

Animal Welfare Assurance for Domestic Institutions

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

I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS and 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 of Auburn University: College of Education, College of Engineering, College of Liberal Arts, School of Pharmacy, College of Sciences and Mathematics, and College of Veterinary Medicine.

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

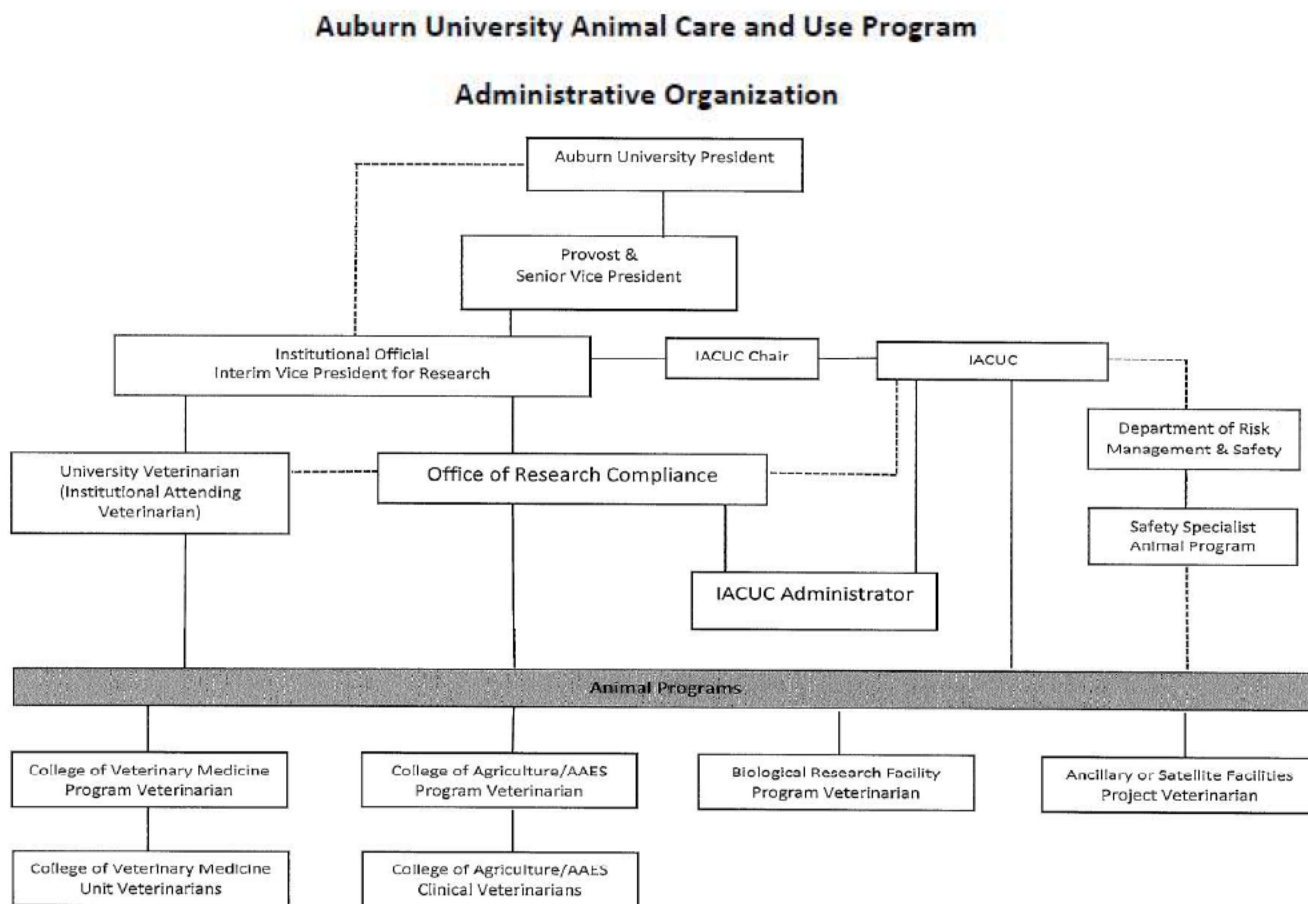
None.

II. Institutional Commitment

- A. This Institution will comply with all applicable provisions of the [Animal Welfare Act](#) and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "[U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training](#)."
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution 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](#)). The Guide for the Care and Use of Agricultural Animals in Research and Teaching (Ag Guide) may be used as a supplemental resource to the Guide for activities involving agricultural animals.
- 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:



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

Veterinarians	Qualifications	Responsibilities	Authority	Time contributed to program
Patricia Rynders	DVM, MS	University Veterinarian (Attending Veterinarian); Director, Division of Laboratory Animal Health (DLAH), Backup Vet Services Oversight of veterinary care of all animals and access to all animals at the university. Oversight of veterinary care provided by Project Veterinarians at COSAM-Aviary #1, CVM-ClinSci #3, and CVM Patho #2. Primary veterinary care at CVM-Patho #3.	Direct	Full Time Employee 100%

Veterinarians	Qualifications	Responsibilities	Authority	Time contributed to program
		<p>Degrees: DVM, North Carolina State University (AVMA accredited), MS, Biomedical Science, Auburn University.</p> <p>Training and/or experience in laboratory animal medicine: 12 years of post-DVM experience in laboratory animal medicine.</p> <p>Because of the diversity of animal species and the decentralized nature of the animal care and use program at Auburn University, the clinical, and after hours/holiday/emergency duties of the University Veterinarian are shared with/delegated to other institutional veterinarians (named below). The assurance of compliance is the responsibility of the University Veterinarian.</p>		

(b) (6)

Veterinarians	Qualifications	Responsibilities	Authority	Time contributed to program
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(b) (6)

In addition, the AU CVM is available to provide back up clinical vet care/services during holidays and emergencies through their small and large animal teaching hospitals.

- 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 or Ag Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

Review at least once every six months the institution's program for humane care and use of animals, using the Guide or Ag Guide (as described in Part II. Section D.) as a basis for evaluation. The IACUC procedures for conducting semiannual program evaluations entail three different venues: (1) IACUC subcommittee consisting of at least 3 individuals from the following group: (Chair; University Attending Veterinarian; Director, Research Compliance; Director, Division of Laboratory Animal Health, CVM; Director, Outlying Units, Alabama Agricultural Experiment Station; Associate Director, Risk Management & Safety-Safety & Health; community member; and/or other IACUC members as appointed by the IACUC Chair); (2) full IACUC Committee; and (3) as a component of the facilities inspections. The reviews are guided by a checklist of itemized considerations wherein each item is judged to be acceptable, a minor deficiency or a significant deficiency. The program review includes evaluation of the Occupational Health and Safety Program, the Veterinary Care Program, the PHS Policy/Animal Welfare Assurance, adherence to/deviations from the Guide, and the Training Program. Plans and schedules for correction are developed for any deficiency. Subcommittee reviews and reports are reviewed and approved at a meeting of the IACUC.

