restraint to try to minimize the occurrence of injuries and exposures to disease. MMPVAE enrollees are placed into one or more categories with regard to animal contact and/or exposure.

  o 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 NP subsequent to the review of the completed questionnaire.

  o If the enrollee will 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).

  o The categories are as follows:
    ▪ Rodents, rabbits, ferrets, birds;
    ▪ Nonhuman primates;
    ▪ Fish, reptiles, amphibians;
    ▪ Animal contact limited to environmental exposure (e.g. physical plant staff, IACUC members, others who may enter animal facility but not have animal contact).
Category 1 participants are those who will handle 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:
  - following the report of an injury; or
  - 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 handle 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.

- **Tuberculosis screening (required)** - Tuberculosis is a zoonotic disease that can be devastating in any nonhuman primate colony.

- **Rubeola (Measles) (required)** - This zoonotic disease can affect nonhuman primates and often causes a fatal pneumonia.

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

- **Tetanus Immunization (recommended See Category 1 description 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).**

Laboratory Animal Allergies - 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.
• Latex Allergies - 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 there is a latex allergy or if there is a 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 and the use of the appropriate PPE will assist in this objective.

  • Personal Protective Equipment (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 responsible for cleaning, laundering, disposal and replacement of PPE. Failure to use appropriate PPE may increase the chance of being exposed to potentially hazardous materials from animal contact so the use of proper PPE is required.

  • Personal Hygiene - There is 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 change into special designated clothing when working with animals. Thorough hand washing must be done after handling the animals and prior to leaving the laboratory.

  • Immunizations.
    o Tetanus - 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.

    o 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 are offered the Hepatitis A vaccination.

    o 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, are offered the Hepatitis B vaccination.

    o Measles - Personnel working with NHP are required to have proof of MMR vaccination or have a measles titer assay. Personnel will be required to have an 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; or
        • Written documentation of vaccination.
      • 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.

• 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. Or they can discuss this issue with the NP 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 species and types of activities involved (e.g. work with an infectious agent, chemical hazard, inhalant anesthetic, radioisotope, etc.) should be discussed so that such individuals become educated about the associated risks and precautionary measures. The individual can also discuss this issue with the NP associated with the MMPVAE who may, in turn, refer the enrollee to an occupational health physician.

• 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 must 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 houses non-human primates. Each form provides relevant information pertaining to risks/hazards as well as procedures to follow while in the animal facility.

• Availability and procedures for treatment of bites, scratches, illness or injury.
  o First aid kits are maintained in each vivarium and are maintained by the Division of Animal Resources management staff.
  o 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. These posters are discussed during the animal facility orientation process for 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. 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 an 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.

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

- Principal Investigators and Managers/Supervisors must ensure that individuals are trained to promptly report (GSU DAR SOP# 021.02 EMERGENCIES and Insurance and Risk Management Incident Report Form) any illnesses, needle stick, bite or scratch wound, or splashes that might result from animal contact to the Principal Investigator(s) and Managers/Supervisors as well as the Insurance and Risk Management Office.
  
  o Any necessary medical services would then be determined and authorization for treatment would be issued if recommended by a physician.

- Herpes B Virus of Macaque Monkeys;
  
  o 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.
  
  o 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.
  
  o Individuals working with macaque monkeys are required to read and follow standard operating procedures designed to prevent potential exposure to this virus. These standard operating procedures outline steps that must be followed in the event of a potential exposure.

- Tuberculosis (TB);
  
  o 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.
  
  o Individuals who have not completed their semi-annual tuberculin skin test or Annual Tuberculosis Screening Questionnaire 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.
    - The MMPVAE program sends reminders when individuals need their semi-annual tuberculin skin test
Testing is done with the Mantoux (PPD) technique that measures hypersensitivity to tuberculin. 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 must 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.

- If the chest x-ray is read as negative (clear) subsequent annual chest x-rays are not routinely needed unless:
  - symptoms develop that could be attributed to TB; or
  - 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.

- Oral Herpes Simplex (Cold Sores);

- The virus that causes the disease is lethal to some NHPs. People with active cold sore lesions must 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.

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:

The IACUC verifies the training of any of the Division of Animal Resources staff listed on an IACUC protocol prior to approval of the protocol. DAR management provides training (see below) for each DAR staff member and maintains the completed training logs. These training records are provided to the IACUC every three years and anytime requested by the IACUC.

