



Policy Number: I.31

Policy Level: Operating Policy

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Animal Care and Use in Institutional Research and Teaching

I. Policy Statement and Purpose

The University advances the best interests of its students and the State of Alabama through teaching, service, research, and other creative activities to empower students to make valuable contributions to their professional, civic, educational, and economic endeavors.

In accordance with the University's mission, this policy establishes the standards associated with Athens State University's commitment to the protection and safety of live vertebrate animals used for research and teaching. Any faculty, staff, or student planning on using vertebrate animals for the purposes of research, sponsored or otherwise, or classroom instruction are required to familiarize themselves with and adhere to the federal laws and policies on animal welfare and use.

Familiarization and adherence by faculty, staff, or students to public laws and guides includes, but is not limited to (a) 'Public Law 99-158, Animals in Research', (b) Public Law 103-43, Plan for Use of Animals in Research 1993, (c) Animal Welfare Act and (d) [Guide for the Care and Use of Laboratory Animals](#) prepared by the Institute of Laboratory Animal Resources, National Academy of Sciences. To establish guidelines and procedures for the humane and safe treatment of animals, the University relies on the federal rules and regulations published in the [Public Health Service Policy on Humane Care and Use of Laboratory Animals](#).

Athens State University recognizes the classification of animal use in research and teaching into two categories in order to specify the standards for animal care and use within each category. These two categories are:

- 1) Laboratory Research and Teaching: This category is intended for any research or teaching activity involving live vertebrate animals that occurs in the laboratory. Athens State University endorses the standards for animal care contained within the following two documents:
 - a. [Animal Welfare Act Regulations](#)
 - b. [The Guide for the Care and Use of Laboratory Animals](#)



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- 2) Field Research and Teaching: This category is limited to the observation or study of live vertebrate animals living in the wild. If animals at any point are captured and brought into the laboratory, all use conducted in the laboratory will be subject to the standards for Laboratory Research and Teaching. For Field Research and Teaching, Athens State University endorses the standards for animal care and use contained in the following documents and any subsequent revisions:
- a. For mammals: [Guidelines of the American Society of Mammalogists for The Use of Wild Mammals In Research](#), American Society of Mammalogists, 2011.
 - b. For birds: [Guidelines to the Use of Wild Birds in Research](#), The Ornithological Council, Washington, DC, 3rd ed., 2010.
 - c. For amphibians and reptiles: [Guidelines for the use of live amphibians and reptiles in field research](#). Joint publication of the American Society of Ichthyologists and Herpetologists, The Herpetologists' League, and Society for the Study of Amphibians and Reptiles, 2nd ed., 2004.
 - d. For fishes: [Guidelines for the use of fishes in field research](#). Joint publication of the American Society of Ichthyologists and Herpetologists, American Fisheries Society, and American Institute of Fisheries Research Biologists. Fisheries, Vol. 13, No. 2, pp. 16-23, 1988.
 - e. For standards of euthanasia in all categories of research and teaching, the University endorses the following document and any subsequent revisions: [AVMA Guidelines for the Euthanasia of Animals: 2013 Edition](#).

This policy applies to all employees, students, vendors/contractors, and all other individuals participating in any research, scholarly activity, or teaching activity involving live vertebrate animals within the scope of the authority of the University's administration, faculty, or staff.

II. Definitions

Animal- Any live vertebrate animal which is being used or is intended for use for research, teaching, testing, experimentation, biological testing, exhibition purposes, or as a pet.

Attending Veterinarian: A person who has (1) graduated from a veterinary school accredited by the American Veterinary Medical Association's Council on Education, or has a certificate issued by the American Veterinary Medical Association's Education Commission for Foreign Veterinary Graduates, or has received equivalent formal education as determined by the IACUC, (2) has received training



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and/or experience in the care and management of the species being attended, and (3) who has direct or delegated authority for activities involving animals used for research and teaching at Athens State University.

Embryonated: having developed into an embryo.

Embryo: in the context of this document, an egg-laying vertebrate animal at any stage of development prior to hatching.

Euthanasia: a method of killing that minimizes pain, distress, and anxiety experienced by the animal prior to loss of consciousness, and causes rapid loss of consciousness followed by cardiac or respiratory arrest and death.