- 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, at least once every six months, all of the institution's animal facilities, including satellite facilities, using the Guide or Ag Guide (as described in Part II, Section D.) as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are:

Each facility is inspected by a subcommittee of the IACUC, usually consisting of two members assigned by the IACUC Chair or his/her designee. For USDA covered facilities, the subcommittee conducting the inspection includes at least two voting IACUC members. All IACUC members participate in the inspections and are assigned approximately equal numbers of facilities to inspect.

A member of each subcommittee is responsible for contacting the individual responsible for the facility to be inspected in order to schedule a time for the inspection. No member of the IACUC inspects a facility for which he/she is directly responsible. All inspections should be completed within six weeks after assignment and written reports forwarded to the Director of Research Compliance or the Chair of IACUC no later than two weeks after an inspection is completed.

The Chair of the IACUC or Director of Research Compliance notifies the individual responsible for a facility regarding the findings of an inspection. Deficiencies are identified as significant deficiencies (serious deviations from the Guide) or minor. Target dates for correction are assigned for each deficiency. Significant deficiencies are followed-up by the IACUC Chair or the Chair's designee. Visual confirmation of corrective actions taken to correct significant deficiencies is performed at the next regularly scheduled inspection.

- 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:

The IACUC Chair or designee prepares a draft of the semi-annual report to be submitted to the Institutional Official. The report includes the following items: (1) membership roster of the IACUC; (2) summary of protocol numbers reviewed and approved; (3) notations pertaining to new policies that impact the animal care and use program; (4) mention of concerns/formal complaints/outcomes relating to animal care and use; (5) progress made since the last report with regard to programmatic issues or facilities; (6) recommendations regarding any aspect of the institution's animal care and use program (e.g., facilities, personnel training, veterinary care, occupational health and safety); (7) any departures from the provisions of the Guide, the Ag Guide and PHS Policy and the reasons for each departure; (8) any deficiencies in programs or facilities categorized as minor or significant; and (9) a reasonable, specific plan and schedule for correcting each deficiency. Items eight and nine are derived from subcommittee reports pertaining to facility inspections or programmatic reviews.

The draft report is reviewed and discussed by the IACUC. The report (or a revision of the report) is signed by IACUC members to signify their endorsement of its content. The final report is then submitted to the Institutional Official. The IACUC Chair, University Veterinarian, and Director of Compliance usually meet with the Institutional Official to review and discuss the report. Any minority views or reports should be submitted directly to the Institutional Official.

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

The institution has developed an Animal Welfare Concern Poster containing names, contact information, and instructions for reporting animal welfare concerns. All animal-use facilities are required to post the information. The poster is available to investigators and the public on the IACUC website. Semiannual facility inspections ensure that the information is appropriately posted in each facility.

The IACUC reviews and/or investigates any concern relating to animal care and use brought to the attention of the Committee. This includes claims by the public concerning any aspect of the animal care and use program or by employees or students who report alleged instances of animal abuse, violation of approved protocols, use of animals not covered by approved protocols, violation of any animal related regulation or standard (such as the AWA, PHS Policy or IACUC Policy), or complaints regarding the care received by animals housed in University laboratory animal, wild animal or agricultural facilities.

Concerns should first be addressed to the individual(s) or unit at whom/which the complaint is directed. If the concern cannot be handled directly and an emergency situation exists, the University Attending Veterinarian should be contacted immediately. The University Attending Veterinarian, or a designee, will take any necessary immediate action. If the concern cannot be adequately addressed, or if there is fear of retribution, a formal complaint should be filed.

A formal complaint is initiated by contacting one of the following individuals: Director of Research Compliance; Chair of the IACUC; University Attending Veterinarian.

Information to be provided in the formal complaint must include:

- **Complainant's Name.**
- **Individual(s) or unit the complaint is against.**
- **Description of the event or charges, including applicable dates of observations and documentation to substantiate the charges.**
- **Signature of complainant.**

A signed complaint must be submitted to an individual listed above for a formal review to be conducted.

While hearsay complaints cannot be formally filed, individuals who have serious concerns based on hearsay evidence can call any of the individuals listed above. The individual contacted, or a designee, may follow-up on concerns by means other than the formal complaint process such as review of protocols, discussions with employees, or unannounced laboratory inspections. The process may lead to the filing of a formal complaint.

The signed formal complaint is submitted to the Chair of the IACUC as soon as possible. A formal complaint remains confidential to the extent possible to protect all concerned. The Chair, within three days of receiving the formal complaint, will appoint a subcommittee to investigate the concern. The subcommittee will consist of at least 3 IACUC members and may include 1 or more non-IACUC members. In an initial inquiry phase, the subcommittee will focus on information gathering and fact-finding to confirm the concern as warranting a formal investigation versus a concern that may be based on mistaken allegations. At the inquiry phase, the individual(s) at whom the concern/complaint is directed will be informed of the nature of the concern/complaint and of the investigative procedures to be followed and given an opportunity to explain her/his side of the issue. As much documentation as is reasonably needed to support or refute concerns involving care and use of animals will be collected. Such information may include, but not necessarily be limited to, interviews of all parties involved, inspecting facilities, collection of pertinent documents, on-site evaluation of animals, and detailed

review of procedures with responsible personnel. Relative to the date that a signed complaint is received by the Chair of the IACUC, the inquiry phase will be completed within 30 calendar days and a formal investigation within 60 calendar days, unless circumstances clearly warrant a longer period.

The subcommittee will prepare a report for the IACUC. The IACUC will immediately review the concern or complaint and will determine what action will be taken. (Majority quorum vote and minority opinions will be recorded.) The Chair of the IACUC will immediately notify the individual(s) at whom the concern/complaint is directed, the relevant facility director, department/unit head, dean/director, the Director of Research Compliance, the University Attending Veterinarian and the complainant. The IACUC Chair or designee will inform the Institutional Official.

Reports will be filed in the Office of Research Compliance to document investigation and resolution of the incident. No employee, student, or IACUC member shall be discriminated against or be subject to any reprisal for reporting perceived noncompliance with any of the regulations or policies pertaining to animal care and treatment.

The IACUC, through the Institutional Official, shall file a report with appropriate federal or state agencies, AAALAC, and/or sponsors as dictated by the actions taken by IACUC and by applicable compliance standards.

- 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 procedures for making recommendations to the Institutional Official are presented under D. 3 above regarding preparation and submission of semi-annual reports by IACUC to the Institutional Official. Otherwise, the IACUC Chair, the Director of Research Compliance, or the University Attending Veterinarian, as the Committee's messenger, may provide written recommendations to the Institutional Official whenever deemed appropriate.

