AUBURN UNIVERSITY

PROCEDURES AND GUIDELINES FOR THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

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ACRONYMS FOR COMMONLY USED TERMS

AAALAC	Association for Assessment and Accreditation of Laboratory Animal Care International
AAES	Alabama Agricultural Experiment Station
APHIS	Animal and Plant Health Inspection Service
APMF	Animal Production/Maintenance Form
ASRF	Animal Subjects Review Form
AU	Auburn University
VMA	American Veterinary Medical Association
AWA	Animal Welfare Act
CV	Clinical Veterinarian
CVM	College of Veterinary Medicine
DHHS	Department of Health and Human Services
DRMS	Department of Risk Management and Safety
DVM	Doctor of Veterinary Medicine
FDA	Food and Drug Administration
IACUC	Institutional Animal Care and Use Committee
IAV	Institutional Attending Veterinarian
INAD	Investigational New Animal Drug
IO	Institutional Official
NIH	National Institutes of Health
OHS	Occupational Health and Safety
OJI	On the Job Injury
OLAW	Office of Laboratory Animal Welfare
ORC	Office of Research Compliance
OUV	Office of the University Veterinarian
OVPR	Office of the Vice President for Research
PAM	Post Approval Monitoring
PV	Program Veterinarian
PHS	Public Health Service
PI	Principal Investigator
PRN	Protocol Review Number
UV	Unit Veterinarian
USDA	United States Department of Agriculture
VMD	Veterinariae medicinae doctor; Doctor of Veterinary Medicine
VPR	Vice President for Research

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INTRODUCTION

Auburn University is committed to the highest quality of animal care. Federal Regulations include: 1) The Animal Welfare Act (AWA, 7 USC 2131) and 2) The Health Research Extension Act of 1985 (PL 99-158, codified at 42 USC 289d), as amended. The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) implements the AWA through its *Animal Care Policy Manual*. (See also the Code of Federal Regulations Title 9, Chapter 1, Subchapter A, Parts 1, 2, and 3.) Standards also are set forth in the current versions of the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* ("Ag Guide," Federation of Animal Science Societies, 2010) and in the *Guide for the Care and Use of Laboratory Animals ("*Guide," National Research Council, 2011).

In 1985, the White House Office of Science and Technology published the *US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*. The United States Department of Health and Human Services (DHHS), Public Health Service (PHS) implements these nine basic principles, developed by the Interagency Research Animal Committee, in its *Policy on Humane Care and Use of Laboratory Animals*. Guidance is provided in the *Guide,* the *Ag Guide,* and other applicable guides*.* [1]

Animals covered by the cited federal legislation/regulations and *Guides* are presented below:

Animal Welfare Act/USDA Animal Care Policy: any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit or any other warm-blooded animal, which is being used, or is intended for use for research, teaching, testing, experimentation, or exhibition purposes or as a pet. It excludes birds, rats and mice bred for use in research, horses not used for research purposes, and other farm animals such as livestock and poultry used or intended for use as food or fiber or for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber.

[1] Other applicable guides include *Acceptable Field Methods in Mammalogy,* the *Guidelines for the Capture, Handling, and Care of Mammals, Guidelines of the American Society of Mammalogists for the Use of Wild Mammals in Research,* the *Guidelines for Use of Fishes in Field Research,* the *Guidelines for Use of Live Amphibians and Reptiles in Field Research,* and the *Guidelines to the Use of Wild Birds in Research*.

PHS Policy: applicable to any live, vertebrate animal (e.g., traditional laboratory animals, livestock, poultry, wildlife, aquatic animals) used in research, research training, experimentation, biological testing, and related activities wherein the activity is supported by the PHS and conducted at Auburn University, or at another institution as a consequence of the sub-granting or subcontracting of a PHS-conducted or supported activity by Auburn University. Applicability includes live vertebrate animals wherein the PHS does not support the activities but the animals are housed in the same facility as PHS-supported animal activities. PHS Policy requires that Auburn University's programs of animal care and use be based on the *Guide for the Care and Use of Laboratory Animals (2011)* and that they comply, as applicable, with USDA regulations and other federal statutes and regulations relating to animals. The PHS, through its Office for Laboratory Animal Welfare (OLAW), advises that the maintenance of uniform and consistent standards is an essential ingredient in the development and implementation of a quality animal care and use program. Only when the institution can document that the animal care and use program funded by a non-PHS source is entirely separate and distinct, physically and

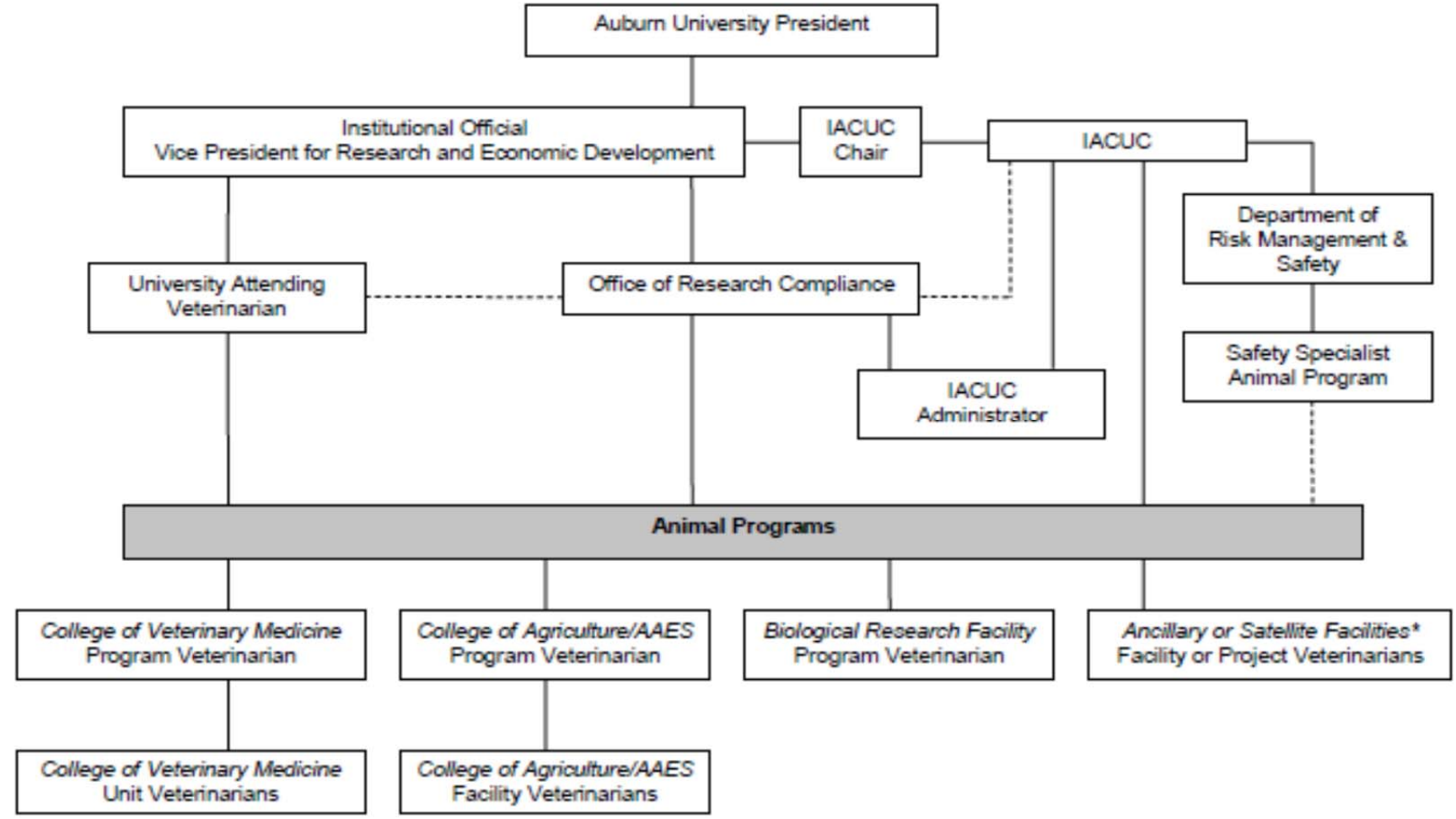
programmatically, from PHS-supported activities will OLAW consider its exclusion from the Auburn University Assurance of Compliance with PHS Policy on Humane Care and Use of Laboratory Animals.