Generalizable Knowledge: The knowledge that is expressed in theories, principles, and statements of relationships that can be widely applied. Generally, the term is used to refer to the intent to disseminate the research results and conclusions beyond an individual or internal group.

Guide: [*Guide for the Care and Use of Laboratory Animals*](#): Eighth Edition, National Academy Press, 2011, Washington, D.C., or succeeding revised editions.

Hatching: to bring forth offspring from the egg.

Institutional Animal Care and Use Committee (IACUC): A committee, appointed by the President and reporting to the IO/Provost/VP for Academic Affairs and Student Services, established to ensure that the University follows federal and state guidelines on the protection of animal subjects involved in research and teaching. Members of the IACUC are responsible for reviewing research and teaching protocols and periodic evaluations of the program of animal care and use, including inspections of facilities.

Institutional Officer (IO): The individual who, as a representative of senior administration (IO/Provost/VP for Academic Affairs and Student Services) bears ultimate responsibility for the IACUC and is responsible for resource planning. This individual has the authority to sign the institution's Assurance, making a commitment on behalf of the institution that the requirements of the [*Public Health Services Policy on Humane Care and Use of Laboratory Animals*](#) will be met.



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IACUC Chair: The individual responsible for assisting PIs with mandatory online training and the IACUC application process. This individual is also responsible for convening and chairing IACUC meetings, preparing and executing the agenda, and ensuring that the attendance at the prospective meetings will provide adequate review of all proposals.

Principal Investigator (PI): University faculty desiring to conduct research or teaching activities using live vertebrate animals. Primary responsibility for assuring that the rights and welfare of the animals involved continues to rest with principal investigators conducting the research or teaching activity. This responsibility is shared by others engaged in the conduct of the activity. Faculty who assign or supervise activities conducted by students have an obligation to properly train students and to consider carefully whether those students are qualified to safeguard adequately the rights and welfare of animal subjects.

Research: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. [45 CFR 46.102].

Research Misconduct: Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, reviewing research, or in reporting research results.

Unanticipated Problem: Any incident, experience, or outcome involving risks to subjects or others that is unexpected (in terms of nature, severity, or frequency), not foreseen, or not previously described in the research protocol or informed consent form.

III. Institutional Animal Care and Use Committee (IACUC)

The IACUC is appointed by the President and reports to the IO/Provost/VP for Academic Affairs and Student Services. IACUC membership shall include, but is not limited to, the following five persons: (1) an attending veterinarian, (2) at least one practicing scientist experienced in research involving animals, (3) at least one member whose primary vocation is in a non-scientific area, (4) at least one member who is not otherwise affiliated with the University, and (5) at least one additional member from any vocation.



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The IACUC's responsibility is as follows:

- Review and approve applications to use animals in research and teaching.
- Review at least once every six months the University's program for humane care and use of animals, using the [Guide](#) and appropriate Field Research and Teaching documents as the basis for evaluation.
- Inspect at least once every six months all the University's animal facilities, including satellite facilities and animal surgical sites, using the [Guide](#) as the basis for evaluation.
- Prepare reports of the evaluations and submit reports to the IO.
- Review concerns involving the care and use of animals at the University.
- Make written recommendations to the IO regarding any aspect of the University's animal program, facilities, or personnel training.
- Review and approve, require modifications in, or withhold approval of activities related to the care and use of animals.
- Review and approve, require modifications in, or withhold approval of proposed significant changes regarding the use of animals in ongoing activities.
- Notify PI and the IO in writing of the decision to approve, withhold approval, or require modifications to secure approval of those activities related to the care and use of animals.
- Conduct continuing review of each previously approved, ongoing activity at appropriate intervals, as determined by the IACUC. This includes a complete review at least once every 3 years according to [Public Health Services Policy on Humane Care and Use of Laboratory Animals](#).
- Be authorized to suspend any activity involving animals according to Public Health Services policy.

No IACUC may have a member participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IACUC.

Proposed research will be reviewed at convened meetings at which a majority of the members of the IACUC are present. In order for research to be approved, it shall receive the approval of a majority of those members present at the meeting [45 CFR 46.108]. The IACUC may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IACUC. These individuals will be non-voting.