The institution provides online education and training to all research personnel including the principal investigator (PI), co-investigators, instructors, staff, students, collaborators, and others working with animals to ensure that they have the necessary knowledge and expertise for the specific animal procedures proposed and the specific species being utilized. This training includes introductory as well as species and procedure-specific training. The institution utilizes the AALAS
Learning Library training modules. Successful completion of the course and passing the exam are required. The following modules are required, depending on the procedures proposed in an individual protocol: Species specific modules, Working with the IACUC (includes discussion of the 3Rs, minimizing animal distress, detecting pain and distress), Ethical Decision Making in Animal Research, Aseptic Technique for Rodent Survival Surgery, Inhalation Anesthesia Systems for Rodents, Pain Management in Laboratory Animals, Post-Procedural Care of Mice and Rats in Research: Minimizing Pain and Distress, ALAT14: Euthanasia (2009), AVMA Guidelines for the Euthanasia of Animals, Health Risks and Safety Procedures for Working with Nonhuman Primates, and Video: Working Safely with Nonhuman Primates. The AALAS Learning Library has an abundance of other courses available for further educational pursuits. The following online required training is available beside the AALAS Learning Library database. The required courses IACUC members are also required to complete assigned online training. The online training modules must be repeated at three-year intervals.

DAR conducts on-the-job training in the form of an apprenticeship whenever a new DAR staff member (e.g. husbandry technician, cage wash technician, management staff) is hired or whenever an established employee needs to be trained for a new task. The employee is assigned to an employee experienced in the area (a mentor). The employee’s supervisor will monitor progress of the employee in training. Once the employee is appropriately trained in this area, then he/she is no longer be assigned to the mentor, but rather is able to work independently. Once an employee is trained in a new area, both the Supervisor and the trainee will sign off on appropriate paperwork (Training Certification Form) attesting to the fact that the employee is now trained in that area.

In addition to the aforementioned apprenticeship, DAR staff (husbandry technicians, cage wash technicians, and management staff) are required to read the Standard Operating Procedures that pertain to their areas of assignment and documentation to this effect is on file. This is completed initially when a new individual is hired, and then annually as a refresher training. Review of the SOPs is completed through an electronic platform that allows DAR to track understanding of the SOP’s content through quizzes associated with each SOP.

Any DAR staff member, including members of the veterinary team, which has responsibility in the containment facilities (ABSL2 and/or ABSL3), are required to complete the in-person pABSL2 and/or ABSL3 annual refresher training. The completion of this training is required for continued access to these facilities, and this training is documented.

Beyond the training listed above, the DAR encourages its employees to seek certification by the American Association for Laboratory Animal Science (AALAS). Specific time is allotted throughout the week to study the certification material designed to prepare them for the certification exams. Individuals also have access to, and are encouraged to utilize, the training resources found in the AALAS Learning Library. Animal care personnel are also encouraged to participate in the biomethodology, and surgery workshops offered by DAR.

The DAR created an institutional certificate program to encourage technicians to further their working knowledge and expertise relevant to the cage wash area. These certificates are based on content taken from the ALAT and LAT workbooks, along with a mentoring component performed by the vendor who services the cage washers and autoclaves.

Selected members of the husbandry and/or cage wash technicians attend continuing education meetings (regional and/or national) whenever possible.
Continuing education opportunities for DAR management staff (Associate Director, Assistant Director(s) and Supervisor(s)), links with the attainment of the Certified Manager of Animal Resources (CMAR) certification.

The DAR requires animal facility orientations for all research personnel needing animal facility access and also conducts hands-on training in the form of biomethodology workshops (attendance at the workshops is typically voluntary but is sometimes mandated by the IACUC on a case-by-case basis).

In addition, the IACUC requires that individuals involved in animal use be identified on the Animal Use Protocol. The animal procedures each individual is to conduct is delineated and their level of competency and experience (credentials) relevant to these specific procedures are also indicated. If experience is lacking, the investigator must indicate how they will be trained and by whom. Training is often provided by the veterinarians, DAR Animal Healthcare Technicians, or an accomplished PI or trained member of the research team. On occasion, the IACUC requires a PI or his or her staff to prove competency prior to conducting a given procedure. If such a competency assessment is requested, typically a member of the veterinary staff will perform the assessment and provide feedback to the IACUC.

Completion of the required training modules, and verification of the level of competency and experience as it relates to the procedures to be conducted (or the provision for training for one or more procedures) are required for the approval of a protocol or personnel amendment. In addition to this training being completed, attendance at an animal facility orientation and enrollment and clearance in the Medical Monitoring Program for Vertebrate Animal User is required in order for access to the animal facility to be granted.

Continuing education opportunities are available via attendance at conferences or seminars, online training such as webinars, hands on biomethodology workshops (the DAR staff conducts a series of biomethodology workshops approximately every 4 months), etc. IACUC members receive an initial training session to introduce them to the GSU IACUC and associated policies, procedures, regulations, and guidelines; continuing education for IACUC members occurs during the IACUC meetings in the form of formal power point presentations, active learning activities, or training materials provided to the committee for review. IACUC members are required to complete the “Working with the IACUC” and Ethical Decision Making in Animal Research modules in the AALAS Learning Library, but they also have free access to the entire AALAS Learning Library.

IV. Institutional Program Evaluation and Accreditation

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past 6 months and will be reevaluated by the IACUC at least once every 6 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.

