THE UNIVERSITY OF GEORGIA
D16-00276
(A3437-01)
ANIMAL WELFARE ASSURANCE
in accordance with the PHS Policy for
Humane Care and Use of Laboratory Animals

I, David Lee, as named Institutional Official for animal care and use at The University of Georgia (A3437-01), 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:

"Institution" includes the following branches and major components the University of Georgia: College of Agriculture and Environmental Sciences, College of Arts and Sciences, College of Family and Consumer Sciences, College of Pharmacy, College of Veterinary Medicine, College of Education, College of Public Health, School of Ecology, and School of Forestry and Natural Resources.

“Institution” also includes the following: the Georgia Health Sciences University/University of Georgia Medical Partnership, a medical school campus at the Institution.

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

Kruger National Park, for purposes of grant 1R01GM131319-01 “Coupled Macroparasite-Microparasite Interactions: Ecological and Evolutionary Consequences of Coinfection”

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 (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:

Responsibility for the institutional program for animal care and use is vested with the Office of Research. The University Director of Animal Care and Use (UDACU) is the Attending Veterinarian, and responsible for oversight of the entire institutional animal care and use program. The AV/UDACU reports to the Associate Vice President for Research Integrity and Safety (AVPRIS), who reports to the IO, Vice President for Research, David Lee. The AV/UDACU has direct access and frequent communication with the AVPRIS, and the AVPRIS has direct access and frequent communication with the IO. Nevertheless, there is nothing organizationally or operationally that would discourage or prohibit the AV/UDACU from bringing an issue straight to the IO. An organizational chart for the Program is appended at the end of this Assurance.

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

The Laboratory Animal Veterinarians shall implement the institutional Program for Animal Care and Use by conducting procedures as necessary to fulfill University Policy and the Institution's obligations under this Assurance. The Laboratory Animal Veterinarians have direct program authority for all animal activities at the institution, including access to all animals. Laboratory Animal Veterinarians are authorized to monitor all animal care and use activities and to cite and refer to the IACUC any activity that is not in compliance with the *Guide*, the Animal Welfare Act Regulations, or any other applicable standards relating to the care and use of animals. Immediate action may be taken by the Veterinarians to resolve situations which may endanger animal life and/or could involve inordinate pain, distress, or suffering.

Name: Christopher S. King
Qualifications:

- Degrees: DVM, DACLAM
- Training and/or experience in laboratory animal medicine: 32 years of post-DVM experience in laboratory animal medicine; completed post-doctoral training in laboratory animal medicine at the Yale School of Medicine; has extensive experience with the care of traditional laboratory animals as well as agricultural animals, primates, fish, reptiles and amphibians.

Authority:
Dr. King is the AVPRIS. The Vice President for Research and Institutional Official has delegated authority to Dr. King to coordinate the formulation of University Policy and conduct procedures necessary to carry out institutional obligations under this Assurance. Dr. King serves as one of theInstitution's Veterinarians supporting the animal care and use program.
Time Contributed to Program:
Full time employee with 25% commitment to the animal care and use program.

Name: Leanne C. Alworth
Qualifications:

- Degrees: DVM, MS, DACLAM

- Training and/or experience in laboratory animal medicine: 22 years of post-DVM experience in laboratory animal medicine; completed post-doctoral training in laboratory animal medicine at the University of Missouri; has extensive experience with the care of traditional laboratory animals as well as agricultural animals, primates, fish, reptiles and amphibians.

Responsibilities:
Dr. Alworth is the UDACU and serves as the Institution's Attending Veterinarian. The Director, Dr. Alworth, has the primary direct program authority for all animal activities at the institution, including access to all animals.
Time Contributed to Program:
Full time employee with 100% commitment to the animal care and use program.

Name: Mary Ann (M.A.) McCrackin
Qualifications:

- Degrees: DVM, PhD, DACVS, DACLAM, CMAR, CPIA
- Training and/or experience in laboratory animal medicine: 30 years of post-DVM experience, including specialty veterinary surgery and laboratory animal medicine; fifteen years of service directing animal care and use programs, including the University of Montana, Virginia Tech, and the Charleston VA; has provided veterinary care and/or oversight for traditional laboratory animals as well as agricultural animals, primates, fish, reptiles, amphibians, birds, and wildlife; and has served for 10 years on the AVMA Panel on Euthanasia.

Responsibilities:
Dr. McCrackin is the Director of University Research Animal Resources (URAR) and serves as one of the Institution's Veterinarians supporting the animal care and use program.
Time Contributed to Program:
Full time employee with 100% commitment to the animal care and use program.

Name: Steven B. Harvey
Qualifications:

- Degrees: DVM, MS, DACLAM
- Training and/or experience in laboratory animal medicine: 22 years of post-DVM experience in laboratory animal medicine; completed post-doctoral training in laboratory animal medicine at the Pennsylvania State University; has extensive experience with the care of traditional laboratory animals as well as agricultural animals, primates, fish, reptiles and amphibians.

Responsibilities:
Dr. Harvey is an Assistant Director of University Research Animal Resources (URAR) and serves as one of the Institution's Veterinarians supporting the animal care and use program.
Time Contributed to Program:
Full time employee with 100% commitment to the animal care and use program.

Name: Jennifer Mumaw Schmiedt
Qualifications:

- Degrees: DVM, MS, PhD
- Training and/or experience in laboratory animal medicine: 3 years of post-DVM experience in laboratory animal medicine; completed post-doctoral training in laboratory animal medicine at the University of Georgia; has experience with the care of traditional laboratory animals as well as agricultural animals, primates, fish, reptiles and amphibians.

Responsibilities:
Dr. Mumaw Schmiedt is Clinical Veterinarian of University Research Animal Resources (URAR) and serves as one of the Institution's Veterinarians supporting the animal care and use program.
Time Contributed to Program:
Full time employee with 100% commitment to the animal care and use program.

Name: Gina Kim
Qualifications:

- Degrees: DVM, MS

- Training and/or experience in laboratory animal medicine: 2 years of post-DVM experience in laboratory animal medicine; completed post-doctoral training in laboratory animal medicine at the University of Georgia; has experience with the care of traditional laboratory animals as well as agricultural animals, primates, fish, reptiles and amphibians.

Responsibilities:
Dr. Kim is Clinical Veterinarian of University Research Animal Resources (URAR) and serves as one of the Institution's Veterinarians supporting the animal care and use program.
Time Contributed to Program:
Full time employee with 100% commitment to the animal care and use program. Her focus (50%) is in the Non-Human Primate Core (NHPC).

Name: Darrell Hoskins
Qualifications:

- Degrees: DVM, DACLAM
- Training and/or experience in laboratory animal medicine: 25+ years of post-DVM experience in laboratory animal medicine; completed post-doctoral training in laboratory animal medicine; has experience with the care of traditional laboratory animals.

Responsibilities:
Dr. Hoskins is a Veterinarian of University Research Animal Resources (URAR) and serves as one of the Institution's Veterinarians supporting the animal care and use program.
Time Contributed to Program:
Half time employee with 50% commitment to the animal care and use program. He works remotely, and his functions are >90% focused on performing veterinary reviews for the IACUC.

NB: UGA is currently hiring a new Director of University Research Animal Resources. The individual in this role will serve as one of the Institution's Veterinarians supporting the animal care and use program and lead the URAR program. The authority and responsibility, otherwise, for this position is identical to the other program Veterinarians. This is a full time position with 100% commitment to the animal care and use program.