Guide for the Care and Use of Agricultural Animals in Research and Teaching (2010): any warm-blooded vertebrate animal used in agricultural research or teaching for which the scientific objectives are to improve understanding of the animal's use in production agriculture and that may require a simulated or actual production agricultural setting consistent with the consideration of the animal's well-being.

The cited federal regulations/legislation and standards are the basis for this, the Auburn University *Policies for Care and Use of Live Vertebrate Animals.* The Auburn University (AU) Policy requires that the Institutional Animal Care and Use Committee (IACUC) oversee the use of all live vertebrate animals at AU, whether for research, instruction, demonstration, production, or maintenance purposes and whether housed in facilities at Auburn or elsewhere. The goal is to apply a single standard of high-quality animal care to the benefit of overall animal health and well-being.

1. ADMINISTRATIVE ORGANIZATION OF THE AUBURN UNIVERSITY ANIMAL CARE AND USE PROGRAM

The organizational structure of the AU Animal Care and Use Program is shown in Figure 1.



*Non AAALAC Accredited Facilities

2. RESPONSIBLE PARTIES

2.1 PROJECT VETERINARIAN

Each approved protocol has an associated Project Veterinarian. By signing the protocol submission form or modification form, the Project Veterinarian agrees to assume the following responsibilities:

a) Oversee the adequacy of all aspects of animal care and use for the approved protocol (i.e., preventative medicine; surveillance, diagnosis, treatment and control of disease, including zoonosis control; management of protocol-associated disease, disability, or other sequelae; anesthesia and analgesia; surgery and post-surgical care; assessment of animal well-being; euthanasia; hazard containment; husbandry and nutrition; and sanitation practices).
b) Provide advice and assistance to project personnel to ensure that the humane needs of protocol/project animals are met and are compatible with the requirements of the protocol.

Some of the responsibilities of the Project Veterinarian may be delegated to another individual with appropriate training e.g., a veterinary technician. When responsibility is delegated, a mechanism for direct and frequent communication must be established to ensure that timely and accurate information is conveyed to the Project Veterinarian concerning problems with animal health, behavior and well-being. The Project Veterinarian must have direct training and/or experience in the care and management of the species being attended.
A Principal Investigator who is a DVM, VMD or equivalent may serve as the Project Veterinarian on his/her own research projects, contingent upon documentation of relevant experience in clinical veterinary medicine (e.g., with the animals species to be used) and availability of appropriate oversight. The attending veterinarian, project or unit veterinarian (IAV, PV, or UV) have the final authority on issues involving animal health and well-being.

2.2 INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) CHAIRPERSON

The responsibilities of the IACUC Chair shall include the following:

a) Coordinate and oversee all functions and activities of the IACUC.
b) Submit annual reports, through the Institutional Official, to OLAW.
c) Convene and conduct the IACUC meetings which are normally scheduled for the first and third Thursday of each month. Other meetings may be called by the IACUC Chair on an ad hoc basis. In the event that the Chair is unable to convene a meeting, the Chair shall appoint an Interim Chair to do so.
d) Assignment of specific animal use forms to IACUC Committee members with assistance from ORC/IACUC Administration.
e) Represent the IACUC in responses to faculty questions or inquiries concerning animal use.

f) Assignment of IACUC members to facilities inspections with assistance from ORC/IACUC Administration.
g) Preparation of semi-annual reports with assistance from ORC/IACUC Administration.
h) In collaboration with the Director of ORC and the IAV, assure that use of all animals by AU complies with the Animal Welfare Act, the Public Health Service Policy, and other relevant and applicable animal use guides.

2.3 IACUC ADMINISTRATION

The ORC, a unit of the OVPR, will provide administrative support and assistance to the IACUC. Responsibilities for ORC's IACUC Administration shall be provided as outlined below.

2.3.1 Policy and Procedures Manual

The ORC shall, as directed by the IACUC, maintain and distribute the official IACUC Policies that are found on the AU website at: https://cws.auburn.edu/vpr/compliance/animalresources/?Policies
The IACUC Procedures Manual is also posted on the AU website at:
https://cws.auburn.edu/vpr/ConMan/ConMan_FileDownload.aspx?filename=AU%20Policy%20Manual%20Sept%201,%202010%20Draft.pdf

2.3.2 Meetings/Minutes

The IACUC Administration shall:

a) Schedule, attend, and take minutes for all IACUC meetings.
b) Prepare and distribute the meeting agenda for each scheduled meeting of the IACUC.

2.3.3 Semi-annual Inspection of Animal Facilities

The IACUC Administration shall:

a) Prepare, under IACUC Chair's direction, the inspection assignment roster and forms.
b) Distribute and collect forms.
c) Type and assemble draft and final reports.
d) Follow-up for correction/modification.

2.3.4 Protocols/Protocol Modification Requests

The IACUC Administration shall:

a) Receive, log, and review (preliminary) all protocols and protocol modification requests.
b) Distribute protocols to members of the IACUC prior to the next scheduled meeting.
c) Provide advice and assistance to investigators in the preparation of protocols and modification requests.
d) Sign protocols and protocol modification requests approved by the IACUC under the direction of the IACUC Chair (or Chair's designated representative).

2.3.5 Correspondence

The IACUC Administration shall be responsible, under the direction of the IACUC Chair (or Chair's authorized representative), for preparing appropriate correspondence for the following actions:

a) Protocol approvals.
b) Protocol denials.
c) Requests for protocol clarification/revisions.
d) Protocol expiration notices.
e) Protocol annual review notices.
f) Semi-annual review reports.
g) Certification forms for occupational safety and health and personnel training.
h) Miscellaneous.

