ANIMAL CARE AND USE PROGRAM

I. Purpose

The purpose of this policy is to describe the mission, scope, authority, and components of the Animal Care and Use Program (ACUP or Program) for ensuring that the welfare of all vertebrate animals used in research, testing and teaching at The Ohio State University is protected, irrespective of funding source.

II. Mission Statement

The mission of the Animal Care and Use Program is to promote the humane care and use of vertebrate animals in activities conducted on behalf of the university by adhering to the ethical principles outlined in U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training, Guide for the Care and Use of Laboratory Animals, Animal Welfare Act, and other applicable regulations and guidance.

The ACUP achieves its mission by:

• Requiring that all activities involving animal subjects receive ACUP approvals before research and teaching activities are initiated
• Creating an environment at the university that promotes the ethical use of animals
• Maintaining an Institutional Animal Care and Use Committee (IACUC) to provide oversight of the Program and report findings to the Institutional Official (IO)
• Appointing an Institutional Attending Veterinarian (AV) to oversee veterinary care for the ACUP
• Providing professional administrative support to the university’s IACUC
• Educating the university community about federal, state, and university regulations, policies, and practices pertaining to the humane use of animals
• Conducting post-approval monitoring activities to promote compliance with the requirements of the ACUP.

III. Scope of the Animal Care and Use Program

All research, testing, and teaching activities involving vertebrate animals overseen and conducted by The Ohio State University, irrespective of funding, must be reviewed by the IACUC, unless the activity has been determined to be exempt. All exemptions are evaluated on a case-by-case basis by the IACUC Chair and the Attending Veterinarian.

The Ohio State University’s animal use policies, guidelines, and operating procedures are intended to comply with applicable federal regulations, guidance, and state laws governing the use of animals in research, testing, and teaching including, but not limited to the following:

• Animal Welfare Act (AWA, Public Law 89-544, 7 U.S.C.)
• Animal Welfare Act Regulations (AWAR, 9 CFR, Chapter 1, Subchapter A)
• Health Research Extension Act of 1985 and Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals
• National Research Council Guide for the Care and Use of Laboratory Animals
- AVMA Guidelines for the Euthanasia of Animals
- The Federation of Animal Science Societies Guide for the Care and Use of Agricultural Animals in Research and Teaching
- Applicable Ohio laws

IV. Authority, Responsibility, and Independence of the Institutional Animal Care and Use Committee

IACUC has the responsibility to oversee the whole animal care and use program. To fulfill its oversight responsibilities, the IACUC has the authority to:

- Ensure that research is designed and conducted in an ethical manner that protects the welfare of animals
- Approve, require modifications to secure approval, or disapprove all research, testing, or teaching involving animals
- Suspend or terminate approval of activities not being conducted in accordance with the IACUC’s requirements or that has been associated with unexpected serious harm to animals
- Utilize the designated member review process as described by federal regulations
- Inspect all facilities where animals are being used
- Develop policies for the use of animals at The Ohio State University.

Animal use may be subject to further approval or disapproval by officials of the institution (i.e. IO, Deans, CROS). No officials of the institution may approve animal subjects use (i.e., authorize it to proceed) that has not been approved by the IACUC. The IACUC’s decision-making must be independent from coercion or undue influence.

The performance of research, testing, or teaching involving animals without IACUC approval or exemption is noncompliance with Animal Care and Use Program requirements and will be handled as described in IACUC policy [Investigating Concerns-Whistle Blowers].

V. Components of the ACUP

The components comprising the Animal Care and Use Program are the Institutional Official, IACUC, and Attending Veterinarian. Their responsibilities, ethical obligations, and authorities for carrying out the activities and mission of the ACUP are described below.

A. Institutional Official for the Animal Care and Use Program

The Institutional Official for the university's Animal Care and Use Program is the Senior Associate Vice President for Research, who is appointed by the President of The Ohio State University and reports to the Vice President for Research. The IO bears the ultimate responsibility for the following activities:

- Communicating the importance of animal welfare across The Ohio State University and regularly demonstrating the institutional commitment to animal welfare at Ohio State
- Assuming the obligations of the Assurance for the Animal Care and Use Program on behalf of The Ohio State University
- Supporting implementation of Program decisions and taking administrative actions to facilitate compliance
- Allocating and distributing resources as necessary to conduct ACUP activities
- Appointing individuals acting on behalf of the university to the IACUC and ensuring that these individuals are protected from coercion or undue influence while serving in this capacity
• Ensuring the Attending Veterinarian has the proper authority and resources to meet his/her responsibilities to the ACUP
• Serving as a point of contact for OLAW, USDA, and other federal agencies sponsoring and overseeing animal use and providing required ACUP reports to these agencies
• Communicating with and advising other senior administrative officials on animal welfare issues as necessary
• Ensuring that ACUP personnel including but not limited to investigators, research staff, IACUC members, and all other pertinent staff possess adequate knowledge of the federal, state, and local requirements pertaining to use of animals in research, testing and teaching.
• Ensuring the support for successful animal experimentation in line with the ethical responsibilities for animal use and good stewardship of research resources.

B. Institutional Animal Care and Use Committee

The IACUC is appointed by the Senior Associate Vice President for Research to:
• Oversee the whole animal care and use program
• Develop, review, and approve policies and procedures for the university’s Animal Care and Use Program
• Solicit input from the university community regarding ACUP operations
• Support the educational, quality improvement, and outreach activities of the ACUP
• Review at least once every six months the program for humane care and use of animals, using the Guide, Ag Guide, and/or the AWAR as a basis for evaluation
• Inspect at least once every six months all institutional animal facilities, including satellite facilities, using the Guide, Ag Guide, and/or AWAR as a basis for evaluation
• Make written recommendations to the IO regarding any aspect of the institution’s animal care program, facilities, or teaching personnel, including the operations of and resources allocated to the ACUP, composition of the IACUC, and staff devoted to support Program activities
• Ensure that an occupational health and safety program is in place for individuals working with or regularly exposed to animals
• Communicate activities to AV staff, IBC, and other support units in the ACUP to help ensure efficient ACUP operation

The IACUC derives its authority from federal regulations and university policies and reports its review of programs and facility inspections to the IO at least semi-annually. The IACUC receives administrative support from the Office of Responsible Research Practices.

This institution maintains an IACUC in accordance with the compositional requirements of IV.A.3.b (PHS Policy), 2.31.b.1-4. (AWAR), and Ag Guide. The IACUC is comprised of at least 5 members that meet specific criteria described in federal regulations, including an individual with scientific experience, veterinarian with designated program responsibilities, and a non-affiliated individual representing community interests.

C. Attending Veterinarian

The Attending Veterinarian is appointed by the IO and has expertise in research animal care and use programs as evidenced by Board Certification by the American College of
Laboratory Animal Medicine. The AV is supported by additional veterinarians with expertise in the species being used and must have access to all animals to carry out the following responsibilities:

- Assuming responsibility for the health and well-being of all animals used under the ACUP
- Providing for veterinary medical care on a 24/7 basis, 365 days per year
- Providing oversight of additional aspects of the veterinary care program for all animals used at Ohio State, such as preventative medicine and health surveillance, medical treatment, establishment of sedation, anesthetic and analgesic guidelines, handling, and immobilization and should have oversight of other related aspects such as housing and husbandry,
- Providing guidance and oversight to surgery programs and perioperative care and assisting the IACUC in determining that personnel performing surgical procedures are appropriately qualified and trained
- Stays abreast of current regulatory requirements as well as best practices as it relates to the ACUP at The Ohio State University
- Serves as the point of authority on regulatory interpretation for veterinary and animal husbandry regulations, and animal facility inspections for external agencies including AAALAC and USDA
- Working with the IACUC and IO on matters requiring regulatory interpretation
- Communicating program issues including problems, regulatory updates and ACUP trends to the IACUC and the IO
- Developing and implementing training for institutional staff in the care and use of animals at The Ohio State University
- Overseeing development and implementation of the environmental enrichment program for animals housed at The Ohio State University
- Assisting institutional health officials to establish and monitor an occupational health program for all animal care workers and others who have substantial animal contact
- Monitoring for zoonotic diseases such as Q-fever, B-virus, and rabies
- Advising and monitoring standards of hygiene among institutional staff involved with research animal care and use
- Advising on biohazard control policies and procedures as they apply to research, testing, and teaching involving animals
- Providing veterinary consultation during protocol review for procedures that may cause more than momentary or slight pain or distress to animals
- Recommending classification of surgical procedures as either major or minor and helping to ensure animals are not used for multiple major surgeries without IACUC approval.