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 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:

At least every six months, the IACUC reviews the animal care and use program elements during a question and answer/fact finding interview using the *Guide* as a basis for evaluation. A semi-annual program and facility review checklist, modeled after the sample provided by OLAW, guides the review process. All IACUC members are invited to attend the semi-annual program evaluations. Program reviews are conducted by one or more members of the IACUC, which usually, but do not necessarily, include the IACUC Coordinator or IACUC Compliance Associate. Furthermore, program review includes an IACUC self-assessment once every six months using the Policy, the *Guide*, and USDA Animal Welfare Act Regulations as the basis for evaluation.

The draft report is prepared and submitted by the IACUC Coordinator in preparation for review by the full committee. The reports are sent to the committee prior to each monthly convened meeting. During the meeting of the quorum, the final report(s) of program evaluation(s) are reviewed, discussed as needed, and each voting member present signs the final report for filing. The reports are provided to the Institutional

Official, Dr. David Lee, and to animal resource directors, other administrators, and facility managers as indicated to ensure that any compliance issues are addressed.

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:

The IACUC inspects all animal facilities at least once every six months. IACUC site visitors inspect the animal facilities using the *Guide* as a basis for evaluation. A semi-annual program and facility review checklist, modeled after the sample provided by OLAW, guides the inspection process. All IACUC members are invited to attend the facility inspections. Inspections are conducted by one or more members of the IACUC, which usually, but do not necessarily, include the IACUC Coordinator or the IACUC Compliance Associate as an alternate member. A minimum of two members conduct each inspection of facilities that include USDA Animal Welfare Act-regulated animals. Inspection sites include all AAALAC- accredited animal facilities included in this Assurance as well as a host of other agricultural and experiment station sites. If indicated, some of the committee members make follow-up inspections to assure that standards are being maintained or to make certain that corrections or improvements are progressing according to the committee recommendations.

Significant deficiencies (serious deviations from the *Guide*), including those that affect animal health and well-being or human safety, are distinguished from lesser problems and are treated accordingly. The draft report is prepared and submitted by the IACUC Coordinator or IACUC Compliance Associate in preparation for review by the full committee. The reports are sent to the committee before each monthly convened meeting. During the meeting of the quorum, the final report(s) of program evaluation(s) are reviewed, discussed as needed, and each voting member present signs the final report for filing. The reports are provided to the Institutional Official, Dr. David Lee, and to animal resource directors, other administrators, and facility managers as indicated to ensure that any compliance issues are addressed.

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:

Following every semi-annual program evaluation and facility inspection, a draft report is prepared and submitted by the IACUC Coordinator or IACUC Compliance Associate in preparation for review by the full committee. The semi-annual program review reports include a description of the nature and extent of the institution’s adherence to the *Guide* and the PHS Policy, including any IACUC-approved departures and reason for each departure; and identification of any significant or minor deficiencies in the program or facility with a reasonable and specific plan and schedule for correction. The facility inspection reports include identification of any significant or minor deficiencies, with a reasonable and specific plan and schedule for correction; and identification of facilities as included in the PHS Assurance and accredited by AAALAC, International. The reports are sent to the committee before each monthly convened meeting. During the meeting of the quorum, the final report(s) of program evaluation(s) are reviewed, discussed as needed, and each voting member present signs the final report for filing. A majority of the IACUC members sign the reports, and any minority views are added to the report. The written reports are provided to the institutional official, Dr. David Lee, and to animal resource directors, other administrators, and facility managers as indicated to ensure that any compliance issues are addressed.

Significant deficiencies (serious deviations from the *Guide*), including those that may be a threat to animal health and safety or human safety, are distinguished from minor deficiencies and identified as such in the inspection report. A proposed plan and schedule for correction is included in the inspection report. If the report contains recommendations for improvements or corrections of deficiencies, it is a shared responsibility of the animal resource director, dean, department head, division head, or investigator(s) involved to arrange for

the necessary corrections. IACUC recommendations include a timetable for correction of the deficiencies. The effort for correction of cited deficiencies is coordinated by the Office of Animal Care and Use and animal facility directors. Within thirty days after the written report from the IACUC is sent, a response must be submitted to the committee accepting the proposed plan and schedule or providing an alternate plan and schedule. The committee will evaluate the plan and schedule to correct the deficiencies with approval or disapproval. In the case of disapproval, a revised plan must be submitted for re-evaluation by the committee. If no response is received by the required date, the responsible party (Management) is sent a reminder. If a response is not received subsequent to the reminder, Management will be reminded again, and notified that if a response is not received by a specific deadline, the lack of response will be considered a matter of noncompliance with IACUC policy and reported to the IACUC. The IACUC will determine the appropriate action on a case-by-case basis. If Management does not submit a plan or if the plan is deemed inadequate, the committee may suspend the use of animals in that unit, as described in III.D.10, until compliance is achieved.

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

The procedures for "Reporting Concerns in Animal Care" is written as an institutional policy for helping to resolve concerns, and serve as a mechanism to help answer questions related to animal care and use. The policy is covered (in "IACUC 101") in the mandatory animal care and use compliance training sessions for faculty, staff, and animal resource personnel. In addition, URAR staff are trained via an SOP that covers reporting of animal welfare concerns. A link for reporting concerns is prominently located on the Office of Animal Care and Use website. All animal facilities have one or more posters posted in prominent locations indicating that the welfare of animals used at the institution is a serious responsibility shared by all and contact information and web links are provided. Employees and others are encouraged, without fear of reprisal, to try to resolve their questions or concerns at the immediate administrative level, but then to move to the next level of responsibility within the department or college. The concerns can also be taken to the Attending Veterinarian or to the Chair of the IACUC or any IACUC member(s). Concerns can be made anonymously and the anonymity of anyone voicing a concern is protected.

In an emergency situation, the Attending Veterinarian can immediately intervene, informing the IACUC Chair, AVPRIS and IO. The IACUC will review the nature, substance, and circumstances of the concern at a convened quorum of the committee. A subcommittee to investigate the matter is charged if the IACUC members believe the concerns are valid. The subcommittee submits a report to the IACUC. The IACUC sends a final report with recommendations for resolution to the Institutional Official, Dr. David Lee, and to other administrators and employees as needed. A report is also sent to the person who submitted the concern, if possible. If the situation involves serious non-compliance with *Guide* or regulations of the Animal Welfare Act, the IACUC is authorized to withhold approval of activities involving animals or suspend such activities, as described in III.D.10, and notify OLAW and/or the USDA as indicated.

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:

The committee routinely makes written recommendations to the Institutional Official regarding fundamental aspects of the institution's animal program, facilities, or personnel training. This is done in the form of a periodic, normally semi-annual, briefing by the Attending Veterinarian and AVPRIS during which reports of semi-annual program evaluations and facility inspections are reviewed. These reports include comments or assessment of personnel training, staffing for animal care, occupational health and safety, facilities maintenance, and availability of support services for animal resources. Special issues of concern are also reported in writing to Dr. Lee with copies to other university administrators as needed.

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:

Prior to beginning any activity requiring IACUC review and approval, the PI must complete an Animal Use Protocol (AUP) utilizing a web-based tool. The PI is frequently aided in this process by a primary Veterinary Reviewer (VR) (VRs listed in Section III-B), who consults with the PI on techniques to minimize pain and distress and on the most appropriate use of anesthetics, analgesics, and tranquilizers. Once a PI has completed the AUP form, it is submitted electronically to the Office of Animal Care and Use (OACU). The IACUC Coordinator or IACUC Compliance Associate conducts a preliminary pre-review of all AUPs to determine if they are complete. The IACUC Coordinator or IACUC Compliance Associate then assigns the AUP to the appropriate VR. The VR pre-reviews the AUP for completeness and, if needed, consults with the PI on techniques to minimize pain and distress and on the most appropriate use of anesthetics, analgesics, and tranquilizers. Once this veterinary pre-review is completed and any necessary revisions are made, the VR electronically signs-off on the AUP, and it is returned to the OACU for further review and processing.