2.3.6 Records

The IACUC Administration shall maintain the following records:

a) Current and terminated protocol files, including all related significant correspondence and/or findings.
b) Minutes of the IACUC meetings.
c) Semi-annual review reports.
d) Annual reports to USDA and OLAW.
e) Certification forms for personnel training.

2.3.7 Support for the Director of ORC

The Director of ORC works directly with the IACUC on all matters involving IACUC Administration and compliance with animal care and use policies and regulations. Further, the ORC shall have available publications that will assist the investigator to perform the project in accordance with applicable federal and state regulations and the policy of AU.

2.4 PRINCIPAL INVESTIGATOR

The Principal Investigator (PI) has primary responsibility for the following:

a) Prepare and submit accurate and complete protocol review forms (Animal Subjects Review Form or Animal Production/Maintenance Form) for approval by the IACUC of all research, teaching, demonstration, production, and maintenance activities involving live vertebrate animals carried out by AU personnel using AU facilities and/or equipment or by visiting investigators conducted in AU facilities.
b) Ensure that all projects are carried out in accordance with the approved protocol.
c) Promptly advise, using a Protocol Modification Request Form, the IACUC of any changes necessary to conduct the project and receiving approval prior to implementing such changes.
d) Ensure that all individuals performing animal procedures are qualified to perform their particular animal-related duties through training and/or experience. The provision of training must be documented on a training certification form. Such documentation must be maintained in the PI's files and a copy submitted to and approved by the ORC prior to final approval of protocols and other submissions to the IACUC. The ORC and OUV will provide training materials and guidance.
e) Ensure that all individuals engaged in activities involving an approved project are fully informed of relevant health and safety issues and, where appropriate, receive training to minimize or eliminate such hazards.
f) Abide by all federal, state, local and AU regulations and policies concerning the use of animals.
g) Allow veterinary oversight/assistance to all project animals showing signs of pain or distress.
h) Promptly report to the Department of Risk Management and Safety in accordance with AU policies and procedures, any personal injuries or accidents that occur during the course of the project. For guidance on reportable incidents, accidents, or injuries and the reporting process see Section 13 of this Manual.
i) Provide annual and final reports (using the approved form) to ORC on the project status and responding to inquiries about project status.

All outstanding documentation (e.g. annual review, final report, personnel training certification) pertaining to any protocol in the PI's name must be received and approved by the ORC prior to final IACUC approval of new animal use forms or modifications to approved protocols.
Any Auburn University faculty member or unit director/supervisor (e.g., AAES Outlying Unit, Swine Research and Education Complex) is eligible, with the concurrence of the appropriate Dean or Department Head/Chair, to serve as the PI. For Resident and Student projects, a faculty member must be designated to serve as the PI. This faculty member will have ultimate responsibility for the project and will serve as advisor to the Resident/Student. The faculty member's advisory capacity should be appropriately reflected on the protocol submission form.

2.5 DEPARTMENT HEADS/CHAIRPERSONS, RESEARCH INSTITUTE AND CENTER DIRECTORS

The chief administrator of each Department, Research Institute, Center or Unit:

a) Is responsible for overseeing faculty, staff, and students working with animals in his/her overall area of jurisdiction. It should be emphasized that this responsibility is in no way altered by the duties of the IACUC and the ORC.
b) Must ensure that prior to animal procurement (order, capture, transfer, or use), each PI using animals for any activity files the appropriate protocol review form(s) and receives IACUC approval for the activity.
c) Is mutually responsible, with the PI, for informing the IACUC of deviations from the approved protocol and reporting accidents or incidents involving such animals to the persons identified in this Manual.
d) Should ensure that all faculty, staff, and students have received instruction regarding the use, care, and handling of animals to be used in the approved activity.
e) Must determine that appropriate facilities and equipment are available for the approved activity involving animals.
f) Should ensure that all faculty, staff, and students provide appropriate notification and file the appropriate forms for any incident/accident that occurs while participating in the approved activity.

2.6 DEAN

The Dean of each unit involved in activities requiring the use of vertebrate animals is responsible for ensuring that all departments have access to the resources necessary to ensure that the activity can be conducted in accordance with the approved protocol. Further, the Dean shall ensure that resources are available to protect the health and safety of both animals used in approved protocols and the faculty, staff, and students engaged in the activity.

2.7 INSTITUTIONAL OFFICIAL

The Institutional Official (IO) has the authority to enforce AU compliance with applicable animal care and use policies, guidelines and regulations. The IO reviews semiannual reports (submitted by the IACUC) assessing AU's Animal Care and Use Program and facilities. The IO ensures that stated deficiencies are addressed according to the schedule for correction of deficiencies developed by the IACUC. If the institution is unable to meet the schedule, the IACUC, through the IO, must inform Animal and Plant Health Inspection Service (APHIS) officials within fifteen working days of the lapsed deadline. If the activity is federally funded, the federal sponsor also must be informed. The IO is the individual who signs, and has the authority to sign, all commitments on behalf of AU that the requirements of the PHS *Policy on Humane Care and Use of Animals* will be met in accordance with the AU's Assurance. The IO is further responsible for signing all institutional reports required by federal regulatory agencies including, but not limited to, the OLAW and the APHIS. The Associate Provost and Vice President for Research is AU's designated IO.

3. AUBURN UNIVERSITY INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) PROCEDURES AND GUIDELINES

3.1. IACUC MEMBERSHIP

The IACUC consists of at least fifteen members. The following shall serve continuing appointments: the Director of the Office of Research Compliance (ORC) - non-voting; University Veterinarian as the Institutional Attending Veterinarian (IAV); the Director of the Division of Laboratory Animal Health; the Director responsible for Outlying Units, Alabama Agricultural Experiment Station; and the Risk Management and Safety representative (non-voting) The following shall serve three-year rotating appointments: at least seven faculty members representative of animal-user disciplines (scientists, animal-users); at least one faculty member (non-animal user) representing non-scientific disciplines; and at least two members from the community who have no other current affiliation with Auburn University (AU) and whose immediate families are not affiliated with AU. Rotating membership vacancies shall be filled for compliance with the regulations and, to the extent possible, with similarly qualified individuals. In addition to the qualifications noted above, one committee member must be a veterinarian. Alternate members and Vice-Chair(s) may be appointed as needed. The chair of the committee shall be a faculty appointment with at least one year of experience as a member of the AU IACUC.

The IO maintains the official IACUC charter and revises the charter as appropriate to comply with regulations and fulfill the needs of the IACUC. The AU President selects and appoints all members, all alternate members, the Chair and the Vice-Chair(s) in consultation with the IACUC. The President may delegate this authority to the IO if the delegation is specific and in writing. The nomination/appointment process for faculty representation is accomplished using a campus-wide process open to all members of the AU faculty. In consultation with the IACUC Chair, the IO may remove IACUC members that do not

fulfill IACUC Member Responsibilities as defined in section 3.2.