- 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:**

The IACUC oversees the use of all live vertebrate animals on behalf of Auburn University, whether for research, instruction, demonstration, production or maintenance purposes. Investigators/instructors using live vertebrate animals in such activities are required to submit the appropriate review form for IACUC review. Two forms are available for submission:

a. "Animal Subjects Review Form" for protocols describing research, teaching, or demonstration activities

b. "Animal Production/Maintenance Facility Standard Operating Procedures" for protocols describing only the production and/or maintenance of animals (e.g., those animals being produced and/or maintained primarily for the purposes of being used in various research or teaching activities)

It is understood that some protocols may involve more than one category of activity. For example, a protocol may involve birds being captured and released in the field for the purpose of data collection for a research project. However, this protocol may involve the simultaneous activity of teaching a class of students the technique of field capture and handling of birds. Furthermore, if animals are being

produced and/or maintained solely for a particular research or teaching project, then the Animal Subjects Review Form may be submitted to reflect activities of production/maintenance and research or production/maintenance and teaching, whichever is applicable.

Information and procedures pertinent to protocol review include:

a. Forms are available to users on the Office of Research Compliance IACUC

Administration website:

<https://cws.auburn.edu/OVPR/pm/compliance/iacuc/forms>

b. Protocols are mailed, emailed, or hand delivered to the Office of Research Compliance, (b) (4).

c. All protocols are checked immediately for the signatures of the principal investigator (PI), department head, project veterinarian and, if appropriate, faculty advisors or lead graduate students and unit veterinarians.

Full Committee Review

d. Protocols received at least seven days prior to a scheduled meeting date (i.e., by 11:30 AM on Thursday of the week prior to a scheduled Thursday afternoon meeting) are placed on the agenda. Protocols received after the aforementioned deadline may be placed on the agenda of the following meeting.

e. A primary and a secondary reviewer of each protocol are assigned by the Chair of the IACUC or Vice Chair(s). Committee members are not assigned as reviewers of protocols on which they or a member of their academic department or unit are listed as the PI, faculty advisor or departmental chairperson on the protocol or on which the member is a veterinarian associated with the project or otherwise would have a conflict of interest as determined by the IACUC.

f. Meeting agendas include review of minutes of prior meeting, list of protocols to be reviewed, and other business (reports, announcements, etc.).

g. Committee members receive minutes, agendas and protocols two to seven days in advance of an IACUC meeting.

h. A simple majority quorum of voting members is required to convene an IACUC meeting.

i. Members should review all protocols before the meeting and be prepared to discuss each protocol and vote (if not excused in accordance with other stipulations relevant to IACUC meetings). Anticipated absences should be reported as soon as possible to the Office of Research Compliance.

j. Members of the IACUC who are listed as either principal investigator or co-investigator on a protocol being discussed by the IACUC may excuse themselves from the room during presentation and discussion. The PI must be absent from the room when final discussion and a subsequent vote are conducted.

k. The primary reviewer presents the protocol to the committee. If the primary reviewer is absent, the secondary reviewer assumes this responsibility. Whenever appropriate, the reviewers may contact the PI prior to the meeting for additional information or clarification.

l. After the primary or secondary reviewer presents a protocol, a motion is then made for approval, modification (to secure approval), withholding of approval. If the motion is seconded, the Chair then asks for questions or discussion. Following

the discussion, a verbal vote is taken. For an action to be approved, the motion must receive a simple majority vote in a quorum of committee members eligible to vote. A committee member can request a written or roll call vote instead of a verbal vote.

m. Regardless of the type of vote (verbal or written), protocol outcomes, deliberations, and decisions made by the IACUC are captured in the meeting minutes. Outcomes include approved as submitted, requirement for modifications (to secure approval), or withholding of approval.

n. If the protocol is approved as submitted, the IACUC Chair or designee will sign the original form, and the Office of Research Compliance will assign a protocol review number (PRN).

o. If the protocol requires minor clarifications/ revisions (to secure approval), then a PRN will not be assigned until such clarifications/ revisions have been submitted in writing by the PI and approved by the IACUC.

p. The IACUC may withhold approval if the IACUC deems that the PI must address major clarifications/revisions and the protocol, therefore, must be resubmitted for review by the IACUC. For example, major clarifications or revisions may entail such items as conduct of invasive procedures, justification of species or number of animals, and changes in experimental design.

Designated Member Review Subsequent to Full Committee Review

q. Designated member review subsequent to full committee review may be used to review modifications (to secure approval) when all IACUC members have agreed in advance in writing. The quorum of members present at a convened meeting may decide by unanimous vote that designated member review subsequent to full committee review is appropriate. Regardless, any member of the IACUC may, at any time, request to see the revised protocol and/or request full committee review of the protocol.

If the committee unanimously votes to use designated member review subsequent to full committee review to review modifications (to secure approval) the IACUC Chair will appoint one or more voting members of the IACUC to conduct the review. Outcomes include approval as submitted, requirement for modifications to secure approval, or referral to the full committee for review at the next scheduled IACUC meeting.

Designated Member Review

r. On occasion, protocols may be reviewed outside of a scheduled meeting of the IACUC. Protocol review outside of a scheduled meeting of the IACUC may occur when the principal investigator submits a written request/justification to the IACUC Chair which details and documents an extenuating circumstance (e.g., impending sponsor deadline). The decision to conduct a protocol review outside of a scheduled meeting of the IACUC will be made by the IACUC Chair or designee. All IACUC members are provided a copy of the protocol. Members are given a specified period of time (e.g., 2-3 working days) to request the protocol receive full committee review. If full committee review is requested by any member, the protocol is placed on the agenda for the next scheduled IACUC meeting. If review by the full IACUC is not requested by the specified time, then the protocol may be assigned for designated review by 2-3 members of the IACUC. The individual(s) assigned to the designated review committee are appointed by the IACUC Chair or Vice Chair(s).

