Introduction

Welcome to the Using Animals for Teaching, Testing, and Research at UAB (AU_UA) Module One Course Material. You must complete this course if you are going to be added to a protocol using animals or if you will be working in an animal facility. The goal of this module is to inform you how regulatory agencies and accreditation organizations are involved in animal research.

Objectives

At the conclusion of this module, participants will be able to:

1. Comply with the requirements of regulatory agencies and accrediting organizations.
2. Recognize the importance of UAB’s Animal Care and Use Program (ACUP).
3. Acknowledge the Institutional Animal Care and Use Committee’s (IACUC) involvement in protocol review.
4. Implement the “Three R’s” and realize how this concept affects a study’s protocol.

Commitment to Humane Animal Care and Use at UAB

Animals used in research are for advancing knowledge, education, or training. After defining the animal’s purpose and alternative methods are studied, projects are designed to utilize the minimum number of animals.

Animals will experience the least possible pain or discomfort consistent with the project goals. A single incident of serious non-compliance with animal welfare regulations or guidelines can jeopardize the entire institution’s privilege of conducting animal research and result in loss of funding and fines.
Three R’s

Anyone planning to use animals for teaching, testing, or research must consider the “Three R’s.” The purpose of these concepts is minimizing or replacing animal use and refining techniques that have the potential to cause pain or distress while still achieving the critical scientific objectives that lead to advances in health and medicine.

Regulatory Agencies

United States Department of Agriculture (USDA)

Animal Welfare Act (AWA)

The AWA was initially enacted in 1966 and gave the USDA the responsibility of regulating any research facility that is:

1. Using live animals in research, tests, and experiments.
2. Purchasing or transporting live animals in (interstate) commerce.
3. Receiving funds under a grant, award, loan, contract from a department, agency, or instrumentality of the United States to carry out research, tests, and experiments.

UAB is firmly committed to treating all research animals humanely. Always remember using animals for teaching, testing, and research is a privilege, not a right!
Definition of an Animal

The AWA defines an animal as “any live, dead, warm-blooded animal, which is being used or intended for research, teaching, testing, experimentation, exhibition purposes, or pet.” This definition excludes farm animals not being used for biomedical research, birds, rats of the genus *Rattus*, and mice of the genus *Mus* bred for use in research.

Required Information

As a research facility registered with the USDA, UAB must submit reports to the USDA regarding:

- Annual usage of animals
- Program changes
- Incidents of non-compliance with the AWA regulations

Compliance and Consequences

Officers of the USDA’s Animal and Plant Health Inspection Service (APHIS) conduct unannounced visits and review UAB policies and Procedures. These checks may include inspecting UAB animal activity areas and animal research records, visiting laboratories, and interviewing research personnel. Consequences of failing to comply with the USDA AWA regulations may include the loss of UAB’s registration to perform animal research and fines levied against UAB. That is why it is imperative that each person working with research animals become familiar with USDA regulations.

The Public Health Service (PHS)

The PHS is a division of the United States Department of Health and Human Services (HHS). One of its goals is to advance public health science and is responsible for overseeing animal use in research. The PHS encompasses eight different organizations. One of these organizations is the National Institutes of Health (NIH), and researchers rely on their grants to fund research.
**Definition of an Animal**

The PHS defines an animal as “any live, vertebrate animal used or intended for use in research, training, experimentation, biological testing, or related purposes.”

**Guidelines for Researchers**

The PHS wants to ensure that any animal research funding by the NIH (or any of its other agencies) involves the most humane treatment of all research subjects. For this reason, it has put forth the *Policy on Humane Care and Use of Laboratory Animals*. The Policy states, “No activity involving animals may be conducted or supported by the PHS until the institution conducting the activity has provided a written Assurance acceptable to the PHS.” Therefore, if you don’t comply with PHS policy, you will not be awarded any research funds.