(1) 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 3 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 Interim Institutional Official, Dr. Michael P. Eriksen; and
   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 3 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 Interim Institutional Official, Dr. Michael P. Eriksen.
   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; and
   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

Name: Michael P. Eriksen, Ph.D.
Title: Interim Vice President for Research and Economic Development
Name of Institution: Georgia State University
Address: (street, city, state, country, postal code)
Centennial Hall
100 Auburn Ave. NE
Suite 534
Atlanta, GA 30303-3999
Phone: 404-413-3517
Fax: 404-413-1140
E-mail: meriksen@gsu.edu
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: [Signature]
Date: 5/11/2020

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

Name/Title: Jane J. Na / Senior Assurance Officer
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive
Suite 2500, MSC 6910
Bethesda, MD USA 20892-6910 (FedEx Zip Code 20817)
Phone: +1 (301) 496-7163
Fax: +1 (301) 451-5672
Signature: Jane J. Na -S
Date: May 12, 2020
Assurance Number: D16-00527 (A3914-01)
Effective Date: May 12, 2020
Expiration Date: January 31, 2024
VIII. Membership of the IACUC

Date: March 31, 2020
Name of Institution: Georgia State University
Assurance Number: D16-00527 (A3914-01)

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<tr>
<th>IACUC Chairperson</th>
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<tbody>
<tr>
<td>Name*: Richard K. Plemper</td>
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<tr>
<td>Title*: Professor, Center for Inflammation, Immunity &amp; Infection</td>
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<tr>
<td>Degree/Credentials*: Ph.D.</td>
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<td>Address*: (street, city, state, zip code)</td>
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<td>712 Petit Science Center (PSC)</td>
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<tr>
<th>IACUC Roster</th>
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<tr>
<td>Name of Member/ Code**</td>
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<tr>
<td>Roberta Attanasio</td>
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<td>Michael Beran</td>
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<tr>
<td>Timothy Denning, Vice Chair</td>
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<tr>
<td>Michael Hart**</td>
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<td>Leszek Ignatowicz</td>
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<td>Mukesh, Kumar*</td>
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<td>Kay Lee Summerville</td>
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<td>Liang-Ching Tsai</td>
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Nursing/Physical Therapy

Bingzhong Xue  Ph.D.  Professor, Biology, Nutrition  Scientist

Amelia Wilkes**  (Alternate for Vet)  D.V.M., Diplomate ACLAM  Clinical lab Animal Veterinarian, Division of Animal Resources  Alternate for Veterinarian

* 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 “Casey” Kilcullen-Steiner, M.S., LATG. CPIA</td>
</tr>
<tr>
<td>Title: Associate 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 Brinsfield, M.P.H.</td>
</tr>
<tr>
<td>Title: IACUC/IBC Compliance Officer</td>
</tr>
<tr>
<td>Phone: 404-413-3649</td>
</tr>
</tbody>
</table>
## 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 Vivarium</td>
<td>4276</td>
<td>Mice</td>
<td>3800</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rats</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Siberian Hamsters</td>
<td>10</td>
</tr>
<tr>
<td>Natural Science Center Aquatics Vivarium</td>
<td>500</td>
<td>Convict Cichlids</td>
<td>125</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mexican Tetra</td>
<td>50</td>
</tr>
<tr>
<td>Language Research Center Outdoor Research Facility</td>
<td>216</td>
<td>Mice</td>
<td>5</td>
</tr>
<tr>
<td>Language Research Center NASA Vivarium</td>
<td>8092</td>
<td>Rhesus Monkeys</td>
<td>7</td>
</tr>
<tr>
<td>Language Research Center Capuchin Vivarium</td>
<td>5359</td>
<td>Capuchin Monkeys</td>
<td>30</td>
</tr>
<tr>
<td>Petit Science Center 9th Floor</td>
<td>19300</td>
<td>Mice</td>
<td>8100</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rats</td>
<td>400</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cotton Rats</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Syrian Hamsters</td>
<td>700</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ferrets</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Guinea Pigs</td>
<td>18</td>
</tr>
<tr>
<td>Petit Science Center Reptile and Amphibian Vivarium</td>
<td>583</td>
<td>Green Anole Lizards</td>
<td>60</td>
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<tr>
<td>Petit Science Center Zebrafish Vivarium</td>
<td>583</td>
<td>Zebrafish</td>
<td>600</td>
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<tr>
<td>Petit Science Center 6th Floor ABSL3-WNV Vivarium and Lab</td>
<td>605</td>
<td>Mice</td>
<td>0</td>
</tr>
<tr>
<td>Petit Science Center 6th Floor ABSL3-TB Vivarium and Lab</td>
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<td>Mice</td>
<td>0</td>
</tr>
<tr>
<td>Research Science Center Vivarium</td>
<td>5952</td>
<td>Mice</td>
<td>4600</td>
</tr>
</tbody>
</table>

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