All members of the designated review committee receive identical versions of the proposed protocol for review. If a protocol is assigned more than one designated reviewer, the reviewers must be unanimous in any decision and agree to any modifications (to secure approval). The outcomes for designated review committee recommendations are approval as submitted, require modification (to secure approval), or referral to the full committee for review at the next scheduled IACUC meeting. The designated review committee cannot disapprove a protocol. The decision of the designated review committee is final.

s. Criteria for granting IACUC approval of a protocol entail:

- **Activities:** Must be in accord with USDA Regulations/PHS Policy. Procedures involving animals are designed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.
- **Animals:** Appropriate species and quality and the minimum number required to obtain valid results.
- **Pain/Distress:** Must avoid/minimize discomfort, distress and/or pain. If pain/distress is likely to result, appropriate sedation, analgesia or anesthesia should be used unless scientifically justified with special approval from the IACUC. The project veterinarian must be involved in the planning. Use of paralytics without anesthesia is prohibited. Animals with chronic/severe unrelievable pain will be euthanized
- **Surgery:** Must meet requirements for aseptic surgery and pre/postoperative care. Cannot use one animal for more than one major operative procedure from which it will recover unless scientifically justified with special approval by the IACUC.
- **Euthanasia:** Euthanasia method must be consistent with recommendations of the most current American Veterinary Medical Association (AVMA) recommendations.
- **Housing/Health:** Living conditions for animals must be consistent with standards of housing, feeding and care directed by the AWA, The Guide, or Ag Guide as appropriate.
- **Alternatives:** Alternatives to painful procedures must be considered; must document consideration of alternatives if animals experience or may be expected to experience pain or suffering.
- **Rationale/Methods:** Must provide written narrative of methods/sources including years searched and keywords searched.
- **Duplication:** Must provide assurance that activities do not unnecessarily duplicate previous efforts.
- **Qualifications:** Personnel must be appropriately qualified.
- **Deviations from Requirements:** Must be justified for scientific reasons, in writing and approved by the IACUC.

t. The following questions are presented as examples that can be used to assess the scientific merit in animal care and use protocols: (a) Is the research design sound? (b) Does the proposal contain appropriate rationale for involving animals? (c) Could the investigator employ alternative procedures or alter study design in a manner that would result in a reduction in pain or distress or decrease the frequency of painful or stressful procedures?

u. A protocol may be approved for up to three years. Reminders are sent to the PI prior to the expiration of the protocol as described in III. D. 9 below. Once a protocol has expired, a notification of expiration is sent to the PI, and copies of the notification are filed in the ORC.

- 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 procedures for reviewing proposed significant changes in ongoing research projects are the same as described for Protocol Review in III. D. 6 above. Forms for submitting proposed modifications are available online from the aforementioned web sites. Examples of significant changes include: change from non-survival to survival surgery; change in degree of invasiveness or discomfort; change in species or number of animals; change in anesthetic agent or use or withholding of anesthesia; changes in animal care or veterinary care; change in euthanasia method; and change in duration, frequency or number of procedures performed.

- 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 administration from the Office of Research Compliance attends all meetings of the IACUC and records minutes of all IACUC meetings. Following the meeting, primary and secondary reviewers are expected to provide written documentation of their review to the IACUC Administrator relating to their assigned protocols. The IACUC administrator then provides detailed written communication to the PI (including those projects where approval is withheld) regarding the committee's deliberations and action on his/her protocol, utilizing the minutes as the content source for the communication. If approval is withheld the PI will be notified of the reasons and given the opportunity to respond in writing to the IACUC. Upon final approval, a copy of the fully signed protocol will be provided electronically to the PI. The Office of Research Compliance, which maintains all official files of the IACUC, will retain the original. In addition, an electronic copy will be sent to each of the following: appropriate Dean and/or Department Head; associated veterinarians, and facility manager(s). Moreover, minutes approved by the IACUC are maintained in the Office of Research Compliance as the institution's official records of the IACUC's activities.

- 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:

Annual reviews of all protocols are conducted in November of each year. The IACUC administration from the Office of Research Compliance notifies PIs by written communication (at least one month in advance of the due date) that an annual review is due. The Annual Review Report Form is provided electronically to the PIs.

Annual reviews are conducted by the IACUC Chair or designee with assistance from the IACUC Administration in the Office of Research Compliance. Outcomes for annual reviews may include approval as submitted, require minor

clarifications/revisions (to secure approval), or referral to the full committee for review at the next scheduled IACUC meeting. Failure to submit an annual review report may result in closure of the protocol and activities being carried out.

Continuation of a project beyond three (3) years requires submission of a new protocol review form for review by the IACUC. The IACUC administration notifies principal investigators and the relevant unit heads of impending expiration in writing at least thirty (30) days in advance of the expiration date. Protocols for project continuation beyond three (3) years are reviewed by the full committee at a convened meeting of the IACUC unless the protocol meets the requirements for designated member review as described previously. Regardless of the method, review of the protocol will include all criteria and procedures required for a new project.

- 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 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. A suspension will not occur prior to consultation with the responsible individual (that person in charge of the activity). Such consultation will allow the responsible individual to be informed of the cause for concern so that an opportunity is afforded to explain his/her side of the issue. As much documentation as is reasonably needed to support or refute concerns involving care and use of animals will be collected. Such information may include, but is not necessarily limited to interviews of all parties involved, inspections of facilities, collection of pertinent documents, on-site evaluation of animals, and detailed review of procedures with responsible personnel. 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 the PHS Office of Laboratory Animal Welfare (OLAW), the Animal and Plant Health Inspection Service (APHIS), USDA, and/or any other Federal agency funding the activity.

- 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:

Risk Management and Safety performs Job Hazard Analysis at each animal facility to facilitate personnel training, immunization needs, and participation in the occupational health and safety program with regard to animal care and use.

An Occupational Health and Safety Program (OHSP) is provided for personnel involved in activities to which the AU Assurance of Compliance to the US Public Health Service applies. These activities include all research, research training, experimentation, biological testing and related activities using live, vertebrate animals wherein the activities are either supported by the PHS or not supported by the PHS but the animals used are housed in the same facility as PHS-supported animals. Moreover, the OHSP is provided to all personnel involved in the care and use of animals in facilities accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).

Certain activities pose no health risk to personnel and individuals participating in such projects may be exempted from the program. Exemptions may be given for activities that involve the observation of animals or for other uses that involve no exposures to safety and health risks. Questions or interpretations concerning potential exemptions are to be directed to Risk Management and Safety.

Physical plant personnel who may encounter animals receive training from the Office of Risk Management and Safety via the online OHSP website and are required to have

approval from animal facility management before entering and performing work in animal facilities. Physical plant personnel are provided with the necessary protective clothing and instruction when entering animal facilities.

At the time of enrollment in the online OHSP and for periodic reviews, all participants are provided an online health questionnaire. Data from completed questionnaires is automatically emailed to the Occupational Health Physician at Alabama Occupational Medicine. The questionnaire deals with any existing medical condition that creates an increased health risk related to animal exposures. Physical examinations and counseling are based on the functional requirements of the position, the type of animal exposure, and the individual's prior medical history.

Aside from the Occupational Health and Safety Program, oversight of occupational health and safety issues is provided by the Institutional Animal Care and Use Committee (IACUC), the Institutional Biosafety Committee, and the Office of Risk Management and Safety. The IACUC has mandated that before a protocol submission may be approved, the principal investigator must document enrollment in the online Occupational Health and Safety Program for all individuals named on the protocol. Occupational health and safety issues are topics for consideration by the IACUC in its semiannual site inspections and programmatic reviews.