AUPs reviewed by the IACUC are designated into one or more of four categories and reviewed as follows:

Category A: Use of animals in experimental procedures that would be expected to produce little or no pain or distress. This category is pre-reviewed by the Veterinarian Reviewer (VR). Once the VR completes his/her veterinary pre-review, it is distributed via a "weekly list" to provide an opportunity for the IACUC to refer any 'A' protocols proposed for designated member review (DMR) for the alternative full committee review (FCR). After all committee members are given the opportunity to call for FCR, in the event that there is no call for FCR, the protocol is reviewed by DMR. The IACUC Chair assigns an IACUC member to perform the DMR.

Category B: Use of animals in procedures that involve minor pain or distress of short duration, or in procedures where pain and distress are alleviated through the use of analgesics or tranquilizers. This category is reviewed by the VR and at least one IACUC member. Once the VR completes his/her veterinary pre-review, the IACUC Coordinator or IACUC Compliance Associate sends the protocol to the IACUC member for a second pre-review. The IACUC Coordinator or Compliance Associate notifies the IACUC Chair which IACUC member has been assigned to pre-review the AUP. Once the VR and IACUC member have completed their pre-reviews of the AUP, it is distributed via a "weekly list" to provide an opportunity for the IACUC to refer any 'B' protocols proposed for DMR for the alternative FCR. After all committee members are given the opportunity to call for FCR, in the event that there is no call for FCR, the protocol is reviewed by DMR. The IACUC Chair assigns an IACUC member to perform the DMR.

Category B (Multiple Major Surgery): Use of animals in procedures that involve multiple major surgeries resulting in minor pain or distress of short duration or where pain and distress are alleviated through the use of analgesics or tranquilizers. All Multiple Major Surgery protocols require a full committee review, as described below for Category C.

Category C: Use of animals in procedures that involve significant but unavoidable pain or distress to the animal. All Category C proposals are held for full committee review at the monthly meeting, or at specially called meetings, as necessary. A veterinary pre-review is provided by the VR for monthly and for specially called meetings. All committee members receive a copy of all C category proposals (and any other AUPs on the agenda) prior to the meeting. For monthly meetings, the committee receives the proposals at least 6 days before the meeting. Specially called meetings almost always include only 1 time sensitive item on the agenda. The item is provided to the committee as soon as possible, generally at least 24 hours before the meeting. At a minimum, a written copy of the item is provided to the committee at the meeting, and members allowed to read the item at the meeting.

Category D: Use of invertebrate animals, cell cultures, embryonated eggs, certain biologic products, or

tissues obtained post-mortem from vertebrate animals, or observation of wildlife species. This category is approved by the Veterinary Reviewer.

The "weekly list" is used to provide an opportunity for the IACUC to refer any protocols that may be reviewed by designated member review protocols ("A" and "B" animal use category) for full committee review. Protocols are posted to the weekly list only after they have gone through the appropriate VR and (if applicable) second member pre-review process and have been certified by the pre-reviewer(s) for posting on the weekly list. The list is distributed by email to the committee members weekly, with the exception of holidays. Information transmitted includes investigator name, AUP number, title of AUP, animal species, number of animals proposed for use, and a brief description that addresses whether the proposal includes surgery or other invasive techniques, prolonged restraint, withholding food or water, or non-standard husbandry. Full copies of AUPs on the weekly list are available to IACUC members on a secure on-line repository. The OACU records receipt and reading of the weekly list by the IACUC members. IACUC members may request additional information or refer for full committee review any of the protocols on the weekly list within 2 business days (approximately 48 hours). If a protocol is not referred for full committee review, the protocol is reviewed by DMR. DMR may result in approval or requirement of modifications in order to secure approval. In addition, the DMR has the ability to send the proposal to FCR. Written notification of the outcome is forwarded to the PI. Hence, the outcomes of designated member review include approval, requirement for modifications to secure approval, or referral to the full committee for review. Designated member review may not result in withholding of approval.

Occasionally, an addendum to the weekly list may be distributed to process time-sensitive protocols. As for the standard weekly list, IACUC members may request additional information or refer for full committee review any of the protocols on the weekly list addendum within 2 business days. If a protocol on the weekly list addendum is not referred for full committee review, the protocol is reviewed by DMR and written notification of the outcome is forwarded to the PI.

The IACUC has also approved a mechanism for processing of especially time sensitive protocols. The protocol is sent to all IACUC members via email, with a request to respond within a specific period of time (e.g., 6 hours), stating whether they request a full committee meeting or not. If <u>all</u> IACUC members respond, all stating that they do not request full committee review, the protocol is sent to DMR for the final approval.

The IACUC Chair assigns a designated member reviewer..

Full committee meetings are held monthly. Material for review/discussion is generally distributed 6 calendar days prior to the meeting; however, material may be distributed on shorter notice, after the main packet of material has been distributed, should the need arise. All official business requires a convened quorum. Members who have any real or perceived conflict of interest in a research protocol or other matters requiring a vote do not participate in the review or approval process other than to provide information as requested by the IACUC. A member who has recused him/herself from voting may not contribute to the quorum. All "C" protocols, all multiple major surgery protocols, all protocols with departures from provisions of the *Guide*, and any referred "A" or "B" protocol are reviewed by the full committee. PIs may be invited to provide additional information for particularly complex protocols but they are excused for deliberations and voting. Possible outcomes to the review of a protocol or significant changes to an existing protocol are as follows: approval, modifications required to secure approval, withhold approval, or defer review. A majority vote of the convened quorum is required to approve, require modifications to secure approval, and withhold approval.

A list of all AUPs, modifications, and annual reviews that have been submitted to the committee since the last convened meeting, is provided as an agenda component for the next scheduled monthly meeting. The committee has the authority to reexamine proposals and, if appropriate, suspend the previous approval and conduct a full committee review to re-evaluate the approval status. The committee can suspend an activity that

it previously approved if it determines that the activity is not being conducted in accordance with the Animal Welfare Act, the Public Health Service Policy, or the Institutional Assurance. The committee may suspend a previously approved activity only after review of the matter at a convened meeting of a quorum of the committee and with a vote for suspension by a majority of a quorum. The Institutional Official, in consultation with the committee and the Director of Animal Care and Use, will review the reasons for the suspension. If the activity involves PHS funding, the Director of Animal Care and Use will report committee findings to OLAW and, as appropriate, the USDA.

When modification is needed to secure approval, the UGA IACUC has elected to have all IACUC members agree in advance in writing that the quorum of members present at a convened meeting may decide to use designated member review (DMR) subsequent to full committee review (FCR). The IACUC-approved SOP outlining the process for executing DMR following FCR establishes the IACUC's written concurrence that the quorum of members present at a convened meeting may decide to use DMR subsequent to FCR. This SOP was initially approved by a quorum of the IACUC at a full committee meeting. This SOP is also posted on UGA's online learning management system, the Professional Education Portal (PEP). All IACUC members are required to verify agreement with the SOP within PEP, which records this agreement.

Once this process is initiated following FCR, the IACUC Coordinator forwards the modifications needed to secure approval to the PI by email, along with any necessary explanation. The designated member reviewers are assigned by the IACUC Chair. Designated member reviewers will review the proposed modifications in a shared electronic document and reply to the DMR group and IACUC Coordinator if the revision adequately addresses the issues and votes to approve, or if further details or clarification is needed. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol. Approval occurs when the DMR unanimously approves the AUP. Failure to obtain unanimous DMR approval results in the modified protocol being returned to the full committee for consideration. Outcomes of this process are recorded in the IACUC minutes.