Membership of AU's IACUC meets the compositional requirements and recommendations set forth in the Public Health Service (PHS) Policy, the Animal Welfare Act (AWA), and the *Guide for the Care and Use of Agricultural Animals in Research and Teaching*, namely at least one: DVM, VMD or equivalent with training or experience in laboratory animal science and medicine who has direct or delegated program responsibility for activities involving animals; practicing scientist experienced in research involving animals; scientist with experience in agricultural teaching and/or research using agricultural animals; animal, dairy or poultry scientist with training and experience in the management of agricultural animals; veterinarian with training and experience in agricultural animal medicine who is licensed to practice (or eligible for licensure); individual whose primary concerns are in a nonscientific area; individual not affiliated with the institution and not a laboratory animal user, who represents general community interests in the proper care and treatment of animals.

3.2. IACUC Member Responsibilities

a) Uphold the precepts of humane and compassionate animal care and use in research, teaching and outreach through IACUC committee participation.

All members are expected to:

(1) Uphold, support, and encourage the principles of ethical animal research and animal use.

(2) Represent the IACUC in a positive, professional manner.

(3) Serve as a representative/liaison for those with similar research programs.

(4) Attend/complete IACUC member training (initial and continuing).

Primary Members are expected to:

(1) Notify the ORC of attendance/absence at least one week prior to the regularly scheduled meeting.

(2) Attend all regularly scheduled meetings.

(3) Review protocols as assigned by the IACUC chair.

(4) Participate in sufficient inspections to complete semi-annual review of all facilities/programs as assigned by the IACUC chair.

(5) Serve on the Semi-annual Program Review Subcommittee as appointed by the IACUC chair.

(6) Serve on special subcommittees (animal welfare, special investigations, compliance, policy, etc.) as appointed by the IACUC chair.

Alternate Members are expected to:

(1) Notify the ORC of attendance/absence at least one week prior to the regularly scheduled meeting.

(2) Attend regularly scheduled meetings on an ad hoc basis as called on by the IACUC chair.

(3) Review protocols as assigned by the IACUC chair.

(4) Participate in sufficient inspections to complete semi-annual review of all facilities/programs as assigned by the IACUC chair.

Non-Voting Members are expected to:

(1) Notify the ORC of attendance/absence at least one week prior to the regularly scheduled meeting.

(2) Provide input or expertise as requested by the IACUC Chair.

(3) Serve on at least 1 Semi-annual Program Review Subcommittee as appointed by the IACUC Chair.

(4) Represent the interest of the office, department, or unit of their employment.

b) Remain aware of real or perceived Conflicts of Interest that could impair the integrity of the IACUC process and/or the animal care and use program.

(1) Member roles where conflict may occur include but are not limited to: PI, Co-I, Sponsor, directly supervises PI or is supervised by the PI, member of PI's family, listed on grant, receives funding from project, financial interest in sponsor.

(2) Member responsibilities for conflicts include:

i. Notification to the IACUC chair and/or ORC Director prior to the meeting.

ii. Declaration of conflict at the IACUC meeting.

iii. Abstention from voting on the protocol/action item.

iv. Exiting the meeting room during IACUC discussion and voting on the protocol/action item.

c) Remain aware of real or potential Confidentiality conflicts that could impair the integrity of the IACUC process and or the animal care and use program.

(1) Members must not disclose Confidential or Proprietary Information (protocol or investigator-specific information) to any non-IACUC member.

(2) Members must not discuss, communicate or disclose any details of IACUC business (e.g. protocol reviews, non-compliance discussions, subcommittee investigations or review, etc.) to a third party without consent of the IACUC Chair; the Institutional Official; or General Counsel.

Failure to fulfill the expectations and responsibilities required of IACUC membership may result in a member being removed from the IACUC by the IO in consultation with the IACUC Chair. Other institutional sanctions may apply.

3.3. *MEETING SCHEDULE*

Meetings of IACUC are generally held on the first and third Thursdays of each month. Regularly scheduled meetings that fall on a University holiday shall not ordinarily be rescheduled. The IACUC Chair may convene additional meetings as needed.

3.4. ANIMALS COVERED BY IACUC PROTOCOLS

The AU Policy requires that the use of all live vertebrate animals for research, instruction, demonstration, production, or maintenance purposes by AU, whether the animals are located in facilities at Auburn or elsewhere, or by visiting investigators in AU facilities be approved by the IACUC prior to animal procurement (order, capture, transfer, and use). Investigators/instructors who wish to use live vertebrate animals in one or more of the activities listed above are required to submit an animal use form for IACUC review. The timing of submission to the IACUC may depend on the funding agency (e.g., if IACUC approval is required prior to scientific peer review) or on the investigator's/ instructor's preference; notably, approval by the IACUC is a prerequisite not only for animal usage but also for establishment of an account for a funded project involving animal usage. The scope of work for funded projects will be reviewed and all activities involving live animal usage must be included in and consistent with approved IACUC Protocol(s).To avoid delay in receipt of an account, investigators may prefer to submit an animal use form to the IACUC office well in advance of knowing the outcome of a proposal relative to funding. Two animal use forms are available for submission. The choice of which form to use is determined as follows:

a) To submit a protocol describing research, teaching, or demonstration activities one should submit the "Animal Subjects Review Form (ASRF)." There is a place on this form to indicate which type of activity is being described (e.g., research, teaching or demonstration).
b) To submit a protocol describing only the production and/or maintenance of animals (e.g., those animals being produced and/or maintained for the purposes of being used in various research or teaching activities), one should submit the form entitled "Animal Production/Maintenance Facility Standard Operating Procedures (APMF)."

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. On such protocols it is necessary and permissible to check the activity as both research and teaching. Furthermore, if animals are being produced and/or maintained solely for a particular research or teaching project, then one may choose to submit the ASRF and check the activity as both production/maintenance and research or production/maintenance and teaching, whichever is applicable.

3.5. REVIEW AND ACTION PERTAINING TO PROPOSED OR ONGOING ACTIVITIES RELATED TO CARE AND USE OF ANIMALS

3.5.1. Submission and Processing of ASRF/APMF (Protocol)

a) Forms are available to users on the ORC IACUC Administration website https://cws.auburn.edu/vpr/compliance/animalresources/?Forms .
b) Protocols can be mailed, emailed or hand-delivered to the ORC, (115 Ramsay Hall Basement). One original form with all signatures should be submitted to the ORC. Additional information is provided on the website to assist PI's with protocol submissions. https://cws.auburn.edu/vpr/compliance/animalresources/?IACUC_Submission .
c) Protocols received at least seven days prior to a scheduled meeting date (i.e., by 11:30 A.M. on Thursday of the week prior to a scheduled Thursday afternoon meeting) will be placed on the agenda. Protocols received after the aforementioned deadline may be deferred to the following meeting.
d) A primary and a secondary reviewer of each protocol are assigned by the IACUC Chair with assistance from ORC/IACUC Administration. 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, co-investigator, faculty advisor, or departmental chairperson; on which the reviewer is a veterinarian associated with the protocol; or if the reviewer otherwise has a conflict of interest as determined by the IACUC.
e) Meeting agendas include review of minutes of prior meeting, list of protocols to be reviewed, and other business (reports, announcements, etc.).
f) Committee members receive minutes, agendas and protocols two to seven days in advance of an IACUC meeting.