AU Central Administration provides the resources to support essential elements of the Occupational Health and Safety Program infrastructure: administrative oversight via the Office of the Vice President for Research (OVPR); salary dollars for the relevant administrative personnel in the Office of Risk Management and Safety, Office of Research Compliance, and Office of the Vice President for Research; and the computer network for information management/exchange, including on-line access to relevant health and safety information. Funds to cover costs resulting from medical evaluation/Occupational Health and Safety Program enrollment of all participants in the program are provided by the Office of the Dean, College of Veterinary Medicine; College of Agriculture; Alabama Agricultural Experiment Station; Office of the Vice President for Research; or other administrative units.

Responsibilities of the Office of Risk Management and Safety include: conducting job hazard analysis to identify potential safety and health hazards; safety training in chemical hygiene, laboratory safety, chemical waste management, radiological safety, medical waste management, bloodborne pathogens, respiratory protection, and hearing conservation; site safety and health surveys; accident/injury/incident investigation; consultation on topics such as ventilation, ergonomics, storage of hazardous materials, and engineering controls (e.g., biological safety cabinets).

The occupational health physician provides medical services and counseling associated with entry medical evaluation, and treating of injuries and illnesses. The occupational health physician is responsible for notifying enrollees of medical follow-ups. Risk Management and Safety Animal Program Specialist is responsible for notifying enrollees of surveillance recalls (e.g., tetanus boosters). Records documenting status of entry medical evaluations and surveillance recalls are maintained by the occupational health physician.

The University Attending Veterinarian provides consultation to researchers, instructors, students, and staff on matters relating to occupational health and safety. In consultation with OHSP administration, the University Attending Veterinarian also may investigate or oversee investigation of accidents or incidents involving occupational health and safety, to determine probable cause and/or the extent of compliance with IACUC and animal care and use guidelines. The Office of Research Compliance IACUC Administration website contains material and links pertaining to entry and annual training on occupational health and safety issues.

The Institutional Biosafety Committee (IBC) is charged by the President of AU with responsibility for the regulation of biohazardous materials, including human and animal pathogens, plant pathogens, toxins, and recombinant DNA. Principal investigators using biohazardous materials within AU facilities must receive authorization for biological use from the Institutional Biosafety Committee. The AU Biosafety Program, under the auspices of the Institutional Biosafety Committee, works collaboratively with the PI to ensure the safety of students, faculty and staff, visitors, and the environment.

All work with radioisotopes conducted at AU must be licensed through the Radiological Safety Committee (RSC). For more information visit the RMS Radiation Safety webpage (<https://cws.auburn.edu/rms/pm/radsafety>).

Other AU safety programs applicable to laboratories that work with hazardous materials include the Chemical Hygiene Plan, the AU Chemical Waste Management Program, Blood-Borne Pathogens, and Respiratory Protection. These plans and the AU Biological Safety Manual are available as paper copies or online (<https://cws.auburn.edu/rms/pm/intro>).

Components of an individual's medical monitoring program reflect the specific surveillance needs of the participant based on real or potential exposure to specific species of animals as determined by the Job Hazard Analysis performed by Risk Management and Safety Personnel. Immunizations are tracked via the Occupational Health and Safety website (<https://cws.auburn.edu/OHS>).

Procedures	Guidelines/Requirements
Allergy risk counseling	All employees with exposure to animal allergens
Tetanus immunization	All employees involved in animal care and use when more than ten years has elapsed from immunization or booster, or date of immunization/booster not documented
Rabies immunization	All employees exposed to bats, unvaccinated carnivores, or other potentially high risk species, e.g., raccoon, skunk, fox
Q-fever counseling	All employees who have exposure to pregnant sheep or goats or who have exposure to the organism <i>Coxiella burnetti</i> in a research laboratory
Toxoplasmosis counseling	All female employees of childbearing age who have exposure to random-source cats
Physical examination, pre-placement	Requirements for a physical examination and components of the examination are based on the position's job hazard analysis and the individual's prior medical history.
Physical movement examination (range of motion analyses and lifting exercises)	Requirements for employees are based on the position's job hazard analysis and/or judgment of the physician.

Blood drawn for serum banking	May be a requirement for employees who will be exposed to animals experimentally infected with a known zoonotic agent or who will be potentially exposed to the zoonotic agent in a laboratory setting via preparations containing the agent, e.g., inoculation, animal tissues/fluids, etc.
Auditory testing	Needs will be identified by the Office of Risk Management and Safety and testing administered by the occupational health physician
Respiratory protection	Needs will be identified by the Office of Risk Management and Safety and testing administered by the occupational health physician
Protection from exposure to radiation	Needs identified by the PI. All personnel caring for/exposed to animals treated with radioisotopes will be issued a radiation film badge by the Office of Risk Management and Safety to monitor external exposures. Each individual issued the film badge is responsible for appropriate wearing of the badge and for surrendering the badge to the Office of Risk Management and Safety for assessment according to established testing procedures.

Immunizations

Tetanus prophylaxis: Every employee should have up-to-date tetanus immunizations consistent with recommendations by the Public Health Service Advisory Committee on Immunization Practices (ACIP); the AU OHSP requires immunization against tetanus every 10 years for all personnel involved in animal care and use. Immunization also is recommended if a particularly tetanus-prone injury occurs in which more than 5 years have elapsed since the employee's last immunization.

Rabies: Immunizations are recommended per ACIP recommendations and recommendations of the Alabama Department of Public Health.

Anyone having exposure, or suspected exposure, to a rabies-positive animal or tissues, or contact from a suspect animal that cannot be tested or quarantined for rabies may be advised to undergo post exposure prophylaxis therapy.

It is the responsibility of supervisors/professors/instructors to monitor the risk to employees, students, and student teachers and obtain the appropriate immunizations for them BEFORE exposure occurs. If there is any question as to whether someone should be immunized, the Occupational Health Physician is contacted for a recommendation.

Employees are advised that prophylactic vaccination should be considered when research is being conducted on infectious diseases for which effective vaccines are available.

Personal Hygiene

Animal care personnel are provided the necessary protective apparel. Such apparel may include the following: rubber boots, coveralls, scrub suits, lab coats, disposable surgical gowns, gloves, shoe covers, goggles, ear plugs and face masks or respirators.

Animal care personnel are required to wash their hands after caring for each group of animals and before eating, drinking, or smoking. Eating, drinking, and smoking are not permitted in animal housing areas. Smoking is not permitted in any AU campus building as stated in AU's University Staff Handbook (Smoking Policy).