Written notification of failure to approve an AUP is provided to the PI, along with a rationale for non-approval and changes or additional information required for resubmission and reconsideration as set forth in the PHS Policy at IV.C.4. Consultants are used as appropriate to help resolve special concerns. If changes or additional information is required before review and consideration for approval, the investigator will be contacted in writing via email and informed of the changes or additional information needed. If the investigator declines to make recommended changes or provide additional information, the committee will be informed as such at a duly constituted meeting and the AUP will remain unapproved.

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:

The IACUC Policy regarding significant changes to an approved protocol is posted on the IACUC website. Significant changes to an approved AUP must be reviewed and approved by the IACUC before the changes are employed. Review and approval of proposed significant changes complies with the same requirements as review and approval of new protocols as set forth in the PHS Policy IV.C. Significant changes include, but are not limited to:

- A change in the objectives of a project
- A cumulative increase in the number of animals by 10% or more of the originally approved number Adding or changing the species
- Substituting a new Principal Investigator
- Addition of surgical procedures or number of surgical procedures, or change from non-survival to survival surgery
- Withholding of analgesics

- Increasing invasiveness of procedures
- Changing animal care methods from accepted standards
- A change in the duration, frequency or numbers of procedures performed on an animal which may increase the potential for pain or distress experienced by the animal
- Using different methods of euthanasia that are not approved in the AVMA Guidelines for the Euthanasia of Animals
- A change in animal housing from group housing to single housing; or changes that affect personnel safety

Depending on the extent of the changes, submission of a complete new proposal may be required. All significant changes are reviewed and are subject to further review at any time in the same manner as protocols are reviewed as described in Part III.D.6. Significant changes may not require the same level of review that the original AUP required; the VR determines the Use Category of each proposed significant change, and the level of review is assigned accordingly.

There are also certain modifications that can be handled simply in consultation with an IACUC- designated veterinarian through a Veterinary Verification and Certification (VVC) process. A policy with evaluation criteria based on guidance from OLAW and USDA has been created and approved by the IACUC. The IACUC has designated the faculty and staff laboratory animal veterinarians as the designated veterinarians for VVC. The designated veterinarians determine which modifications meet the criteria for this level of review, and verifies that the requested change is within the parameters approved in the IACUC policy. If the veterinarian determines that the requested change is not within the parameters approved in the IACUC policy, the change is submitted as an amendment for standard IACUC review. The general criteria are:

- Changes in anesthesia, analgesia, sedation, or experimental substances
- Changes in euthanasia techniques to any method approved in the AVMA Guidelines for the Euthanasia of Animals
- Changes in the duration, frequency, type, or number of procedures performed on an animal which do not increase the potential for pain or distress experienced by the animal.

Also, any changes that increase risk to personnel safety (e.g., adding a biohazard) do not meet VVC criteria. The VVC process is documented in the record of the modified protocol. A list of modifications that have been verified to comply with the IACUC approved VVC policy and documented in the record is included on the monthly IACUC meeting agendas.

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 notifies investigators, and, when applicable, the directors of animal resources in writing via email of its decision to approve or withhold approval of an AUP or of modifications required to secure approval. The IACUC provides written notification of failure to approve along with a rationale for non-approval and changes or additional information required for resubmission and reconsideration. The investigator may respond in person or in writing. The letters are formatted to enable effective communication of approval and institutional compliance to granting agencies. Copies of the approval letters and all other official communications with the PI are maintained in a secure online repository by the OACU. The Office of Sponsored Programs has access to the IACUC database of approved protocols.

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:

Committee members may review ongoing activities under approved AUPs at any time, and accordingly may request further review and reconsideration by the committee. Approved proposals are reviewed annually by a Veterinary Reviewer, and then distributed via the weekly list to IACUC members to call for FCR or send to DMR, as described in Part III.D.6. A reminder that annual review is due is sent automatically via email to each investigator 90, 60, 30, and 10 days prior to the anniversary date of initial approval. Once submitted, the annual review form is reviewed by the VR. Once the VR completes his/her review, it is sent to the IACUC Coordinator or Compliance Associate for further processing. The protocols up for annual renewal are then put up for review on the weekly list for approval by the IACUC using the process described above for new protocols. All members have the opportunity to review the renewal and request full committee review of the entire proposal. After 2 business days, with no call for further review, the annual renewal is reviewed by DMR and a letter of approval is sent to the principal investigator. This process is also used to confirm that the approved activities are ongoing, and to remind the investigator that amendments must be submitted for any proposed changes. Annual renewals must be approved by the 1st and 2nd anniversary of initial approval or the animal use proposal is terminated and a new complete proposal must be submitted for review.

All approved AUPs expire on the 3rd anniversary of initial approval. Animal work may not continue past the 3 year expiration date even if IACUC review is pending. Investigators are automatically notified of impending protocol expiration via email 120, 90, 60, 30, and 10 days prior to the 3rd anniversary of initial approval. Investigators are notified that a complete new proposal must be submitted for review and approval using the same procedures as used for the initial submission. IACUC approval of newly submitted protocols is required for ongoing activities to proceed once the original protocol has expired.

Post-approval monitoring is performed on an ongoing basis using a variety of mechanisms. These mechanisms include the following:

- Continuing protocol review
- Semi-annual laboratory inspections (conducted either during regular facilities inspections or separately) including examination of surgical areas, anesthetic equipment, use of appropriate aseptic technique, and handling and use of controlled substances
- Review of protocol-related health and safety issues by the Research Safety and Health Review Committee
- Risk-based veterinary or IACUC observation of selected procedures
- Observation of animals by animal care, veterinary, and IACUC staff and members for adverse or unexpected experimental outcomes affecting the animals
- External regulatory inspections and assessments

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:

In accord with PHS Policy IV.C.6, 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 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, 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, APHIS, and any federal agency funding that activity. In extreme circumstances where there is an immediate threat to animal or human health and well-being, the IACUC Chair and the AV also have the authority to halt an ongoing study until the IACUC can convene to review the situation and conduct official business.

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:

An Occupational Health and Safety Program (OHSP) exists for personnel who work in animal facilities and have exposure to animals. The goal of the OHSP is to prevent occupational injury and illness by avoiding, controlling or eliminating hazards in the workplace. The level and extent of participation by personnel in the OHSP is based on a risk assessment completed by institutional and contracted occupational medicine professionals. The OHSP provides for application of elements appropriate for the species of animals used, the etiologic agents involved, host factors of the employees, and facilities and equipment at the work sites. The OHSP is designed using the NRC publication, *Occupational Health and Safety in the Care and Use of Research Animals*, as a reference.

There are three principal groups that provide oversight, guidance, and training for the use of hazardous agents on the UGA campus. The Office of Research Safety (ORS) is responsible for activities involving the use of hazardous materials and radiation. The University Office of Biosafety (OBS) is responsible for the use of recombinant DNA, toxins, and microbiologic hazards. Both of these units are within the Office of Research Integrity and Safety, along with the OACU and URAR. Environmental Safety Division's (ESD) Occupational Health unit is responsible for industrial hygiene and general occupational health oversight.

The shared purview of the ESD and the ORS is assessing the risk and minimizing injury and illness associated with radiation, chemicals, other hazardous materials, and laboratory practices. Their activities include protocol review; inspection of facilities; permitting and other compliance functions; consultation with investigators; training of faculty staff and students; maintaining liaison with compliance and regulatory bodies; and occupational safety surveillance.