3.5.2 Criteria for Granting IACUC Approval of a Protocol

Criteria are presented below. Additional information may be found in the AU IACUC Policies that are found on the AU website: https://cws.auburn.edu/vpr/compliance/animalresources/?Policies .

• Activities	Must be in accordance with United States Department of Agriculture (USDA) Regulations/PHS Policy.
• 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 withholding is scientifically justified with special approval by the IACUC. Project veterinarian must be involved in planning. Use of paralytics without anesthesia is prohibited. Animals with

	chronic/severe unrelievable pain will be euthanized.
• Humane Endpoints	Discomfort to animals must be limited to that which is unavoidable for the conduct of scientifically valuable research, and that unrelieved pain and distress will only continue for the duration necessary to accomplish the scientific objectives. Humane endpoint criteria must be addressed on the IACUC protocol form when it is anticipated that an animal will endure painful or distressful conditions.
• 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 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 veterinarian or scientist with appropriate expertise.
• Alternatives	There must be considered alternatives to painful procedures; also must document consideration of alternatives if animals experience or may be expected to experience pain or suffering
• Rationale and Methods	Must provide written narrative of methods/sources including the years searched and keywords searched.
• Duplication	Must provide assurance that activities do not unnecessarily duplicate previous efforts.
• Qualifications	Personnel must be appropriately qualified.
• Hazardous Agents	Use of hazardous agents in animals may require approval of the appropriate institutional committee. The Department of Risk Management and Safety (844-4870) may be contacted for specific information
• Deviations from Requirements	Must be justified for scientific reasons, in writing.
• Unexpected Outcomes (Guide, 2011)	Unexpected outcomes such as new phenotypes from genetically modified animals (GMA's) or other unexpected

results must be closely monitored. The IACUC protocol must contain how unanticipated results will bedetected, managed and reported in a manner to ensure the animals' health and well-being. A large number of deaths in a litter produced by crossing GMA's would be considered an unexpected outcome. When such an event occurs, it must be reported to the IACUC chair by memo or e-mail for subsequent reporting to the IACUC and appending to the protocol. The written communication must contain how subsequent activities in the experimental protocol will be modified to ensure animals' health and well-being.

3.5.3 Assessment of Scientific Design in Animal Care and Use Protocols

Review and evaluation of study design may be necessary to assess one or more of the following: (Note: the following are presented as examples; additional IACUC justifications for scientific review also may be employed).

a) Is the study, as designed, likely to yield results that justify the use of animals?
b) Could a change in study design reduce the numbers of animals that are used? For example, could animals be utilized as their own controls prior to introducing the study variable(s)? Alternatively, is the sample size sufficient to answer the question being addressed in the research?
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?

3.5.4 Procedures for IACUC Meetings Convened for Consideration of Protocols

a) A quorum of voting members is required to convene a meeting and approve protocols.
b) Members should review all protocols before the meeting and be prepared to discuss each protocol and vote (if not excused in accordance with provisions and stipulations found elsewhere in this manual). Anticipated absences should be reported as soon as possible to the ORC.
c) Members of the IACUC who are listed as either PI or co-investigator on a protocol being discussed by the IACUC may excuse themselves from the room during the reviewers' presentation. The PI on a protocol under consideration must be absent from the room when the discussion and vote are conducted on the protocol.

d) 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.

e) After the primary reviewer presents a protocol, a motion is then made for approval, to require minor clarifications/revisions (to secure approval), for deferral, or for rejection of the protocol. 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 majority vote of the total number of committee members present and eligible to vote.

   If the motion is to require minor clarifications/revisions (to secure approval), the motion may incorporate a second portion for either DMR or FCR. Following any discussion, a verbal vote is taken. A unanimous vote is required for subsequent DMR. If DMR is approved, the IACUC Chair will appoint one or more voting members of the IACUC to conduct the review.

   If electing to use DMR, all members, including the members not present at the meeting, must have the revised research protocol available to them and must have the opportunity to call for FCR. A DMR may be conducted only if all members of the committee have had the opportunity to request FCR and none have done so.

f) A committee member can request a written or roll call vote instead of a verbal vote.

g) If the protocol is approved as submitted, the IACUC Chair or designee will sign the original form, and ORC/IACUC Administration will assign a protocol review number (PRN).

h) 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 Chair or his/her designee.

i) A protocol may be deferred if the IACUC deems that the PI must address major clarifications/revisions and the protocol, therefore, must be resubmitted for review by the IACUC. Examples of major changes include but are not limited to conduct of invasive procedures, change in species or number of animals, and change~~s~~ in experimental design. A more complete listing of significant changes is included in the Policy Statements located in the appendix.

j) Members who are designated as the PI or Co-PI cannot offer a motion or vote on their own protocols or protocols on which they are the Project Veterinarian, project personnel, or otherwise have a conflict of interest as determined by the IACUC.

k) A PI may request and receive approval from the IACUC Chair in advance of the relevant IACUC meeting to present his/her protocol to the Committee prior to the protocol being presented by the Primary or Secondary Reviewer.

3.5.5 Reporting of Committee's Action to PI

ORC/IACUC Administration will provide written communication to the PI regarding the committee's action on his/her protocol.

3.5.6 Designated-Member Review

A designated-member review may be conducted under the following circumstances: (1) when the PI submits a written request/justification to the IACUC Chair which details and documents an extenuating circumstance (e.g., impending sponsor deadline or sponsor required changes in numbers of animals, addition of procedures or methodologies, or changes in the amounts or frequency of collecting blood, tissues, urine or other specimens wherein the deadline date for IACUC approval precedes the next regularly scheduled IACUC meeting).

In circumstances presented above, the decision to conduct a review will be made by the IACUC Chair (or his/her designee) with assistance from ORC/IACUC Administration. All IACUC members are provided a copy or summary of the protocol. Members are given a specified period of time (e.g., 2-3 working days) to request the protocol undergo review by the full IACUC. If review by the full IACUC is not requested by the specified time, then the protocol may be assigned for designated review by 1-3 members of the IACUC. The individual(s) assigned to the designated review committee are appointed by the IACUC Chair (including a subcommittee chair designated at the time of the appointment) who are without conflict of interest and do not hold an appointment in the departmental/unit affiliation(s) of the PI or co-investigators. Procedures for consideration of protocols include the relevant items presented in Section 3. 3. 4. The options for subcommittee recommendations are approval, require minor clarifications/revisions (to secure approval), or review at a convened meeting of the IACUC.

The recommendations of the subcommittee are shared electronically or by other means with the other members of the IACUC. If any member of the IACUC requests that a protocol be reviewed at a convened meeting of the IACUC, then the protocol is deferred until such time that a meeting can be convened or the next regularly scheduled IACUC meeting.