VI. Principal Investigator Responsibilities

Investigators who utilize animals in their research or teaching, have the following responsibilities:

- Ensure that all personnel involved in animal research, testing, and teaching complete the following prior to initiating work with animals:
  - Animal Usage Orientation course (every 3 years)
  - Occupational Health and Safety course (every 3 years)
  - Occupational Health Risk Assessment
  - Annual University Financial Conflict of Interest (eCOI) Disclosure
  - Approved as protocol personnel for the relevant IACUC protocols

- All personnel in their laboratory are familiar with and conduct activities as described in the IACUC protocol
• Promote humane animal care and ethical treatment of animals in their studies

VII. Additional Components Supporting the ACUP

A. Office of Research

The Office of Research (OR) provides oversight for all animal research, teaching, and testing conducted at The Ohio State University. The Vice President for Research, assisted by the Senior Associate Vice President for Research and Associate Vice Presidents for Research, reports to the university Executive Vice President and Provost. The Vice President for Research has responsibility for the development of overall research policies and operating procedures and for providing advice and assistance to college research administrators in the development of research programs within the colleges under the Bylaws of the Board of Trustees for the Administration of the University [Ohio Administrative Code § 3335-1-03(M)].

Administrative units with distributed responsibility for animal research, testing, and teaching that report to the Vice President for Research include the Office of Responsible Research Practices (ORRP), University Laboratory Animal Resources (ULAR), Office of Sponsored Programs (OSP), and Office of Research Compliance (ORC).

B. Office of Responsible Research Practices

The Office of Responsible Research Practices, an administrative unit of The Ohio State University Office of Research has the following responsibilities:

- Receipt and screening of protocols submitted for IACUC review that involve the use of animals for teaching, testing, or research
- Verifying that the principal investigator proposing the project is eligible to serve in the capacity of principal investigator and that all compliance-related requirements (e.g., COI disclosure) have been met
- Recommending full committee or designated member review of protocols to the IACUC Chair
- Providing administrative support to the IACUC by keeping investigators and others informed of IACUC decisions and performing all other IACUC-related recordkeeping and administrative processing
- Gathering and maintaining information related to exceptions to the Guide and AWA for inclusion in regulatory reports and advising IACUC on best practices related to regulatory requirements for IACUC administrative function.
- Verifying the number of animals approved and used on IACUC approved protocols is accurate, and providing this information in regulatory reports
- Notifying investigators of expired/terminated/suspended protocols and facilitating transfer of animals to another approved protocol, as applicable
- Facilitating semi-annual, quality improvement, USDA inspections, and AAALAC site visits. Assisting in the IACUC’s investigation of ACUP findings or concerns
- Preparing regulatory reports and agency notifications (e.g., noncompliance) per IACUC direction to appropriate institutional officials, OLAW, and other federal agencies as required
- Maintaining IACUC records per the university’s “Records Retention Schedule” and arranging for inspection or provision of records as legally required
- Participating in the quality improvement program as described below
- Providing administrative support to the Institutional Biosafety Committee (IBC), which is an ancillary component of the ACUP.
- Communication of ACUP activities to the IACUC and AV on a regular basis
C. University Laboratory Animal Resources (ULAR) and other dedicated housing facilities

Dedicated animal housing facilities supports the ACUP by providing resources to facilitate teaching and biomedical and agricultural research. These dedicated facilities include ULAR centralized facilities, College of Veterinary Medicine facilities including the Veterinary Medical Center and Finley Farm, and College of Food, Agriculture and Environmental Science facilities including Ohio Agricultural and Research Development Center (OARDC) and Agricultural Technical Institute (ATI) in Wooster OH. These facilities have the following responsibilities:

- Managing the daily care of animals and operating the university’s animal housing facilities in compliance with regulatory requirements
- Notifying the IACUC if facility conditions fall outside the regulatory requirements and animal health may be impacted
- Ensuring veterinary care is provided to all animals as needed
- Providing enrichment and social housing to all animals unless exempted by the IACUC
- Ensuring that husbandry personnel comply with the requirements for protocol personnel in terms of training requirements and Occupational Risk Assessments
- Ensure an Emergency Plan +/- Disaster Contingency Plan is in place and responsible personnel are familiar with the plan
- Assessing the performance of environmental monitoring systems if present at least quarterly to ensure functionality

D. Occupational Health and Safety Program (OHSP)

The OHSP program is jointly administered by the Office of Environmental Health and Safety (OEHS), Employee Health Services, and Student Health Services. The IACUC, AV, and IO in conjunction with the above entities oversee the overall program in support of the ACUP.