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Minutes of meetings will show: (1) attendance at the meetings, (2) actions taken by the IACUC, (3) the vote on these actions including the number of members voting for, against, and abstaining, (4) the basis for requiring changes in or disapproving research, (5) and a written summary of the discussions of controverted issues and their resolution.

IV. Occupational Health and Safety

In an effort to address the health and safety hazards and risks of occupational illness and injury that are associated with the care and use of research animals, the University provides training and oversight to those individuals who are involved in the care and use of animals.

V. Training and Instruction

The training, instruction, and qualifications of personnel are assessed in the review of protocols by the IACUC. Vitae detailing the experience and qualifications for all individuals with significant involvement in the care and/or use of animals in approved protocols are maintained by the IACUC Chair.

Individuals using animals are trained by the personnel in charge of the facility they are using. Students are instructed and supervised in the proper techniques, handling and use by the Principal PI in charge of the project.

All faculty, staff, or student researchers who use live, vertebrate animals for teaching or research purposes are required to complete mandatory training. Applications are not reviewed until all research or teaching personnel have completed the mandatory training. This training is provided by CITI, and is available through web access.

All faculty, staff, or student researchers who use live, vertebrate animals for teaching or research are required to complete the following CITI module:

- Using Animal Subjects in Research, which is part of the Social, Behavioral, and Educational (SBE) Sciences RCR Training.



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Individuals may also be required to take one or more of the following CITI training modules:

- [Working with the IACUC](#)
- [Essentials for IACUC Members](#)
- [IACUC Community Member](#)
- [Institutional Official: Animal Care and Use](#)
- [IACUC Chair](#)
- [Post-Approval Monitoring \(PAM\)](#)
- [Minimizing Pain and Distress](#)
- [Wildlife Research](#)
- [Working with Amphibians in Research Settings](#)
- [Working with Fish in Research Settings](#)
- [Working with Mice in Research Settings](#)
- [Working with Reptiles in Research Settings](#)
- [Working with Zebrafish \(*Danio rerio*\) in Research Settings](#)

VI. Application/Review Process

All research conducted at or sponsored by the University that involves animal subjects must be approved prior to research and teaching initiation.

A main goal of the review is to determine if the research and teaching activities adhere to the humane treatment of animals as required by PHS policy and University requirements. The IACUC has the authority to approve, disapprove, or require project modification. Approval must be obtained from the IO/Provost/VP for Academic Affairs and Student Services and the IACUC prior to conducting any research or teaching activity involving animals. No research or teaching activities involving animals may be started without IACUC review and approval.

Individuals responsible for conducting animal research or teaching are required to complete the **mandatory** online training modules outlined in the previous section. Final approval to conduct research will not be granted until all required training modules have been completed.



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The following process must be followed when seeking approval to conduct research or teaching involving animal subjects:

1. The PI must complete the [Application for Animal Care and Use in Institutional Research and Teaching.](#)
2. The PI must complete the appropriate **mandatory** CITI training for Researchers (see Section V of this policy). Additional training may be required by the IACUC after review of the application. Information regarding access to the training modules may be obtained from the IACUC Chair.
3. The PI must submit the completed application packet to the IO. The application packet includes: 1) application, 2) relevant grant application summary, and 3) CITI training verification. Additional supplementary items may be added or required as appropriate.
4. Within five (5) business days of receipt, the IO will forward the application packet to the IACUC Chair.
5. Within ten (10) business days of receipt of the application from the IO, the IACUC Chair will convene an IACUC meeting to review the application. Review may take up to 30 business days.
6. The IACUC Chair will communicate, in writing, the final decision to the PI and the IO. The IACUC's response will be:
 - approve the application with no revision needed, OR
 - require modifications to secure approval, OR
 - reject the application and provide a rationale as to why the application was rejected.
7. Questions and/or approved application will be sent to the email address that is provided on the application.
8. The IACUC Chair will forward the application and supporting documentation to the IO to be stored in a secure location. All records shall be retained for at least three (3) years, and records relating to the research or teaching which is conducted shall be retained for at least three years after the completion of the research or teaching. [45 CFR 46.115].