3.5.7 Duration of Approval

A protocol will be approved for up to three years. Continuation of the project/activities beyond three years requires submittal of a new ASRF or APMF for review by the IACUC. Notifications of impending expiration are sent to PIs and the relevant department/unit head at least 90 days in advance of the expiration date. Second and third notices are sent 60days and 30 days respectively, in advance of the expiration date. Once a protocol has expired, a notification of expiration is sent to the PI; co-investigator(s); lead graduate student/resident; Project Veterinarian; and relevant department/unit head; and copies of the notification are filed in the ORC.

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.

3.5.8 Requests for Modifications

All modifications to an approved protocol requested by the PI must be approved by the IACUC Chair prior to being implemented. A Protocol Modification Form can be obtained on-line from the aforementioned website. At the Chair's discretion, the proposed modification may be referred to IACUC for full-committee review or to a subcommittee of IACUC as a designated-member review provided the modification meets the requirements of Section 3.4.6. A copy of the approved modification request must be sent to the PI; co-investigator(s); lead graduate student/resident; Project Veterinarian; and relevant department/unit head; and be on file in the ORC.

In accordance with Office of Laboratory Animal Welfare (OLAW) and USDA, the IACUC classifies change of personnel on a protocol, excluding the PI, as minor. Following guidance from both OLAW and USDA, minor personnel modifications may be reviewed and approved administratively by the IACUC Chair or their designee provided that all such personnel are appropriately identified, adequately trained and qualified, enrolled in the occupational health and safety program, and meet other criteria as required by the IACUC.

3.5.9 Annual Review of Approved Protocols

a) Annual Reviews of protocols are conducted during October and November of each year. The ORC will send a reminder and the reporting form to PI's at least four weeks prior to the due date. The Annual Review Report form also includes the information needed for the annual USDA report.
b) All changes to the approved protocol must be reported, and, if significant, will be reviewed by the IACUC at a convened meeting. Minor personnel changes will be reviewed administratively as described in 3.5.8.
c) Failure to submit an annual review report may result in closure of the protocol and suspension of animal activities being carried out.

3.5.10 Distribution of Approved Protocols

Upon final approval, a PRN will be assigned to the protocol and the final approved version with all required signatures will be provided electronically via email to the PI. The ORC which maintains all official files of the IACUC, will retain the original. In addition, the following will be copied on the email to the PI: co-investigator(s); lead graduate student/resident; associated veterinarians; relevant department/unit head; the IAV, and other appropriate personnel.

3.5.11 Records

Official records of the IACUC shall be maintained by the ORC in accordance with federal and state regulations. Retention time shall be not less than three years past project end date. The State of Alabama and the federal regulatory agencies prescribe record retention periods. Records will be kept for the longer (federal or state) period of time before being destroyed or discarded.

3.5.12 Additional Actions and Sanctions for Failure to Follow an Approved Protocol

See Section 9 for Suspension of Animal Activities. As with any policy of AU, sanctions shall apply for non-compliance with this animal care and use policy. The appropriate Dean (or designated Associate Dean), Director, or Vice President shall utilize the standard disciplinary procedures set forth as a condition of each person's employment with AU. Other sanctions may be imposed in accordance with sponsor requirements and obligations or other applicable AU policies.

3.5.13 Appeal

If a PI disagrees with the revisions required by the IACUC to obtain approval of a protocol, or with the disapproval of a protocol, the investigator may, with the concurrence of the appropriate Dean/Department Head or Chair, submit a written appeal to the IACUC stating the reasons for objecting to the required changes and/or proposing an alternative resolution. The PI may also request a meeting with the IACUC to discuss the differences of opinion and resolve them.
If no satisfactory resolution is reached, the PI may submit a written appeal to the Associate Provost and Vice President for Research (VPR) requesting assistance. The VPR will attempt to mediate a solution to the situation. However, neither the VPR nor any other administrative official can override a disapproval by IACUC.

4. POST-APPROVAL MONITORING OF IACUC PROTOCOLS FOR COMPLIANCE

4.1 DEFINITION

Post-approval monitoring (PAM) encompasses all university activities designed to assure the institution that investigators and others involved in conducting and supporting research do not stray or drift from approved procedures and accepted practices.

EXAMPLES OF PROTOCOL DRIFT AND NONCOMPLIANCE

a) Unapproved increases in number of animals used.
b) Change of species without authorization by IACUC.
c) Use of animals in non-approved sites.
d) Lack of adherence to humane endpoints.

e) Changes in approved method of euthanasia.
f) Changes in approved routes of administration of medications or test substances.
g) Outdated drugs.
h) Improper housing.
i) Failure to properly train new hires.

4.2 OBJECTIVE FOR PAM

The primary objective of post-approval monitoring (PAM) is to assure "high-quality research, proper animal care, and communication between researchers, veterinarians, regulatory agencies, and the IACUC" (*The IACUC Handbook*, 2nd Edition, p. 572).

4.3 RESPONSIBLE PARTIES FOR PAM

Individuals involved with PAM include the Principal Investigator, veterinarians, research support staff, animal care staff, facilities managers, compliance/safety officers, and IACUC members. The process of monitoring includes observations by facility staff, walk-through of facilities, and review of charts/animal records.

4.4 CURRENT PAM ACTIVITIES

<u>Self-Reporting</u>

1. PIs Reporting Animal Issues to IACUC, UV, Vets
2. Facility Managers Reporting Animal Issues to IACUC, UV, Vets
3. Animal Welfare Concerns Reporting Signage
4. Investigation of Animal Welfare Concerns
5. Veterinary Observation
6. Animal Care Staff Observation
7. Laboratory Inspections:
    a. General Lab Safety Inspection
    b. Chemical Inventory Inspection
    c. Radiation Safety Inspection – At least annual with survey to test for contamination

<u>IACUC</u>

1. Continuing Protocol Reviews:
    a. Annual Reports
    b. Three Year *de novo* Review
2. Semiannual IACUC Facility Inspections
3. Semiannual Program Review

External Compliance Reviews/Oversight

1. Annual USDA Inspections, Annual USDA Reports, and Self-Reporting of Issues
2. Annual Reports, Self-Reporting of Issues, and oversight from Office of Laboratory Animal Welfare
3. Triennial AAALAC Site visit with Annual Reports

5. INSPECTION OF ANIMAL FACILITIES

5.1 ANIMAL FACILITY (DEFINITION)

An animal facility is defined as any place in which animals subject to approval of the Auburn University (AU) Institutional Animal Care and Use Committee (IACUC) are housed for greater than twelve consecutive hours exclusive of facilities located outside the state of Alabama.

5.2 INSPECTION SUBCOMMITTEE APPOINTMENT

The Chair of the IACUC with assistance from the ORC/IACUC Administration will appoint an appropriate subcommittee of at least two IACUC members to inspect assigned facilities. A member of each subcommittee will be responsible for contacting the individual responsible for the facility to be inspected and set a time for the inspection. No member of the IACUC shall inspect a facility for which they are directly responsible. All inspections must be completed within four weeks after assignment and written reports forwarded to the Director of the Office of Research Compliance (ORC) or the Chair of IACUC no later than two weeks after an inspection is completed.