Work-related Injuries or Illnesses

All on-the-job injuries, disabilities, or illness, regardless of their severity, should be reported immediately to the employee's supervisor. The employee (or supervisor if the employee is unable) is responsible for reporting the incident to the On the Job Injury Program (OJI) claim manager within 72 hours of the incident. To report an OJI the employee or supervisor can call (b) (6) or use the following link:

<https://cws.auburn.edu/rms/pm/claims>

Provision for Treating Injuries and Illnesses:

- Weekdays between 8:00 a.m. and 4:45 p.m.: Auburn University Medical Clinic or Alabama Occupational Medicine.
- After work hours: East Alabama Medical Center (EAMC) emergency room
- Anytime if immediately life threatening: East Alabama Medical Center emergency room

If the injury involves random source dogs or cats, the animal is quarantined according to federal and state law or euthanatized and tissues submitted to the Alabama State Diagnostics Lab for rabies evaluation.

Training

Investigators are responsible for ensuring that all personnel participating in work involving hazardous agents in animals will have had appropriate training. Specifically, as a part of the IACUC review process, the investigator provides the following assurance: *"All individuals working with animals, animal tissues, or animal products on this protocol will be informed of relevant occupational health and safety issues prior to performing their duties."*

As a part of the IACUC review process, investigators are directed to an Occupational Health & Safety web link for assistance in this area. This link is found at (<https://cws.auburn.edu/OVPR/pm/compliance/iacuc/ohs>)

This aforementioned link provides information on such topics as zoonosis, allergies, physical injuries, and the reporting of incidents, injuries and/or hazardous agent exposure.

Safety Data Sheets (SDS) are available for all chemicals used in an animal facility. SDS are located conspicuously where the chemicals are stored, or are available through the Chemical Inventory System. Adherence to the Chemical Hygiene Plan developed by the Office of Risk Management and Safety is required.

Training is provided by employing units and/or by personnel from the Office of Risk Management and Safety on relevant hazards and control strategies pertaining to the individual's work assignments. Training modules are available on the online OHSP site (<https://cws.auburn.edu/OHS>) and is also tracked by the Office of Risk Management and Safety Animal Programs Specialist via this website.

- 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:

a. IACUC members are provided the following training opportunities:

- **Orientation session/training workshop for new members is conducted by the IACUC Chair.**
- **Reference materials discussed during the annual orientation/training include relevant institutional policies, federal regulations, and guidelines which are provided to new members electronically and/or in hardcopy if requested. Updates are provided to all members as information becomes available.**

Reference materials include: PHS Policy, the OLAW/ARENA IACUC Guidebook, the Animal Welfare Assurance, the Animal Welfare Act and Regulations, the Guide, the Ag Guide, and the AVMA Guidelines for Euthanasia.

- **Online training, such as AALAS and/or CITI, is provided.**
- **Attendance at national conferences or regional workshops.**
- **Participation in webinars.**

b. As a part of the IACUC review process, investigators are required to assure the following: "Individuals performing animal procedures on this protocol are or will be qualified to perform their particular animal related duties through training and/or experience (individuals will be supervised until adequate training has occurred). Training and/or experience must encompass the following: biology, handling, and care of the species; aseptic surgical methods and techniques (if applicable); the concept, availability, and use of research or testing methods that limit the use of animals or minimize distress including alternative methods; the proper use of anesthetics, analgesics, and tranquilizers (if applicable) and euthanasia; and procedures for reporting animal welfare concerns." Informative links regarding training resources have been provided for assistance as needed at <https://cws.auburn.edu/OVPR/pm/compliance/iacuc/training>

c. The above link then directs the investigator to a number of training opportunities as described below to facilitate their own training and training of personnel or students involved with the protocol. In addition, these items serve as the basis for training animal technicians and other personnel involved in animal care along with the training described in sections d and e below.

- **IACUC Training Requirements (addresses the following topics: Training Policy; Regulations, policies and laws; Administrative organization of the AU Animal Resources Program; IACUC; The "three R's" – Replacement, Reduction, Refinement; Identification and evaluation of alternatives to animal use; Mechanism for receipt and review of concerns involving the care and use of vertebrate animals at AU; Occupational Health and Safety Issues)**
- **Hands-on Workshops – Conducted by the Division of Laboratory Animal Health to address the care and use of mice, rats, and rabbits. The following topics are addressed: basic biology; handling and restraint; substance administration techniques; blood collection; anesthesia; and euthanasia**
- **AU Manual on Occupational Health and Safety in the Animal Care and Use Program**
- **PHS Assurance of Compliance – Auburn University's document assuring compliance with the PHS Policy on Humane Care and Use of Laboratory Animals is available upon request from the ORC**
- **Auburn University Procedures & Guidelines for Care & Use of Live Vertebrate Animals and AU Institutional Animal Care & Use Policies**

<https://cws.auburn.edu/OVPR/pm/compliance/iacuc/guidance> —developed by Auburn University to address such issues.

- **Templates for species-specific training are available at the Office of Research Compliance IACUC Administration website for over 20 species.**

e. One-on-one training is emphasized by research investigators and supervisors. Animal care personnel learning a new task are usually paired with an individual experienced in the task and are required to work in association with the trained individual until they have demonstrated their ability to perform the task safely and effectively.

f. Investigators and research staff are required to complete CITI Training Modules and enroll in the Occupational Health and Safety Program. Training completion and enrollment are verified electronically prior to IACUC Protocol and/or Modification approval.

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 2 — not 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. The report of the most recent evaluations (program review and facility inspection) is attached.

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. Jennifer L. Kerpelman, Interim Vice President for Research, Auburn University.**
 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. Jennifer L. Kerpelman, Interim Vice President for Research, Auburn University.**
 - 5. Any minority views filed by members of the IACUC
- B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
 - 1. Any serious or continuing noncompliance with the PHS Policy
 - 2. Any serious deviations from the provisions of the *Guide*
 - 3. Any suspension of an activity by the IACUC
- C. Reports filed under VI.A. and VI.B. above should include any minority views filed by members of the IACUC.