Minimizing the risks of injury and illness associated with biohazardous research is the goal of the OBS program. Biosafety is a cooperative effort of the Institutional Biosafety Committee (IBC), the Biosafety Officer (BSO), investigators, and laboratory staff. The Biosafety Officer, in conjunction with the IBC and program staff, reviews proposed research involving recombinant DNA techniques and other biohazards (i.e., infectious or venomous agents); consults with researchers on biosafety procedures; trains faculty, staff, and students involved in biohazardous research to obtain compliance with appropriate rules; maintains liaison with biosafety personnel at state and federal agencies, industries, and other universities; inspects laboratories and facilities; and does surveillance of laboratory accidents involving biohazardous agents.

Hazards related specifically to an animal research protocol are identified in the Animal Use Protocol and require review by the Biosafety Program, ORS, and/or the ESD.

All personnel with animal contact must enroll in the Occupational Health and Safety program by completing an online Occupation Health and Safety questionnaire. This includes investigators with active animal use protocols and their staff members as well as animal care personnel. Personnel who have frequent or substantial contact with animals are required to participate in the program and complete the questionnaire. This includes the animal care personnel and researchers working with ABSL-3 agents, BSL-3Ag agents, and rabies. For personnel who do not have frequent or substantial contact with animals, enrollment in the OHSP of all personnel involved in a particular study is required for approval of AUPs. However, personnel who do not have frequent or substantial contact with animals may decline to participate; they must enroll and sign a waiver at the beginning of the questionnaire that provides informed consent if they choose to decline.

The questionnaire is the fundamental part of risk assessing employees with research animal contact. This Occupational Health and Safety questionnaire is reviewed as part of the risk assessment process by an occupational medicine nurse in the Office of Research Integrity and Safety Support Services. The OH nurse can also consult with, or send personnel to, a contracted occupational medicine physician. The risk assessment includes hazards posed by the animals and materials used; animal exposure intensity, duration, and frequency; susceptibility of personnel; and history of occupational illness and injury in the workplace. All personnel on active protocols receive annual recommendations to update their OHS questionnaire to provide updates on exposure to new species or hazards, or changes in medical status. Submission of an up to date OHS

questionnaire is required every 3 years, unless they have declined to participate, in which case an update is not required.

Other personnel (Facilities Maintenance Division, custodial staff, contractors, etc.) who may enter animal facilities but who do not have any animal contact are enrolled in a "noncontact" OHSP. This non-contact program consists of providing information about the health and safety risks inherent to animal facilities, then verifying they understand the risks and the means to mitigate them by having the person sign the "Animal Noncontact Release Form." Personnel entering high containment facilities complete a "noncontact" form specific to high containment facilities.

All animal care personnel before beginning work, whether full-time or part-time, are required to participate in a health evaluation including the documentation of a health history. If tetanus immunization is not current (within 10 years), a booster is offered. TB skin tests are repeated at least every 6 months for those personnel working with non-human primates, and annually for personnel working with *Mycobacterium tuberculosis*, vaccine strains of TB, or other Mycobacteria species. Pre-exposure rabies immunization is provided and rabies titers are repeated every 2 years, for personnel at risk due to working with species that may be inadvertently infected. Personnel working with rabies infected animals or a rabies research study have their titers checked every 6 months. Rabies booster vaccinations are provided if indicated by low titers.

All animal care personnel and anyone involved in an animal use protocol working with human blood, body fluids, tissues, feces, or human cell lines must be offered protection for Hepatitis B per Georgia law. A participant can choose to decline Hepatitis B protection but must sign a Hepatitis B Declination Form that is kept on file. Vaccination is provided for other agents on an as-needed basis with the consultation of health providers and the institutional Biosafety Program.

The IACUC AUP form requests information on the use of biological, chemical, or radiation hazards. The use of hazardous biologic, chemical, and physical agents in animals is allowed only after a thorough review of both the nature and the scope of the experiment by the responsible users, veterinarians, the OBS, ORS, ESD as applicable, and/or appropriate oversight committees. All such experiments are conducted under the direction of a PI who is responsible for ensuring the safety of the operation and for following written policies for the use of such agents. All personnel, including laboratory and support staff, are required to receive orientation and training in many key areas prior to participating in experiments involving hazardous materials.

Biological hazards on AUPs are assessed by the Office of Biosafety. General and chemical safety concerns identified in AUPs are referred to the Office of Research Safety (ORS). Radiologic hazards are assessed by the Radiation Safety experts within ORS.

The IACUC and IBC share a close working relationship: the BSO serves on the IACUC and one of the Lab Animal Veterinarians serves on the IBC. Additionally, approval of the related IBC protocol is required to secure AUP approval. The IACUC Coordinator or Compliance Associate confirms such approvals. Approval by these oversight groups is contingent upon the investigator adequately addressing a variety of safety issues, including appropriate work practices, administrative controls, PPE, and occupational medicine interventions. During the protocol review, the PI is contacted to review and confirm the necessary oversight requirements, ensure appropriate facilities are available, determine what sorts of personal protective equipment are needed, and establish SOPs. Before work commences, a meeting is held with animal care management and supervisors along with the PI and their staff to provide training and review the SOPs.

Zoonosis surveillance is primarily the responsibility of the Lab Animal Veterinarians through review of quality assurance data from quarantine, routine colony health monitoring, and animal health data provided by vendors. The Occupational Health Nurse is informed of any exposures, potential exposures, or possible occupationally acquired illnesses. A serum banking program is in place for specific situations, such as personnel

working with specific BSL-3 agents or other agents which may require this level of surveillance, or when it is required by funding agencies. Procedures for reporting exposure and potential exposure to hazardous agents include:

1. Reporting incident and possible occupationally acquired illnesses to immediate supervisors
2. Providing first aid treatment as directed per lab exposure manual and directing exposed personnel to our occupational health services group or to the closest emergency room, for evaluation
3. Reporting exposure and potential exposure to ESD (i.e., exposure to a chemical substance) or the Office of Biosafety and the Research Occupational Health Nurse
4. An "Incident/Accident Report" is filed with ESD and a copy is maintained in the facility supervisor's files.

Eating drinking, smoking and applying cosmetics are not permitted in any University animal rooms. Smoking is not allowed in any UGA buildings. The URAR facilities and PDRC have dedicated break areas for eating and drinking. Hand washing facilities are located throughout all animal facilities. Most animal rooms have hand washing sinks in them or in close proximity. Hand washing sinks are also located in procedure rooms and cage wash areas. All hand washing sinks are supplied with disinfectant soap and disposable paper towels. Hand sanitizer dispensers are located at entry and exit points in URAR laboratory animal facilities. Changing facilities, locker rooms, and showers are available in or adjacent to the all the conventional laboratory animal facilities.

Hazardous agents are contained within the study environment and animal housing area through a combination of engineering controls, administrative controls, and PPE.

Engineering controls include facility and animal room construction. Specifics vary with the level of hazard risk, from sealed rooms with gasketed doors to standard animal holding rooms with impermeable and easily sanitized surfaces. Engineering controls also include biosafety cabinets and fume hoods, automatically locking doors, sanitation equipment, and HEPA filtered housing systems. Whenever possible, biological hazards are contained at the primary enclosure by using static microisolators or individually ventilated cages under negative pressure exhausted through HEPA filters. Negatively pressurized rooms and 100% fresh air/100% exhaust are engineering features used in animal housing areas to contain hazardous agents. All work with biohazardous agents is performed in Class II BSCs. Rodent caging contaminated with hazardous agents is bagged out of the housing area and handled as appropriate for the nature of the hazard (e.g., autoclaved before disposal, collected by ESD as chemical waste).