**Office of Laboratory Animal Welfare (OLAW)** has oversight responsibility for NIH funded projects following PHS Policy and individuals institutions PHS Assurances. The PHS Policy states: “The Assurance shall fully describe the institution’s program for the care and use of animals in PHS-conducted or supported activities.” An Assurance is a contract with PHS indicating UAB will abide by all of the following:

- The US Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training
- PHS Policy Requirements
- Animal Welfare Act Regulations (as applicable)
- Standards outlined in *The Guide for the Care and Use of Laboratory Animals*

**OLAW Requirements, Compliance, & Consequences**

OLAW is responsible for monitoring institutional compliance with the *Humane Care and Use of Laboratory Animals PHS Policy*. Part of the monitoring process requires UAB to submit specific information to OLAW and (although rarely) undergo site inspections if necessary. Non-compliance is monitored and reported throughout the year. Potential consequences for failure to comply with the *PHS Policy* include loss of PHS funding and fines.
OLAW requires the following information:

- Program changes
- Dates for semi-annual evaluations
- Minority views during reporting periods from committee members

### Association for Assessment and Accreditation for Laboratory Animal Care, International (AAALAC)

AAALAC is a non-profit organization that accredits research animal programs. AAALAC requires compliance with *The Guide for the Care and Use of Laboratory Animals* and other applicable standards. Participants are peer-reviewed every three years to ensure conformity. Its requirements apply to all animals used in research, teaching, or testing. Failing to meet these guidelines can result in a loss of accreditation.

AAALAC has no regulatory authority, and participation in the accreditation process is voluntary. However, being accredited is often recognized by the USDA, OLAW, and granting agencies as an indicator of having high-quality animal care and use program.

**Why Is It a Good Idea to Obtain Accreditation?**

- The Veterans Administration and other research sponsors may require AAALAC Accreditation of its animal use components or of those with which it does business.
- Some funding agencies may request information about the accreditation status or loss of status on applications.

**Animals Covered**

According to AAALAC’s Rules of Accreditation, “This includes traditional laboratory animals, farm animals, wildlife, and aquatic animals. Nontraditional animals, inclusive of invertebrate species, are also included wherever they are relevant to the unit’s mission.”
ACUP was formed to ensure humane treatment and care for all research animals at UAB. Each of these entities comprises the ACUP.

1. Institutional Official (IO)
2. Institutional Animal Care and Use Committee (IACUC)
3. Animal Resources Program (ARP)
4. Principal Investigators (PI)
5. Occupational Health & Safety (OH&S)

**Institution Official (IO)**

The Vice President for Research serves as the Institutional Official (IO) for UAB’s ACUP. The IO is authorized to commit the institutional resources keeping the ACUP compliant with regulatory requirements and appointing IACUC members.
Using Animals for Teaching, Testing, and Research at UAB (AU_UA)
Module One Course Material

Institutional Animal Care and Use Committee (IACUC)

IACUC is responsible for implementing all federal regulations, accrediting organization requirements, and institutional policies for animal use in research, teaching, or testing. Think of IACUC as an institutional committee that is responsible for all things related to the animal use here at UAB (specifically animal welfare).

**Ultimate IACUC Goals**

To fulfill its committee function, the IACUC must meet these goals:

1. Protect the animal’s welfare, individual investigators, and the institution.
2. Ensure animal research complies with animal welfare laws, regulations, and guidelines.
3. Assure the general public that the animal research performed at UAB is ethical and humane.

**Work Requiring IACUC Oversight**

- Use of all live (or viable fetal) vertebrate animals and some invertebrates used in research, testing, or teaching in UAB facilities.
- Research conducted by or for UAB faculty, staff, or students at other sites if funds administered through UAB are used to pay for the animal work.

**Work Not Requiring IACUC Oversight**

Some research does not require IACUC’s oversight; however, it may still need approval by one or more safety committees. Some examples include the use of:

- Animal cells or tissues for *in vitro* studies if acquired from an approved source.
- Use of insects (not in central animal facilities and no contact with other animals).

If ever in doubt about if IACUC oversight is required, contact the IACUC office at (205) 934-7692.
Members

The IACUC consists of people from a variety of professions and fields.

- UAB Scientists
- Laboratory Animal Veterinarians
- Representatives from Occupational Health & Safety (OH&S)
- UAB Non-Scientists
- Community or Unaffiliated Members with no UAB affiliation

Responsibilities

The IACUC is responsible for:

- Reviewing proposed animal use (called a Protocol Review).
- Developing and implementing animal use policies and procedures.
- Conducting thorough reviews of the program by monitoring the ACUP.
- Inspecting (at least twice each year) animal housing and activity areas.
- Monitoring personnel training and safety.
- Making recommendations to the IO regarding the program and facilities.
- Investigating reported concerns involving the use and care of animals.
- Suspending any animal use or research in cases of non-compliance.