The Office of the IO/Provost/VP for Academic Affairs and Student Services will maintain, for at least 3 years: (1) minutes of IACUC meetings including reports of attendance, activities of the committee, and committee deliberations, (2) records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was granted or



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withheld, (3) records of semiannual IACUC reports and recommendations as forwarded to the IO, and (4) records of accrediting body determinations.

VII. Use of Live Embryonated Eggs

The PI must inform the IACUC of the intent to use live embryonated eggs of avian and other egg-laying vertebrate species prior to hatching by submitting the [IACUC Notice of Intent to Use Embryos](#) form to ensure that appropriate plans are in place to address the care and euthanasia of animals that may hatch unexpectedly.

If the PI has an approved protocol to use egg-laying animals and the animals lay eggs, the information below must be incorporated into the protocol via [the IACUC Certification of Project Changes](#) to include:

- A succinct explanation of the purpose of the activity and the procedures involved;
- A clear indication of when all live embryonated eggs will be used or disposed and the method of disposition; and
- What steps will be taken to ensure animal welfare in the event that any egg inadvertently hatches.

VIII. Research Review, Modification, Termination and Completion

Continuing Review

All protocols must be submitted as new proposals for review once every three years. These renewals are treated as a new application and are reviewed as such. Protocols that are not scheduled for 3-year full review are subject to annual review. The IACUC may, at its discretion, require more frequent periods of review as a condition of protocol approval. PIs are responsible for reporting significant project changes, project termination, or project completion to the IACUC chair within ten (10) calendar days utilizing the appropriate form(s).



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Project Review

The continuing review date will be determined and noted on the initial approved application for research and teaching. Prior to the review date, the IACUC Chair will solicit, from the PI, a progress report that will be reviewed by the IACUC. The IACUC will use the requirements of the Animal Welfare Act, PHS policy, the [Guide](#), and/or appropriate Field Research and Teaching document as a basis for evaluation.

Following the review, the IACUC Chair will complete the [IACUC Certification for Project Review](#) form and forward a copy to the PI and the IO.

Project Suspension/Termination

Following any review, should the IACUC determine that the research or teaching be suspended or terminated, the IACUC Chair will complete the [IACUC Certification for Project Status](#) form providing rationale for the suspension or termination. Copies of this form will be sent to the PI, and the IO.

Project Changes

If significant changes are proposed in ongoing projects, it is the responsibility of the PI to communicate these changes to the IACUC Chair. The IACUC will review any proposed significant changes in projects involving animal subjects. Changes considered significant include: (1) changes in objectives, (2) switching from a survival study to a non-survival study, (3) changes to the degree of invasiveness, pain, or distress to an animal, (4) changes in species or increase in the number of individuals used, (5) changes in personnel involved in the project, (6) changes in the type or use of anesthetics, (7) changes in methods of euthanasia, (8) changes in the duration, frequency, or number of procedures used on an animal, or (9) any changes deemed by the PI to be significant. PIs are responsible for submitting the [IACUC Certification for Project Changes](#) form to report changes and requesting review of the changes for continuing IACUC approval. The procedures for the submission and review of a new proposal will be followed for review and submission of a proposal for project changes. The IACUC has the authority to approve, deny, or request modifications to the requested project changes. Copies of this form, indicating approval of project changes, will be sent to the PI and the IO.

No significant project changes may be implemented without approval of the IACUC. If significant changes are implemented without IACUC approval, the IACUC has the authority to suspend or terminate the research or teaching activity.



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Project Completion

Within ten (10) calendar days of completion of the research or teaching activity, the PI must submit the [IACUC Certification for Project Status](#) form to the IACUC Chair. The IACUC Chair will confirm the completion of the project, close the IACUC file, and forward all research or teaching documents to the IO. The IACUC Chair will forward copies of the completion form to the PI and the IO.