Administrative controls include institutional policies, facility access practices limit access to only those personnel required to conduct the work, SOPs, and training related to proper practices for working with hazards. Depending on the agent involved, practices may include all or some of the following: 1) posting of hazard signage, 2) wearing protective attire, 3) changing animal caging under Class II Biological Safety Cabinets, 4) housing animals in filtered or negative pressure HEPA filter ventilated caging, 5) autoclaving exposed equipment and materials prior to cleaning, 6) decontamination of animal rooms following completion of studies, and 7) autoclaving exposed materials in biohazard containers prior to incineration or disposal.

Additionally, PPE is used to contain hazardous agents, by preventing contamination of personnel or their clothing. Animal care personnel are provided with and required to wear uniforms provided by the institution. Rubber boots, disposable dust/mist masks, vinyl or nitrile gloves, safety glasses or goggles, disposable lab coats, coveralls or shoe covers, hearing protection, and rain suits are provided and used when appropriate. Protective clothing worn in research animal environments is not to be worn outside of animal facilities. A clean lab coat is worn over protective clothing if personnel enter public spaces in areas contiguous with the animal facility.

When working with acidic cage cleaners, a face shield (visor) or safety goggles must be worn. Face shields, acid aprons, and respirators are available. Hearing protection (plugs, ear muffs) is provided for use in noisy areas such as dog or pig housing areas. Hearing protection and safety glasses are also provided for personnel working with tractors, mowers, chain saws, and trimmers. Signage is posted wherever hazardous agents or conditions are

encountered. A variety of species appropriate caging and handling equipment is used to minimize animal-related risks.

If specific protective apparel or equipment is required for a particular animal species or hazardous agent, it is provided to personnel, and training is provided on the handling of that species and use of special equipment prior to the initiation of the project. The Institutional Biosafety Committee in an approved Biosafety Protocol describes required equipment and procedures. Personal protective equipment provided depends entirely on the hazards encountered and may range from exam gloves, lab coat and a dust/mist mask to double layer Tyvek coveralls, full face respirator, boots, and double gloving. A respiratory protection program is in place for personnel who require protection of a fitted face-piece respirator (such as an N95 respirator) or powered air purifying respirator (PAPR).

Training and education is a key component of the health and safety program for personnel potentially exposed to hazardous agents. The veterinarians, PI, and health and safety professionals provide training and education on a case-by-case basis for the specific hazard. All new employees are required to participate in a New Employee Orientation program presented by the UGA. This informs the new employee of his/her "Right-to-Know" with regards to chemical hazards in the workplace. Training opportunities for staff involved with the use of hazardous agents in animals includes seminars given by the ORS, ESD and the OBS, web based activities, video libraries, and one-on-one consultation regarding specific practices.

The educational programs for occupational health and safety matters take several forms. The IACUC and Office of Research sponsor and conduct training programs using several formats. Programs are offered for the University community as well as more specific programs for animal care staff. The courses “Staying Healthy While Working with Laboratory Animals” and “Sharps Training” are requirements for all personnel working with animals in research. Topics covered in “Staying Healthy While Working with Laboratory Animals” include zoonoses, personal hygiene, protective equipment, ergonomics, sharps, dangerous chemicals, laboratory animal allergies, and animal handling as well as special precautions for pregnancy, illness, and immune suppression. “Sharps Training” focuses on the safe handling and disposal of sharps in the research setting.

Zoonotic disease risks are of special concern with primates, and the UGA Non-human Primate Core (NHPC) houses macaques. Animal care personnel and researchers working with primates are trained and cautioned on the dangers of working with nonhuman primates by the URAR Veterinarians and/or PI. Animal care personnel and researchers using primates are required to be TB skin tested at least every 6 months, be immunized for measles, and wear protective clothing and face shields and face masks. The URAR Facility Supervisor is responsible for insuring compliance by animal care staff. The PI is responsible for insuring compliance by their own research staff, although URAR staff members monitor compliance closely as well. “Bite/wound” first aid kits are located throughout the NHPC for rapid access. The kit includes materials for cleaning a wound appropriately. Also contained in the kit is an information sheet for physicians indicating risks associated with wounds, the risk of exposure to Macacine herpesvirus 1, and other zoonotic risks associated with macaque monkeys. Bites and scratches for all species are treated immediately with referral to the Occupational Health Physician during business hours, or an emergency or primary care physician after business hours/weekends/holidays as needed.

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 institution endorses, supports, and promotes training and instruction to all personnel involved in the care and use of research animals to ensure they are qualified to do so. Within the Office of Research Integrity and Safety, the Support Services unit facilitates the development, delivery, and documentation of training for

scientists, animal technicians, and other personnel involved in animal care, treatment, or use. Elements of the training program consist of required courses provided by the OACU, formal course work leading to certification, seminars, workshops, on-line modules through the AALAS Learning Library, informal meetings, one-on-one instruction, professional and graduate level curricula, and participation in national and regional symposia.

Training and continuing education of all animal care staff is required and supported; a bonus program is funded by the Office of Research for URAR staff who achieve certification and maintain a registered status through continuing education. AALAS certification of all eligible employees is a unit goal. All new employees are required to participate in a New Employee Orientation program presented by the UGA. This informs the new employee of his/her "Right-to-Know." In addition, all new employees are required to complete a mandatory "IACUC 101" online course that provides a review of applicable laws, regulations, and guidelines, as well as the University Policy on reporting concerns in animal care. Additional information provided in this course focuses on alternatives, the Three Rs, humane endpoints, and minimization of animal numbers while obtaining scientifically relevant results. The U.S. Government Principles, alternatives, methods to search for alternatives, and institutional format for submission of proposals to use animals are discussed. New employees must also complete the online "Staying Healthy While Working with Laboratory Animals" and "Sharps Training" courses that informs them of occupational health risks, including sharps, inherent to working with research animals and the ways in which those risks can be mitigated. All online courses must be completed before they have animal contact. All new employees must complete online training on "Hazardous Communication," "Personal Protective Equipment," "Back Safety," "Bloodborne Pathogens in Animal Research," "Working in Animal BSL1, BSL2 and BSL3," "Biosafety Cabinet and Change Station Operation" and "Cage Wash and Autoclave Safety" within 60 days of hire. They must receive documented training on the University Research Animal Resources Disaster Plan within 30 days of hire. Additionally, staff with responsibilities in high containment areas must complete online courses in "Concepts of Biosafety" and "Working with Laboratory Animals in Biocontainment" within the first 60 days of employment. New employees are also required to read and sign specific standard operating procedures for the animal species/housing type prior to working in the animal room itself.

Technical training for animal care staff is managed by the facility supervisors and includes hands-on demonstrations and individualized instruction. New employees work one-on-one with a well experienced technician for at least one week, then shadow a senior caretaker until the supervisor is assured they have mastered assigned tasks. Employees assigned to help Laboratory Animal Health Technicians perform more involved techniques, e.g., blood collecting and administering medication, receive specialized training when these duties are assigned. All part time students are trained by full time staff and are encouraged to attend onsite training sessions and seminars offered by the URAR; many have achieved AALAS certification. Currently, of all URAR employees, 15 are AALAS certified: 4 at ALAT, 5 at LAT, 5 at LATG, and 1 at CMAR.