5.3 FACILITIES INSPECTION REPORTING

The Director of ORC and/or the Chair of IACUC will prepare a report summarizing the inspection of facilities (from subcommittee reports) and will have it signed by the IACUC before submitting it to the Vice President for Research (VPR). Copies of the report will be maintained in the ORC.

5.4 DISSEMINATION OF FINDINGS

The Chair of the IACUC will notify the individual responsible for a facility regarding the findings of an inspection. If deficiencies are identified, a timetable to initiate corrective action will be included with the notification. Except for housekeeping items which should be corrected immediately, the target date for correction of minor deficiencies will usually be six months from date of citation or by the next IACUC facility inspection, whichever is sooner. Significant deficiencies (defined as those that are or may be a threat to animal health or safety) will require immediate corrective action. The urgency of the corrective action for a significant deficiency should be cited in the timetable to initiate the action. The responsible individual must respond in writing to the ORC within thirty days to define action taken to correct significant deficiencies. The IACUC Chair is responsible for assessing the corrective actions for significant

deficiencies, and the next inspection team is responsible for assessing the corrective actions for minor deficiencies. Visual observation of corrective actions taken on significant deficiencies will be reported at the next regularly scheduled inspection.

5.5 RESPONSE TO FINDINGS

If a written response is not received within thirty days from the person responsible for a facility identified to have a significant deficiency or significant deficiencies are not corrected by the specified target date, a report detailing the alleged violation(s) will be sent to the VPR.

6. REVIEW AND EVALUATION OF ANIMAL CARE AND USE PROGRAMS

A subcommittee of the Institutional Animal Care and Use Committee (IACUC) consisting of at least 5 members (Chair of the IACUC, University Veterinarian, Director of the Office of Research Compliance; Associate Director of the Division of Laboratory Animal Health; Director, Outlying Units, Alabama Agricultural Experiment Station (AAES); community representative; and/or other IACUC members as appointed by the IACUC Chair) will conduct a review of the animal care and use program every six months. A report summarizing the review will be reviewed and approved by the IACUC committee. When approved, the report will be submitted to the Institutional Official.

7. SUBMISSION OF REPORTS BY IACUC

7.1 REPORTS SUBMITTED TO VICE PRESIDENT FOR RESEARCH (INSTITUTIONAL OFFICIAL)

The aforementioned reports (inspections of facilities that house animals, program reviews) will be submitted to the Institutional Official every six months.

7.2 REPORTING TO OLAW

At least every twelve (12) months, the Institutional Animal Care and Use Committee (IACUC), through the Vice President for Research, will report in writing to Office of Laboratory Animal Welfare (OLAW):

a) Any change in the status of the institution (e.g., receipt of AAALAC accreditation or revocation of AAALAC accreditation).
b) Any change in the description of the institution's program for animal care and use as described in the assurance.
c) Any changes in the IACUC membership.
d) If no changes are reported in the IACUC membership, the institution's program for animal care and use as described in the assurance, or in the accreditation status of the institution, a letter will be submitted to OLAW stating there are no changes.

e) The dates the IACUC conducted semiannual program evaluations and facility inspections and the dates the reports were submitted to the Institutional Official.
f) Any departures from the guide and state reasons for departure; and
g) Any minority views of the IACUC.

A new assurance must be prepared and submitted to OLAW every five years.

8. MECHANISM FOR RECEIPT AND REVIEW OF CONCERNS INVOLVING CARE AND USE OF ANIMALS

8.1 GUIDELINE

The Institutional Animal Care and Use Committee (IACUC) will review and/or investigate 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 Animal Welfare Act, PHS Policy or IACUC Policies and Procedures), or complaints regarding the care received by animals housed in any Auburn University (AU) facility.

8.2 PROCESS OF REPORTING CONCERNS

a) 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 Veterinarian should be contacted immediately (334/844-5667, cell: 334/321-7842). The University Veterinarian, or a designee, will take any necessary immediate action. If the concern is not an emergency, is not adequately addressed, and/or if there is fear of retribution, a formal complaint should be filed (see below).

b) A formal complaint is initiated by contacting one of the following individuals:

Director, ORC 334/844-5978
The Chair of the IACUC: (Name and phone number may be obtained by calling ORC 334/844-5978)
University Veterinarian: 334/844-8979, 334/844-4622 or 334/703-7421 (cell)

c) Information to be provided in the formal complaint shall 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

d) A signed complaint must be submitted to an individual listed under b (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 in b (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 will be submitted to the Chair of the IACUC as soon as possible. A formal complaint should remain confidential to the extent possible to protect all concerned. Within three days of receiving the formal complaint, the Chair will appoint a subcommittee composed of three IACUC committee members to investigate the concern. Initially, the subcommittee will determine whether the concern warrants a formal investigation. If this is deemed to be the case, 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. 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. 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). If the complaint is substantive, the Chair of the IACUC will immediately notify the individual(s) to whom the concern/complaint is directed, the relevant facility director, department/unit head and dean/director, the Director of ORC, University Veterinarian, and the complainant. If the complaint is non-substantive, results of the subcommittee investigation become a non-issue and remain confidential. The IACUC Chair will inform the IO and others of the results of the investigation as directed by the IACUC.

Reports will be filed with the ORC for documentation purposes. No employee, student, IACUC member or laboratory personnel 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 and applicable sponsors as dictated by the actions taken by IACUC and by applicable compliance standards.

9. SUSPENSION OF ANIMAL ACTIVITIES

The Institutional Animal Care and Use Committee (IACUC) may suspend any previously approved activity if it determines that the activity is not being conducted in accordance with an approved protocol, applicable provisions of the Animal Welfare Act, the *Guide for Care and Use of Laboratory Animals*, Public Health Service (PHS) Policy, and/or AU's Animal Welfare Assurance with the National Institutes of Health. The investigative process will coincide with the procedure described in Section 8 of this manual, "MECHANISM FOR RECEIPT AND REVIEW OF CONCERNS INVOLVING CARE AND USE OF ANIMALS"" 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. However, in the extreme case where animal welfare is in jeopardy, the IACUC chair, University Veterinarian, Project, Unit or Clinical veterinarians may conditionally suspend animal activities until a subcommittee can be convened and a decision voted upon by the IACUC committee. A suspension will not occur prior to consultation with the Principal Investigator. Such consultation will allow the responsible individual to be informed of the cause for concern so that an opportunity is afforded to explain their side of the issue. 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), United States Department of Agriculture (USDA), and/or any other Federal agency funding that activity.

10. TRAINING Program

The Office of Research Compliance (ORC) and Office of the University Veterinarian (OUV) will provide or coordinate training for faculty, staff, students and others (e.g., visiting faculty) engaged in the care and use of animals for research, teaching and/or demonstration purposes. Training will include review of institutional policies and procedures governing all activities involving live vertebrate animals, as well as species-specific technical training in animal husbandry, handling and related areas of animal care and use in research and education.