IX. Rights of Appeal

If a protocol application is disapproved, suspended, or terminated, the PI may appeal the decision, in writing, to the Institutional Official within five (5) calendar days. Within ten (10) calendar days of receipt of the appeal, the IO will meet with the PI and the IACUC to allow the PI to answer questions about the proposal raised by the IACUC and to demonstrate procedures to be used in research if requested by the IACUC. If the first appeal does not resolve matters with the IACUC, the PI may request either 1) a second meeting with the IACUC to present expert witnesses or 2) may request (at the discretion of the IACUC) external review of the application by a PHS-approved IACUC of an equivalent institution and/or by expert consultants in the field. The Athens State University IACUC shall be the final authority in determining the acceptability of a proposal and the IACUC's decision after the second appeal is final. The IO or other officials of the institution may review IACUC decisions but cannot approve an activity involving the care and use of animals if it has not been approved by the IACUC. However, protocols approved by the IACUC may be subject to further review by the IO or officials of the institution.

X. Reporting Unanticipated Problems and Adverse Events

An unanticipated problem includes any untoward sign, result, event, misadventure, injury, dysfunction, or any other undesirable happening or unanticipated problem that involves risks to animals or others not previously reported, and that could reasonably be related to the activities of the study.

All unanticipated problems and serious adverse events shall be reported in writing to the IACUC Committee Chair and the IO within seven (7) calendar days. Within seven (7) calendar days, the IACUC Committee Chair will convene the IACUC to review the report and notify the IO of the decision.



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Based on the findings in the report, the IACUC has the authority to suspend, terminate or require modification to the research or teaching project.

XI. Reporting Concerns Involving the Care and Use of Animals

Any individual, whether or not an employee of Athens State University, may submit concerns or complaints about the use, care, or handling of animals to the IACUC Chair or the IO. All university facilities housing animals will post in a prominent place the policy and contact information for reporting concerns and/or complaints.

Allegation Resolution Procedures

The University will follow the below four stages to resolve charges:

1. **Inquiry:** If a charge is made, the IACUC Chair or his/her designee will initiate an inquiry of the charges via informal discussion, observation, or other reasonable means to determine whether 1) a minor issue can be resolved to the satisfaction of all parties or 2) whether an allegation warrants a formal investigation. Confidentiality must be maintained to protect the identity of all parties beginning with this stage and throughout the other three stages.
2. **Investigation by the IACUC:** If a full investigation is indicated, the IACUC Chair or his/her designee will appoint a committee of at least three members, one of which is the Attending Veterinarian, to conduct a full investigation of the charge. The committee will collect and thoroughly examine all the available evidence to determine whether any infractions took place. The accused will be allowed to submit a written statement to the IACUC Chair. The committee may interview witnesses and the PI during the investigation. The committee will make their final determination through a preponderance of the evidence in a closed session. In most cases, the investigation and the determination should be made within sixty (60) calendar days of receipt of an allegation of concerns involving the care and use of animals. If there is apparent research misconduct, the report will also be referred to the IO/Provost/VP of Academic Affairs and Student Services for a potential employee misconduct investigation.
3. **Reporting of Findings:** The IACUC Chair will provide a written report of the committee's findings and recommendations to the IO within fifteen (15) calendar days of their final determination.



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4. **Resolution:** The IO/Provost/VP of Academic Affairs and Student Services will make a final determination, notify the PI and, if warranted, take appropriate disciplinary action or measures to correct the PI's unacceptable behavior. The IO/ Provost/VP of Academic Affairs and Student Services may consult with the IACUC Chair to determine if outside agencies should be notified of the incident and corrective measures taken by the University.

XII. Research Misconduct

Refer to [*Institutional Research Misconduct*](#) policy.

XIII. Responsibility for this Operating Policy

Policy Owner

As part of the initial approval of this policy by the President and subsequent to the original dissemination of the policy, the IO/Provost/VP of Academic Affairs and Student Services is the policy owner for the ongoing evaluation, review, and approval of this policy. Subsequent reviews and revisions to this policy must be in accordance with approved operating policy procedures and processes.

This policy will be reviewed every year or more frequently as needed by the Policy Owner. Revisions will be reviewed/affirmed by the Faculty Senate and the Cabinet and approved by the University President. This policy will be updated/published in the University's Policy Library.

Responsibility for Policy Implementation

The President has assigned the responsibility of implementing this policy to the Institutional Animal Care and Use Committee (IACUC) under the direction of the IO/Provost/VP of Academic Affairs and Student Services.