Continuing education is required of all animal care staff. Staff are encouraged to customize their continuing education to match with their work responsibilities and their personal interest areas for professional growth. Staff must complete 15 hours of training per year. Mandatory training accounts for 10 hours every 3 years, as the courses required at hire must be repeated every 3 years. Otherwise, the remaining hours of the 15 per year can be customized by the employee. Training is accepted using the standards and credits allowable by AALAS. Continuing education opportunities include branch and national AALAS meetings, and University sponsored programs, such as lectures, workshops and webinars. Vendors also provide valuable training on caging systems, operation for BSCs and change stations, operation of cleaning equipment, appropriate use of chemicals and PPE. All personnel are encouraged to participate in branch and national AALAS with memberships, travel and per diem provided by the Office of Research and the URAR.

As part of the institution's program for animal care and use, training/educational programs are provided to scientists, animal technicians, and other personnel involved in animal care, treatment, or use. Anyone listed on an Animal Use Protocol must also complete the mandatory online training courses "IACUC 101," "Staying Healthy While Working with Laboratory Animals," and "Sharps Training." Completion of these training courses

by all listed personnel is required prior to approval of any Animal Use Protocol. In addition, all animal research personnel must take “IACUC 101 Refresher” and “Sharps Training” every 3 years and complete at least 1 additional documented hour of animal research-related continuing education every 3 years. The OACU regularly provides continuing education opportunities through lectures, workshops and hosted webinars. Reference materials and internet based materials are used adjunctively. Instructional videos and books are available from the OACU training library. Investigators can request specific hands-on training with URAR. Other training involves animal use proposal development and review with the laboratory animal veterinary staff prior to IACUC review. During this process, a critical review of proposed techniques and the methods for handling, housing, and minimizing pain and distress is conducted. This includes the use of anesthetics, analgesics, and tranquilizers. The OACU website also features online detailed descriptions of appropriate techniques for common technical procedures involving the most commonly used research animal species.

Records of all required training are maintained by the Office of Research Integrity and Safety Support Services using an electronic learning management system, the Professional Education Portal (PEP).

Orientation sessions are conducted on an ongoing basis for faculty, visitors, and research personnel working with animals. Participation in the orientation sessions is required for access authorization to the facility. The sessions are conducted at the facility in which their animals are housed. The sessions cover husbandry procedures, veterinary medicine, PPE requirements, general occupational health and safety concerns, regulatory issues including discussion on the Guide, and instructions in special procedures for their research area.

Graduate course offerings and professional curriculum electives include a laboratory animal medicine course (POPH 5202) and wet lab (POPH 5203L), and pathology of laboratory animals (VPAT 8320). All these courses may be audited by faculty, staff, and students.

IACUC members receive orientation training, reference and web-based resources, and in-service training. The orientation consists of a one-on-one session with the OACU staff that reviews the laws, regulations, and guidelines regarding the use of animals in research; the roles and responsibilities of the IACUC; standard operating procedures for the IACUC; and a review of reference materials. Reference materials provided electronically for each IACUC member include the *Guide*, the *Animal Welfare Act Regulations*, the *Institutional Animal Care and Use Committee Guidebook*, the *Guide for the Care and Use of Agricultural Animals in Research and Teaching*, *Report of the AVMA Panel on Euthanasia*, the *PHS Policy on Humane Care and Use of Animals*, and *Occupational Health and Safety in the Care and Use of Research Animals*. An IACUC web site provides links to resources such as to the OLAW web site, a variety of web sites regarding alternatives, the USDA policies and Animal Care web site, and a variety of documents, including the PHS Animal Welfare Assurance, NIH guidance documents on monoclonal antibody production and guidance documents from learned societies such as the American Society of Ichthyologists and Herpetologists Guidelines for the Use of Live Amphibians and Reptiles. In-service training and regulatory updates are provided at the IACUC monthly meetings and periodic retreats. The institution encourages and supports travel for IACUC members to national and regional meetings, such as SCAW’s IACUC 101 and other IACUC-focused conferences.

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 Institutional Official, Dr. David Lee, the Vice President for Research.
5. Records of accrediting body determinations

B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional 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 Institutional Official, Dr. David Lee.
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

Institutional Endorsement and PHS Approval

A. Authorized Institutional Official	
Name: David Lee	
Title: Vice President for Research	
Name of Institution: University of Georgia	
Address: *(street, city, state, country, postal code)* 500 D.W. Brooks Drive 150B Paul D. Coverdell Center for Biomedical & Health Sciences Athens, GA 30602-7396	
Phone: 706-542-5969	Fax: 706-542-5978
E-mail: dclee@uga.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: David Lee	Date: 11/25/19

B. PHS Approving Official *(to be completed by OLAW)*	
Name/Title: **Paula Knapp, Animal Welfare Policy Scientist** Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6700B Rockledge Drive Suite 2500, MSC 6910 Bethesda, MD USA 20892-7982 Phone: 301-496-7163	
Signature: Paula E. Knapp -S Digitally signed by Paula E. Knapp -S Date: 2019.11.25 15:18:51 -05'00'	Date: **November 25, 2019**
Assurance Number: **D16-00276 (A3437-01)**	
Effective Date: **November 25, 2019**	Expiration Date: **November 30, 2023**

VIII. Membership of the IACUC

Date: November 13, 2019
Name of Institution: The University of Georgia
Assurance Number: D16-00276
IACUC Chairperson
Name*: Gaylen L. Edwards
Title*: Department Head Degree/Credentials*: D.V.M., Ph.D
Address*: Physiology and Pharmacology, College of Veterinary Medicine University of Georgia Athens, Ga 30602
E-mail*: gedwards@uga.edu
Phone*: 706-542-5854 Fax*: 706-542-3015

PRIMARY MEMBERS

Name of Member or Code	Degree/ Credential	Position Title	PHS Policy Membership Requirements
Gaylen Edwards	**DVM, PhD**	**Department Head, Physiology & Pharmacology**	**IACUC Chair**
1 Leanne Alworth	**DVM, MS, DACLAM**	**Director, Office of Animal Care and Use; Attending Veterinarian**	**Veterinarian**
2	**PhD**	**Professor, Animal and Dairy Science**	**Scientist**
3	**JD**	**Attorney**	**Non-Scientist, Non-Affiliated**
4	**DVM, MS, DACLAM**	**Asst. Director, University Research Animal Resources**	**Veterinarian**
5	**PhD, MS**	**Professor, Poultry Science**	**Scientist**
6	**DVM, PhD**	**Associate Professor, Infectious Diseases**	**Scientist**
7	**PhD**	**Professor, Psychology**	**Scientist**
8	**AS, RLAT**	**URAR Facility Supervisor**	**Member**
9	**PhD**	**Associate Professor, Cellular Biology**	**Scientist; IACUC Vice Chair**
10	**PhD**	**Professor, Wildlife**	**Scientist**
11	**BS, RALAT**	**IACUC Coordinator, Office of Research**	**Member**
12	**MS, RBP**	**Biosafety Officer, Office of Research**	**Member**
13	**BA, JD**	**Retired Attorney; Animal Clinic Manager**	**Non-Scientist, Non-Affiliated**

ALTERNATES

Community Members

Name of Member or Code	Degree/ Credential	Position Title	PHS Policy Membership Requirements
C1	**MA**	**Retired Librarian**	**Alternate for Members 3, 13**

Members

Name of Member or Code	Degree/ Credential	Position Title	PHS Policy Membership Requirements
M1	**BS**	**Director EHS Technical Services**	**Alternate for Members 11, 12**
M2	**BS, RLATG**	**Support Services Director, Office of Research**	**Alternate for Members 11, 12**
M3	**BS, RLATG**	**IACUC Specialist, Office of Research**	**Alternate for Members 11, 12**
M4	**BS, SM (NRCM)**	**Biosafety Manager, Office of Research**	**Alternate for Members 11, 12**