The Auburn University (AU) animal care and use training program is provided in accordance with recommendations in *The Guide for the Care and Use of Laboratory Animals (2011)*, The PHS Policy for the Care and Use of Laboratory Animals, The Animal Welfare Act, and *The Guide for the Care and Use of Agricultural Animals in Research and Teaching (2010)*. Specific elements of the training program are defined in the context of and tailored to institutional needs at AU, and in light of federal policies governing animal use, all of which are likely to be dynamic.

The AU training program addresses:

a) Origins and evolution of institutional animal care and use programs and the regulations, policies and laws governing their operation.
b) Organization of the AU Animal Care and Use Program.
c) The role of the Institutional Animal Care and Use Committee (IACUC) and procedures necessary for completion of the Animal Subjects Review Form (ASRF).
d) The “three R’s” - Replacement, Reduction, and Refinement - as defined by Russell and Burch (*The Principles of Humane Experimental Technique*, 1959) and their application to the design of activities involving animals.
e) Requirements and procedures for identification and evaluation of alternatives to animal use.
f) Procedures for reporting animal welfare concerns and for responding to such reports.
g) Occupational health and safety issues.
h) Other such topics and issues as may be essential to satisfy regulations, policy or law governing animal use.

In addition, species-specific training addresses:

a) Basic biology, handling, husbandry and care of live vertebrate animals used in teaching, research and demonstration.
b) Basic techniques for intradermal, intraperitoneal, intramuscular and intravenous administration of drugs and for collection of blood and body fluids.
c) Methods of tranquilization, analgesia, anesthesia, and euthanasia.
d) Principles and applications of surgery and guidelines for planning invasive procedures involving animals.

All Principal animal users (i.e., PIs and/or course instructors; hereinafter referred to as Principals), as well as staff and students with assigned responsibilities for animal care and use in the context of research, teaching or demonstration activities, will receive and/or document training appropriate to their qualifications, experience and the specific circumstances of animal use proposed by them, in the case of Principals, or assigned to them, in the case of staff and students. Principals must be members of the AU faculty and/or a unit director with primary oversight responsibility for design and management of research, teaching and/or demonstration activities involving animals. Principals are identified through ASRF review by the IACUC. Each principal, as part of completing the ASRF, agrees (by signature) to a certification statement assuring that all individuals performing animal procedures as a component of activities described in the ASRF either are, or will be, prepared to perform their particular animal-related duties through documentable training and/or experience. To facilitate their own training and training of staff and students, Principals will be referred to the ORC IACUC Administration website, where information regarding training opportunities is posted.

Individuals to be engaged in activities involving animals must be apprised of relevant occupational health and safety risks before being allowed to work with the particular species. In addition, individuals must have the appropriate animal care and use training before being allowed to execute their particular duties

without supervision or assistance. The Principal will have his/her staff sign a training certification form to assure and document the appropriate level of training or experience is in place. The Principal will keep a copy of this form and must submit a copy of the training certification form to the ORC prior to protocol approval.

11. OCCUPATIONAL HEALTH AND SAFETY PROGRAM

An Occupational Health and Safety (OHS) program for employees and students involved in animal care and use is an important component of the institution's overall animal care and use program. Topics addressed include risk assessment; personnel training; standard operating procedures; facilities, medical evaluation, and preventive medicine. Health and safety needs are addressed in the context of existing environmental health and safety programs at Auburn University (AU), e.g., blood-borne pathogens, chemical hygiene, respiratory protection, handling/disposal of hazardous waste materials, radiological safety, biological use authorization, and containment and handling requirements for biological agents. Animal protocol approval by the Institutional Animal Care and Use Committee (IACUC) is contingent upon enrollment in the AU OHS Program and documentation of relevant core, specific and procedural-specific training for all personnel involved in care and maintenance and/or conduct of animal related procedures pertinent to the protocol.

The OHS program is facilitated and monitored as a continuing activity of the Office of Research Compliance, Department of Risk Management and Safety (DRMS), Alabama Occupational Medicine, and the IACUC. The IACUC, for example, conducts a programmatic review of the institution's animal care and use program at 6-month intervals, and the OHS program is always a topic for review and evaluation in these reviews. Guidelines, recommendations, and requirements for the AU OHS program are derived or influenced by relevant resource materials: *Guide for the Care and Use of Laboratory Animals* (National Research Council, 2011); *Guide for the Care and Use of Agricultural Animals in Research and Teaching* (Federation of Animal Science Societies, 2010); *Occupational Health and Safety in the Care and Use of Research Animals* (National Research Council, 1997); and *Biosafety in Microbiological and Biomedical Laboratories* (Centers for Disease Control and Prevention and National Institutes of Health, 1999). A description of our OHS program must be included in the AU Assurance of Compliance that is required by the Public Health Service.

The effectiveness of AU's OHS program ultimately relies on effective interactions among several institutional functions or activities: e.g., research and teaching program directors; the IACUC; providers of veterinary care; environmental health and safety program; DRMS; medical services; facility-maintenance personnel and administrative support. Essential to effectiveness, of course, is a continuing performance of safe practices by all personnel with exposure to animals or animal tissues.

12. INCIDENT OR ACCIDENT REPORTING

Employees or students shall promptly inform their supervisors of all on-the-job injuries, disabilities, or illness, regardless of their severity. The employee or student must then report to the On the Job Injury (OJI) program claim manager within 72 hours of the incident. Instructions for reporting claims through the OJI program can be found at: https://cws.auburn.edu/shared/content/files/1414/oji-contact.pdf .

If the employee or student is unable to report the incident, the supervisor will be responsible for reporting to the OJI Claims Manager. Department of Risk Management and Safety (DRMS) will review all injuries and follow-up with an incident investigation if necessary. Records are available to the Institutional Animal Care and Use Committee (IACUC), University Veterinarian, and the Office of Research Compliance (ORC).

In addition to reporting to the OJI Claims Manager as described above, all accidents or incidents judged to be serious by the Principal Investigator (PI), director or instructor/course director shall be reported promptly to DRMS; and to the chief administrator (e.g., Chair, Head, Director, etc.) of the reporting unit. DRMS will notify the IACUC through the ORC of any serious incidents. Subsequently, and promptly, the ORC shall inform the Office of the Vice President for Research (OVPR). Deans and Associate Deans will be notified by the chief administrator of the reporting unit. Communication of a serious incident or accident to the President, Provost, or Public Relations is the responsibility of the OVPR. Examples of serious accidents or incidents include injuries involving hospitalization or extended recovery periods; loss of consciousness; fractures; severe hemorrhages; nerve, muscle or tendon damage; and exposure to toxic chemicals.

Investigation of serious accidents or incidents will be conducted by the IACUC and by DRMS. The investigation by IACUC will focus on determining probable cause and identifying any violation of an approved animal use protocol, animal care and use guidelines, or acceptable safety practices. Upon completing the investigation, the Chair of the IACUC will prepare a written report of findings for review and possible action by IACUC and the OVPR. The incident investigation by DRMS will focus on cause. DRMS's investigation report will be forwarded to the relevant Dean and/or chief administrator of the reporting unit.