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official	
Name: Dr. Jennifer L. Kerpelman	
Title: Interim Vice President for Research	
Name of Institution: Auburn University	
Address: <i>(street, city, state, country, postal code)</i> (b) (4) Samford Hall Auburn University, AL 36849	
Phone: (b) (6)	Fax: (b) (6)
E-mail: kerpejl@auburn.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: (b) (6)	Date: 8/30/18

B. PHS Approving Official (to be completed by OLAW)	
Venita B. Thornton, DVM, MPH Senior Assurance Officer Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6700B Rockledge Drive Suite 2500 - MSC 6910 Bethesda, Maryland 20892 Email: thorntov@od.nih.gov	Venita B. Thornton -S Digitally signed by Venita B. Thornton -S Date: 2018.09.07 16:08:24 -04'00'
Signature:	Date: Sept. 7, 2018
Assurance Number: D16-00092 (A3152-01)	
Effective Date: Sept. 7, 2018	Expiration Date: August 31, 2022

VIII. Membership of the IACUC

Date: April 25, 2016			
Name of Institution: Auburn University			
Assurance Number: A3152-01			
IACUC Chairperson			
Name*: Dr. Timothy Braden			
Title*: Associate Professor, APP, CVM		Degree/Credentials*: PhD	
Address*: (street, city, state, zip code) (b) (4) Greene Hall Auburn University, AL 36849			
E-mail*: bradetd@auburn.edu			
Phone*: (b) (6)		Fax*: (b) (6)	
IACUC Roster			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
#1 Timothy Braden	PhD	Associate Professor, Anatomy, Physiology, and Pharmacology	IACUC Chairperson Scientist
#2 Patricia E. Rynders	DVM, MS	University Veterinarian; Director Lab Animal Health	Veterinarian
(b) (6)			Scientist
			Scientist
			Nonaffiliated
			Scientist
			Scientist
			Veterinarian
			Scientist
			Nonscientist
			Veterinarian
(b) (6)			Scientist
			Scientist

(b) (6)	
	Alternate Member for #2: Dr. Patricia Rynders
	Alternate Member for #'s 3,4,6,7,9,12
	Alternate Member for #'s 8,11
	Alternate Member for #5

* 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:

<i>Veterinarian</i>	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.
<i>Scientist</i>	practicing scientist experienced in research involving animals.
<i>Nonscientist</i>	member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).
<i>Nonaffiliated</i>	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.

Contact #1	
Name: Dr. Timothy Braden	
Title: IACUC Chair/Associate Professor, Anatomy, Physiology, and Pharmacology	
Phone: (b) (6)	E-mail: bradetd@auburn.edu

Contact #2	
Name: Niki L. Johnson	
Title: Director, Office of Research Compliance	
Phone: (b) (6)	E-mail: IACUCadmin@auburn.edu

X. Facility and Species Inventory

Date: 4/25/2018			
Name of Institution: Auburn University			
Assurance Number: A3152-01			
Laboratory, Unit, or Building*	Gross Square Feet [include service areas]	Species Housed	Approximate Average Daily Inventory
(b) (4)	N/A	Dogs	Intermittent Use
	See CVM-ClinSci #2	Horses	44 Horses
	52,372 sq. ft.	Cattle Goats Llamas Sheep Donkeys Alpacas Horses	139 Cattle, 21 Goats, 1 Llama, 7 Alpacas, 44 Horses
	4,841sq. ft.	Dogs Cats	Intermittent Use
	1,854 sq. ft.	Raptors	25
	28,079 sq. ft.	Dogs	94
	7,333 sq. ft.	Mice Rats Chickens Cats Rabbits	140 Mice, 2 Rats, 37 Cats
	874 sq. ft.	Fish	150
	800 sq. ft.	Chickens	Intermittent Use
	596 sq. ft.	Fish	1,500
	4,976 sq. ft.	Cattle Sheep Goats Horses Pigs	1001 Cattle, 5 Sheep, 1 Horse, 8 Pigs
	14,630 sq. ft.	Dogs Cats	34 Dogs, 144 Cats
	3,100 sq. ft.	Cattle	See CVM-Patho/VMA #1
	7,200 sq. ft.	Horses	88
	41,602 sq. ft. 500 acres	Cattle	308
	1,819 sq. ft.	Mice Rats Pigeons	99 Mice, 28 Rats, 7 Pigeons
	Outdoor housing/ no fixed structure	Amphibians & Reptiles	Intermittent Use
	3287 sq.ft.	Birds	275 Birds
	540 sq. ft.	Wild Mice	200 Mice

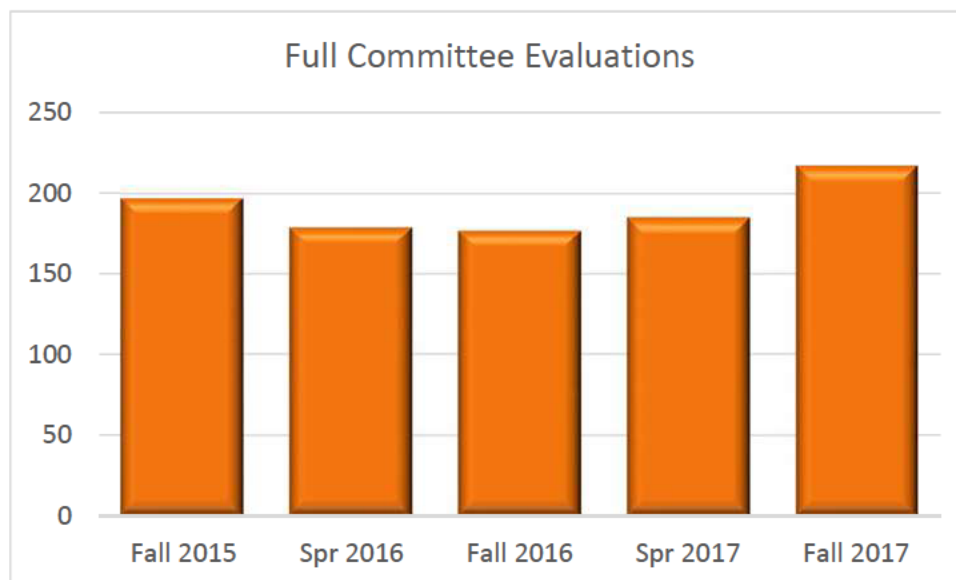
*Institutions may identify animal areas (buildings/rooms) by a number or symbol in this submission to OLAW. However, the name and location must be provided to OLAW upon request.

**Semiannual Report
Facilities Inspections and Program
Evaluation December 2017**

A. IACUC Membership and Activities

The 16 members (12 voting, 4 voting alternates) of the Institutional Animal Care and Use Committee (IACUC) are indicated on the attached list. The voting membership of sixteen meets all requirements set forth by federal or state laws and regulations. Membership for 2017-2018 includes 5 veterinarians, 1 faculty non-animal user, and 2 community members. Nine members of the 2017-2018 IACUC have IACUC-approved protocols.

The IACUC continues to meet regularly on the first and third Thursdays of each month (with only one meeting in December) to review protocols and to consider other business as necessary. Average member attendance was 10 for the reporting period. As of December 18, 2017, active approved protocols numbered 444 (313 research, 52 teaching, 59 production/maintenance, 20 demonstration). The average number of items reviewed at a meeting was 20. New submissions reviewed for the period June 16, 2017 through December 19, 2017, totaled 217. Protocol reviews at IACUC meetings included: 96 research, 19 teaching, 7 demonstration, 7 production/maintenance. Also reviewed during this period were 15 deferrals and 73 modifications. The designated member review process was used to review 8 protocols and 7 modifications; while 69 minor revisions (personnel changes not requiring review by the full IACUC) were approved administratively. Announced semiannual inspections of facilities were conducted in October 2017 – December 2017 (see section C below and attached tables).