Scientists

Name of Member or Code	Degree/ Credential	Position Title	PHS Policy Membership Requirements
S1	**DVM, PhD**	**Assistant Professor, Large Animal Medicine**	**Alternate for Members 2, 5, 6, 7, 9, 10**
S2	**VMD, DACVAA, DACVECC**	**Professor, Small Animal Medicine and Surgery**	**Alternate for Members 2, 5, 6, 7, 9, 10**
S3	**PhD**	**Associate Professor, Animal and Dairy Science**	**Alternate for Members 2, 5, 6, 7, 9, 10**
S4	**PhD**	**Assistant Research Scientist, Infectious Diseases**	**Alternate for Members 2, 5, 6, 7, 9, 10**
S5	**PhD**	**Associate Professor, Poultry Science**	**Alternate for Members 2, 5, 6, 7, 9, 10**
S6	**PhD**	**Professor, Population Health**	**Alternate for Members 2, 5, 6, 7, 9, 10**
S7	**PhD**	**Associate Professor, Population Health; Professor, Wildlife Disease**	**Alternate for Members 2, 5, 6, 7, 9, 10**

Veterinarians

Name of Member or Code	Degree/ Credential	Position Title	PHS Policy Membership Requirements
V1	**DVM, DACLAM**	**VP for Research Compliance, Office of Research**	**Alternate for Member 1, 4**

* 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.

IX. Other Key Contacts (optional)

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

Contact #1	
Name: Dr. Leanne Alworth	
Title: Director, Office of Animal Care and Use	
Phone: 706-542-5933	E-mail: alworth@uga.edu
Contact #2	
Name: Dr. Christopher King	
Title: Associate Vice President for Research Integrity & Safety	
Phone: 706-542-4016	E-mail: cking@uga.edu

X. Facility and Species Inventory

Date: Nov 13, 2019			
Name of Institution: The University of Georgia			
Assurance Number: A3437-01/ D16-00276			
Laboratory, Unit, or Building*	Gross Square Feet [*include service areas*]	Species Housed	Approximate Average Daily Inventory
ANIMAL FACILITIES			
A	19,743		
		Mouse	501
		Ferret	11
		Chicken	52
		Deer	1
B	4,213		
		Mouse	1.9
		Rat	4.9
		Ferret	141
		Cat	0.75
C	3,843		
		Pig	0.15
		Sheep	3.3
		Deer	0.42
D	2,596		
		Catfish	811
E	12,213		
		Avian, misc.	2
		Cat	35
		Dog	1
		Gerbil	234
		Mouse	877
		Pig	3
		Sheep	0.03

		Rat	23
		Turtle	0.07
F	894		
		Mouse	83.3
G	19,307		
		Mouse	2930.8
		Rat	19
		Zebrafish	7,000
H	171		
		Mouse	3.3
I	5,167		
		Dog	30.6
J	6,846		
		Guinea pig	1.9
		Mouse	77.4
		Rat	345.3
		Cat	3.9
		Ferret	16
		Anole	215
		Fish	10,273
K	8,951		
		Nonhuman primate	79
L	180 acres		
		Cattle	75
		Horse	43.9
		Pig	17
M	31,661		
		Chicken	362
		Turkey	22
		Quail	15
		Duck	14

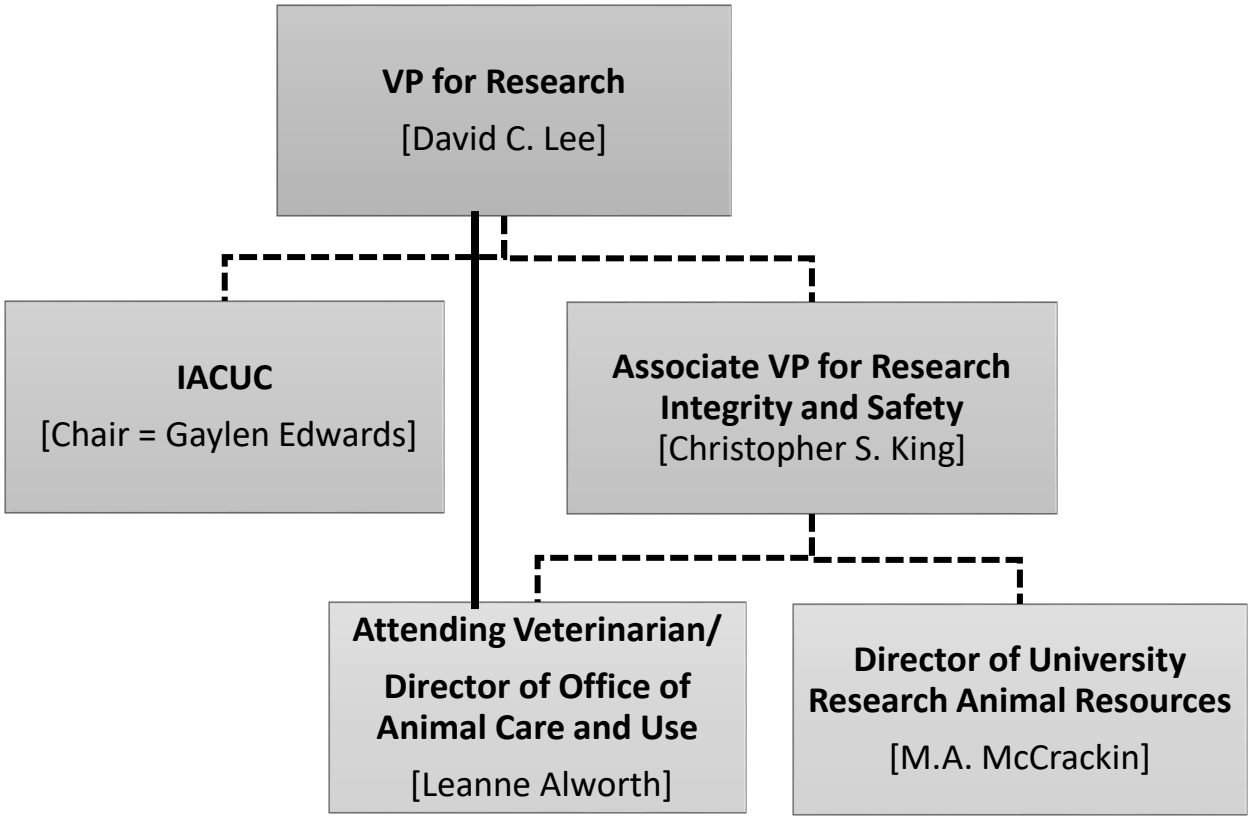
		Ibis	4
N	2,226		
		Rat	44
O	10,129		
		Mouse	239.8
		Rat	3
		Pig	9.8
		Chicken	0.7
P	38 acres		
		Cattle	1.3
		Horse	0
Q	5,357		
		Cat	8
		Dog	17.5
		Rabbit	0.92
R	3,002		
		Horse	0.3
		Cattle	0.02
		Goat	0.1
		Sheep	0.03
S	185		
		Cat	6
T	9,609		
		Horse	2.5
		Cattle	3
		Goat	2
SATELLITE HOUSING			
U	148		
		Mouse	103
V	20		

		Koi	9
		Plecos	2
W	66		
		Fish	10
X	1,874		
		Mouse	3
Y	1,946 (embryos are within incubator)		
		Fish (embryos)	150
Z	1,780 (embryos are within incubator)		
		Fish (embryos)	800
AA	3,053		
		Cattle	0.2
		Pig	3

UNIVERSITY OF GEORGIA

ANIMAL CARE AND USE PROGRAM

ORGANIZATIONAL CHART



KEY

Line of reporting and communication

Line of communication outside of official reporting line