

Arkansas Tech University Institutional Animal Care and Use Committee Standard Operating Procedure

Subject: Principal Investigator Responsibilities

BACKGROUND

This Standard Operating Procedure (SOP) describes the role of the Principal Investigator (PI) designated on an Institutional Animal Care and Use Committee (IACUC) protocol. A PI must have the experience, professional qualifications, and access to the research facilities and resources necessary to ensure the proper care and use of vertebrate animals in research and/or teaching. For purposes of the submission of all research proposals involving vertebrate animals at Arkansas Tech University (ATU), the IACUC recognizes only one individual as the PI. All other investigators on the protocol are considered co-investigators or key personnel.

Scope

This Standard Operating Procedure applies to all persons who accept the responsibility as Principal Investigator to conduct research using vertebrate animals at Arkansas Tech University or any of its affiliate institutions. This includes faculty, staff, and students at the institution.

General Responsibilities

The Principal Investigator must:

- Comply with the Animal Welfare Act Regulations (AWRs [CFR 1985]), the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy [PHS 1996]), U.S. Department of Agriculture, and other applicable federal, state, and local laws, regulations, and policies. The Guide for the Care and Use of Laboratory Animals (the *Guide*, NRC 2011) outlines all the PHS requirements followed by the IACUC.

The *Guide*, Ethics and Animal Use

“The decision to use animals in research requires critical thought, judgment, and analysis. Using animals in research is a privilege granted by society to the research community with the expectation that such use will provide either significant new knowledge or lead to improvement in human and/or animal well-being (McCarthy 1999; Perry 2007). It is a trust that mandates responsible and humane care and use of these animals. The *Guide* endorses the responsibilities of investigators as stated in the U.S. Government Principles for Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training.” (p. 4)

- Establish a culture of compliance; zero tolerance for non-compliance with established policies, standard operating procedures, and regulations

- Conduct the study in accordance with the written protocol approved by ATU IACUC
- Abide by the Protocol's Certification of Compliance statement
- Comply with all ATU IACUC policies, procedures, decisions, conditions and requirements
- Ensure that the PI and all animal handlers on the research team read the applications and amendments after approval and be familiar with all animal procedures
- Maintain oversight of the research protocols and research staff
- Ensure that all members of the research team (including the PI) are adequately trained, both initially and throughout the course of the study. This includes students and other trainees, visiting scientists, and volunteers who are directly involved with the project.
- Work closely with the ATU veterinarians for animal care issues, especially if complications arise
 - Per the Guide (p.114): In the case of a pressing health problem, if the responsible person (e.g., investigator) is not available or if the investigator and veterinary staff cannot reach consensus on treatment, the veterinarian has the authority to treat the animal, remove it from the experiment, institute appropriate measures to relieve severe pain or distress, or perform euthanasia if necessary.
- Maintain complete records and documentation appropriate to the type of research
- Implement appropriate safety practices and procedures while working with hazardous agents or materials for staff

Official IACUC Procedures

The Principal Investigator must:

- Submit a new protocol and the associated grant, if applicable, for all research and/or teaching involving vertebrate animals to the IACUC for review by the first business day of the month. Research and/or teaching cannot begin until all requested changes or clarifications are described in the revised protocol, all paperwork/approvals from other Compliance Committees (i.e., Institutional Biosafety Committee) have been received by the IACUC Office, and all training has been completed by the PI and laboratory personnel. After all the requirements have been met, the IACUC Office will generate a letter of approval; the PI cannot begin the project until he/she receives written notification.
- Submit revised protocols and new applications to IACUC on time

- Submit an amendment request for all proposed protocol modifications before any changes are initiated. Animal related work associated with amendment cannot proceed until the PI receives written notification from the IACUC that the proposed change(s) have been approved.
- Complete the appropriate paperwork for annual review of all approved animal use protocols to receive continued protocol approval.
- Submit a new protocol for work that will continue beyond the three year (with annual review) approval period.

Ensure that research personnel adhere to procedures described within approved animal use applications, and IACUC policies

- Review new and revised IACUC policies with research staff, for example:
 - Proper CO₂ euthanasia
 - Amendments required for new procedures and personnel
 - Social housing for social species
 - Proper transport of animal(s)
 - Carcass disposal
 - Ensure proper documentation: The USDA and PHS policies require proper documentation of animal care and use to assess compliance with research protocols and clinical care procedures. Dates of all observations, treatments, and procedures must be recorded. Dates and times (including AM/PM) of all time-sensitive observations or treatments (post-operative evaluations, pain medication) must be recorded. The extent of the records vary based on the nature of the procedure; however, at a minimum, records of the procedure must consist of: Animal ID, date of procedure, type of procedure, anesthetics/analgesics used (dose, route, time), anesthesia chart (vital signs – e.g. pulse rate, heart rate), drugs given (dose, time), general procedures (e.g. intubation, beginning and end of surgery, etc.). Any deviations from the procedure as approved in the protocol due to emergency need must be documented, explained, and reported to the Institutional Animal Care and Use Committee. All records must be available for review at any time by IACUC and external regulatory officials.

Protocol Compliance

- Conduct and document appropriate monitoring of animals as deemed indicated in the approved protocol
- Report to the IACUC unanticipated adverse effects occurring in experimental animals

Laboratory Personnel Who Use Live Vertebrate Animals

The Investigator must ensure the adequacy of training and the level of experience of all animal handlers in the laboratory. The Investigator must ensure that all individuals in their laboratory who handle animals either have the necessary training or will receive the training necessary to conduct procedures according to federal regulations and IACUC policy. The training may be conducted by DAR technicians and veterinarians or other approved investigative staff. All animal handlers must be listed on the appropriate animal use protocol application. Completion of the on-line training does not add personnel to an animal use protocol application. This must be done when the animal use protocol application is initially submitted or later as a personnel amendment.

Required Training, Enrollment in the Medical Monitoring Program, Animal Facility Orientation and Addition of Personnel Listed on the Animal Use Application

Before research begins on an approved IACUC animal use protocol there are four steps to be completed by every person working with live vertebrate animals at Arkansas Tech University must document training experience and/or receive hands-on training, if needed.