Principle Investigator Responsibilities

This Guideline 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 Georgia State University (GSU), the IACUC recognizes only one individual as the PI. All other investigators on the protocol are considered co-investigators or key personnel.

This Guideline applies to all persons who accept the responsibility as Principal Investigator to conduct research using vertebrate animals at Georgia State 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 GSU IACUC;
- Abide by the Protocol’s Certification of Compliance statement(s);
- Comply with all GSU 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;
- Establish a 24-hour contact number so that the Division of Animal Resources (DAR) can contact lab personnel at any time to ask animal health related questions;
- 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 GSU 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;
• Participate in the Post Approval Monitoring (PAM) program as requested by the Office of Research Integrity; and

• Implement appropriate safety practices and procedures while working with hazardous agents or materials for lab staff and DAR 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 submission schedule found at: [https://ursa.research.gsu.edu/iacuc/iacuc-calendar/](https://ursa.research.gsu.edu/iacuc/iacuc-calendar/). Research and/or teaching cannot begin until all requested changes or clarifications are described in the revised protocol, all documentation/approvals from other Compliance Committees (i.e., Institutional Biosafety Committee, Radiation Protection Committee, etc.) have been received by the IACUC Office, and all training has been completed by the PI and laboratory personnel. After all 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 the amendment cannot proceed until the PI receives written notification from the IACUC Office that the proposed change(s) have been approved;

• Complete the appropriate submission for annual review of all USDA covered animal use protocols to receive continued protocol approval; and

• Submit a new protocol for any animal work that will continue beyond the three-year approval period.

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

• Review new and revised IACUC and DAR guidelines and Standard Operating Procedures with research staff, for example, but not limited to:
Proper CO₂ euthanasia;
Amendments required for new procedures and personnel;
Social housing for social species;
Proper procedures in DAR facility;
Proper transport of animal(s);
Carcass disposal;
No sharing of DAR facility access cards; and
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 indicated in the approved protocol; and
- Report to the IACUC any unanticipated adverse event 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 animal use protocol application. Completion of the on-line training alone 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 Georgia State University: 1) complete the AALAS Learning Library IACUC online training; 2) attend an animal facility orientation meeting; 3) enroll in the Medical Monitoring Program; and 4) document training experience and/or receive hands-on training, if needed. The following outline briefly describes each of these steps and special considerations.

**I. AALAS Learning Library IACUC Online training**

Before handling animals, the individual must complete the appropriate courses, based on the species of animals used and the procedures that will be done, in the AALAS Learning Library IACUC Online training. Online training is located via [https://ursa.research.gsu.edu/animals-use-training/](https://ursa.research.gsu.edu/animals-use-training/).

**II. Animal Facility Orientation**

A facility orientation is required for access to the animal facilities at Georgia State. To request a facility orientation for an individual or group, please e-mail dar@gsu.edu with the subject line "Facility Orientation." In the text of the email please provide:

- Your name
- Primary investigator's name
Your work phone number
Your work email address
Downtown animal facility orientations are generally held on Wednesdays from 10 am to 11:30 am and require pre-registration. LRC animal facility orientations are scheduled as needed. To attend an orientation, you must be enrolled in the Medical Monitoring Program (http://mmpvae.gsu.edu/) and be added onto an IACUC-approved protocol.

All visitors to Georgia State’s animal facilities must first complete a Visitor Access Form (http://ursa.research.gsu.edu/files/2016/07/DAR-Visitor-Access-Form.pdf) and return it to the DAR office. Visitors may not be unattended in the facility and must abide all DAR policies.

Manuals about using the DAR facilities at the Petit Science Center, Natural Science Center, and the Language Research Center are available in the Research Portal at DAR Facilities Manuals (https://dar.gsu.edu/Home/SOPPublic?Id=3) (log in with campusID and password for access).

III. Enrollment in the Medical Monitoring Program for Vertebrate Animal Exposure (MMPVAE)

The National Institutes of Health (NIH) requires that each university receiving federal support for research involving vertebrate animals develop and implement a Medical Monitoring Program for personnel with exposure to laboratory animals. Enrollment in the MMPVAE is online (http://ursa.research.gsu.edu/ursa/compliance/research-occupational-health-and-safety/). Follow the directions on the form for submission. Please note that enrollment in the program (completion of the MMPVAE Enrollment Form: https://mmpvae.gsu.edu) is mandatory.
IV. Hands-on and Species-Specific Animal Handling and Procedure Training

Arrangements for hands on training are made through the Department of Animal Resources at 404-413-3560. Examples of available hands on training (not an inclusive list):

- Biomethodology of Rats
- Biomethodology of Mice
- Biomethodology of Hamsters
- Introduction to Surgery
- Advanced Surgical Techniques: Ovariectomy
- Advanced Surgical Techniques: Gonadectomy

The **biomethodology workshops** will address the following:

- Methods of handling and restraint
- Administration of substances via various routes (subcutaneous, intraperitoneal, intravenous, intramuscular, and per oral using gavage)
- Methods of blood collection
- Methods, principles, and protocols for sedation, anesthesia, and analgesia
- Methods of euthanasia

The **surgery workshop** will address the following:

- Principles of aseptic technique
- Basic surgical instruments (handling and use)
- Pre-operative preparation (animal, surgeon, instruments, etc.)
- Basic surgical techniques (tissue handling, making an incision, closing an incision)
- Intra-operative animal care
• Post-surgical animal care (analgesia, removing wound clips/sutures, etc.)

All individuals in need of such training are welcome and encouraged to attend. Each workshop will be offered approximately 3 times a year.