Updates:

1. A new IACUC Manager is being actively recruited. Phone interviews have taken place, and on-site visits are being scheduled.
2. Turnover of (b) (6) resigned (Jan, 2018) and (b) (6) has transitioned into the position.
3. AAALAC site visit in late February, early March.
4. Significant modifications were made to the CVM Preventive Care Program for improvement.

B. Program Evaluations

Programmatic evaluation entails a review conducted in 3 different venues: (1) IACUC subcommittee consisting of the IACUC Chair, Director of Division of Laboratory Animal Health, University Veterinarian, College of Agriculture Program Veterinarian, the Director of the Office of Research Compliance (ORC), the Assistant Director ORC, and the Associate Director (Safety and Health) Risk Management and Safety; (2) full AU-IACUC; and (3) as a component of the facilities inspections. The reviews, guided by a checklist (see attached) of itemized consideration, identified one deficiency, and a few areas targeted for improvement. Clarifications of the deficiency, and improvement targets are provided in D below.

1. Animal Care, Health, and Husbandry

Animal care, health, and husbandry are evaluated as a component of our facilities inspections. Units where animals are housed continue to provide high-quality care and husbandry for their animals. Emergency veterinary care is available via the College of Veterinary Medicine (CVM) emergency services and clinical veterinarians are assigned to animal research units that are beyond 25-30 miles from the CVM.

2. Personnel Training

The IACUC and the ORC continued the commitment of offering assistance to PIs with regard to strengthening their training programs. Training has been documented from animal care staff, principal investigators, students, and other animal users.

Although CITI can provide much of the necessary training of personnel involved with the AU Animal Program, the IACUC believes that an increased level of coordination and oversight to produce a more formalized program would be necessary to formulate an excellent university-wide training effort. To initiate such an effort, the IACUC recommends the hiring of an IACUC manager. A search to fill this position is presently underway.

3. Occupational Health and Safety Program (OHSP)

OHSP continues to work with the IACUC in assessing Job Hazard Analyses (JHA) to determine OHS risks. The OHSP continues to develop protocols with respect

to particularly hazardous agents that are commonly utilized by researchers and other animal workers. As they become available, the standardized protocols are being incorporated into the IACUC protocol to insure effective communication of standards to investigators. Additionally, OHSP is working directly with some investigators to identify specific risks associated with their research activities, and develop appropriate safety protocols.

At present, all personnel identified on an animal care and use protocol are required to enroll in the OHSP as a stipulation of IACUC approval.

All animal units at Auburn University have Disaster Plans in place. Training of affected personnel at the specific units is being documented.

C. Facilities Inspections

During Oct-Dec, 2017, the IACUC conducted semiannual inspection for 83 facilities and procedural areas approved for animals used in research, teaching, demonstration, and production or maintenance. Each facility was evaluated for quality of animal care and use and for evidence of significant or minor deficiencies. Significant deficiencies are defined as those that are or may be a threat to animal health or safety, and/or to personnel health and safety. Results of the inspections and timelines for correction of deficiencies are summarized in the attached Table. These correction notices were communicated to the respective facility managers/representative at the time of inspection, and formal notifications were sent on January 24. The correction status and due date for correction completion are identified in the last column.

D. Clarifications of Deficiencies-NA

E. Informational items for the Institutional Official

1. Concerns, but not identified as deficiencies

a. Records and Reporting Requirements: b) Submission of annual report (containing the required information) to the United States Department of Agriculture.

Concern: The lack of the ability to track individual animals throughout our system means that our annual reports of animal usage are only estimates since they are based on the numbers provided by the animal users. Moreover, we have the possibility of "double counting" some animals as re-use cannot be completely eliminated. The implementation of a database capable of tracking individual animals will provide much greater accuracy in the numbers of animals reported to outside agencies. Until the database is implemented, we will try to capture some of this information from each protocol as it is approved thereby minimizing the chance of errors in the report.

b. #5b Veterinary Care – Preventive medicine/animal procurement and transportation:

Concern: The animal procurement process is an ongoing concern in the Animal Care and Use Program. Without a centralized animal ordering process, oversight by the facility managers, project veterinarians and principal investigators in the animal ordering process is perilous. This can result in animals being procured, acquired and/or bred outside of the approved channels of IACUC oversight.

Commentary: The OVPRED has committed to funding and coordinated faculty/staff reviews with a software vendor to obtain an IACUC management program. Interface with payment and procurement services and Research Compliance will facilitate congruency between protocol and animals numbers required for specific research. Additional modules of the Management Program are expected to be available to capture animal data and integrate with other capabilities of the Program.

c. **Aging Vivaria (not on checklist)**

Concern: A number of investigators are expressing frustration with the current biosecurity practices and the limitations of the vivaria to accommodate research programs which utilize large numbers of rodents. These practices and limitations are due to the design and infrastructure of the two existing facilities which were constructed 30 years ago prior to the emergence of transgenic rodent use in research.

Commentary: This situation is not currently causing the Animal Care and Use Program to fail at maintaining appropriate animal care. However, a significant amount of effort is currently expended to find ways to work around the limitations of the facilities without compromising animals care and welfare. Moreover, both vivaria lack sufficient redundancies to quickly manage equipment (e.g., washers, autoclaves) or to manage a biosecurity breach.

Long term consideration should be given to development of a state-of-the art animal housing facility.

d. **Animal Housing Creep/Sprawl (not on checklist)**

Concern: As investigators work with more diverse species, and require housing of those animals, the number of animal housing areas on campus seems to be increasing. Additionally, plans are being developed for establishing a rodent vivarium in the Pharmacy Research Building

Commentary: While this indicates a growing and expanding research enterprise, the number of facilities requiring semi-annual review, and continuing oversight could become unwieldy. The IACUC is considering implementing an expectation of consolidation of animal housing areas when possible to reduce the number of animal housing areas on campus.

Approval for Fall 2017 Semiannual IACUC Report

Timothy D. Braden
Associate Professor,
Anatomy, Physiology, & Pharmacology

(b) (6)



Aime Johnson
Associate Professor, Clinical Sciences

(b) (6)



Patricia E. Rynders
Director, Division of Laboratory Animal Health
University Veterinarian

(b) (6)



(b) (6)



Approval for Fall 2017 Semiannual IACUC Report
Alternate Members

(b) (6)

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