Protocol Review

The review of proposals to use animals is the responsibility most frequently associated with the IACUC. The electronic protocol form (including instructions) is located here. During the review process, the IACUC assesses the following areas (this is not a comprehensive list).

- Animal living conditions are appropriate to the species.
- Veterinary medical care is available and provided by qualified personnel.
- Proposed activities do not unnecessarily duplicate previous work.
- Planned procedures avoid or minimize pain or distress.
• Procedures causing pain or distress will incorporate pain-relieving measures unless justified.
• Performance of survival surgery in aseptic and approved facilities, and the inclusion of appropriate pre-post-operative care procedures.
• Animals are not used in more than one major, survival operative procedure without justification.
• Methods and timing of euthanasia are appropriate.
• Personnel is properly trained.

Unique Animal Project Number (APN)

An approved IACUC protocol is assigned a unique Animal Project Number (APN). Every animal is associated with an authorized IACUC protocol. Without this number, the ARP will not be able to fulfill your requests when ordering more animals or medication. The APN is used as identification on cage cards.

The Animal Resources Program (ARP)

The ARP operates under the administrative authority of the UAB President. It is directly managed by the Assistant Vice President for Animal Research Services and reports directly to the Vice President for Research. ARP is the service unit that provides care for all animals required in research and teaching programs at UAB and affiliated hospitals. The ARP has an independent budget that is supported by a system of uniform charges to investigators.
ARP responsibilities include:

- Ordering animals
- Assisting with intra- and inter-institutional transfer of animals
- Quarantine and animal health surveillance
- Daily care and facility management
- Veterinary care (clinical and surgical)
- Provision of environmental enrichment to promote the animals’ psychological well-being
- Providing assistance and support for researchers

**Animal Housing**

While the IACUC oversees animal housing facilities, the ARP assigns space and manages the facilities on UAB’s campus. It oversees over 200,000 square feet of space designated for use or care of laboratory animals. This area encompasses multiple buildings.

- UAB Animal Facilities provide housing options and support equipment to accommodate a variety of animal models and research models.
- The facilities are constructed and managed to meet the requirements of regulatory agencies and accrediting organizations in addition to the needs of the animals.
- As a security measure, only approved persons have access to animal facilities.

**Protocol Involvement**

Regulations require laboratory animal veterinarians to be involved in the development of protocols that may include more than mild or momentary pain or distress to the animals. UAB meets this requirement by incorporating ARP Veterinarians during the protocol review process. Even if the proposed research does not legally require their involvement, researchers are encouraged to consult with ARP Veterinarians for advice during the planning stages of their protocols.
**How can the ARP Veterinarian Staff help me?**

ARP Veterinarians can assist in the planning of experiments by providing medical and procedural guidance related to:

- Animal model selection or development
- Determining appropriate endpoints
- Specialized husbandry needs
- Personnel training
- Proper use of sedation, anesthesia, and analgesia
- Selection of therapeutic drug regimens and dosing
- Surgical and non-surgical techniques
- Pre-, peri, and post-operative care and monitoring

**Other Entities**

**Principal Investigators (PI)**

PI’s are committed to the humane care and use of research animals and ensuring the health and safety of their staff while working with animals. PIs are responsible for many items related to their protocols and personnel. Examples include:

- Confirming their research staff is trained and qualified for any IACUC approved procedures in the protocol.
- Adhering to the Three R’s Concept.
- Implementing processes ensuring the health and well-being of research animals, personnel safety, and regulatory compliance.

The Occupational Safety and Health Administration (OSHA)’s Occupational Exposure to Hazardous Chemicals in Laboratories (also known as The Lab Standard) is explicitly written to address chemical handling in the research setting.
Chemical Hygiene Plan (CHP)

A detailed written plan explaining the hazards present, how to manage them safely, and be specific to the individual lab or research group. Must be available to all employees working in the area. For more information, see this sample of a Chemical Hygiene Plan.

Chemical Hygiene Officer (CHO)

Department heads or the Principal Investigator (PI) will appoint someone to this position. A CHO is also known as a Lab Coordinator. A CHO is responsible for:

- Serving as liaison with UAB Occupational Health and Safety (OH&S).
- Implementing, updating, and administering the CHP (including the provisions for obtaining prior approval for dangerous procedures).

Conclusion

You have completed the Using Animals for Teaching, Testing, and Research at UAB (AU_UA) Module One Course Material. Before you access the second module of this course, you must take the assessment for this module. The passing score is 80% or higher.