OEHS is responsible for:
- Initial and annual evaluation of the occupational risk assessment for all animal users
- Conducting Chemical Hygiene Plan reviews and Standard Operating Plan approvals for all Principal Investigator’s using hazardous chemicals as part of an IACUC protocol
- Developing hazard information forms to be posted at the lab, housing or procedure space for the duration of the hazard
- Assisting in the maintenance of the IACUC Occupational Health & Safety online training program

Employee Health Services is responsible for:
- Evaluation of employees whose exposure or history presents a potential occupational risk
- Providing information on zoonotic diseases to which employees may be exposed
- Providing ongoing care and assessments to personnel according to the “Animal Care Handler Medical SOP.”
Student Health Services is responsible for:

- Evaluation of students whose exposure or history presents a potential risk and who are involved in the ACUP in animal care or animal research/teaching in an unpaid position
- Providing information on zoonotic diseases to which students may be exposed.

E. Institutional Biosafety Committee

The Institutional Biosafety Committee is charged with ensuring that all Ohio State research involving recombinant DNA, regardless of funding source, is registered with the IBC and conducted in accordance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*. The IBC is further charged with reviewing and approving research conducted with microorganisms pathogenic to humans, plants, or animals. This review is conducted pursuant to the Centers for Disease Control and Prevention/NIH publication, *Biosafety in Microbiological and Biomedical Laboratories*. The IBC supports the ACUP by:

- Categorizing biohazard use according to CDC classifications
- Reviewing institutional risk associated with the proposed hazardous work
- Ensuring that appropriate animal care and use precautions are identified and communicated to investigators and the IACUC
- Reviewing work using hazardous materials in animals or genetically engineered animals prior to IACUC approval
- Providing guidance to the Ohio State research community regarding proper acquisition, handling, transfer, and disposal of potentially hazardous or regulated biological materials.

F. University Radiation Safety Committee

The University Radiation Safety Committee (URSC) has the following responsibilities:

- Oversight of radiation generating devices (including x-rays, nuclear medicine studies, DEXA scans, CT scans)
- Oversight of and ensuring compliance with the radiation safety program
- Establishment of university policies consistent with Ohio Department of Health and federal regulations
- Ensuring that the appropriate use precautions are identified and communicated to investigators and the IACUC

G. Office of Legal Affairs

The Office of Legal Affairs provides the IACUC, Office of Responsible Research Practices, AV, IO, and other components of the ACUP with counsel on an as needed basis, primarily on matters related to state laws, cooperative agreements, noncompliance, conflicts of interest, and contractual issues in animal research.

H. Office of Sponsored Programs

The Office of Sponsored Programs is responsible for overseeing and coordinating sponsored research at The Ohio State University to support the university’s educational and research objectives and the academic plan. OSP staff act as the interface between Ohio State investigators and sponsors and are responsible for ensuring that proposals, budgets, and contracts comply with federal and state laws, sponsor guidelines, and university policy. In support of the ACUP, OSP staff are responsible for verifying that an IACUC protocol is approved prior to grant award and working with the ORRP staff and IACUC to ensure congruency between sponsored research agreements and IACUC approved research.
I. Office of Research Compliance

The Office of Research Compliance supports and promotes ethical research practices at The Ohio State University. The ORC serves the Ohio State research community by coordinating institution-wide research compliance policy development and by partnering with researchers so that the university is compliant with federal, state, and local laws and regulations and university policies. In direct support of the ACUP, ORC staff provide support in instances and investigations of noncompliance and maintain the university’s anonymous reporting line for reports involving alleged unethical behavior or inappropriate activity that violates the university’s established policies.

J. Conflict of Interest Advisory Committee

The Conflict of Interest Advisory Committee (COIAC) reviews financial interests that are disclosed through annual reports and during the IACUC submission and review processes, discusses potential management plans for eliminating or managing such conflicts, and addresses conflict of interest related issues, policies, and procedures. Recommendations resulting from COIAC review of conflicts involving animal research are communicated to the IACUC, including any proposed management plans. The IACUC has final authority regarding approval of research involving a potential conflict of interest. Following its evaluation, the IACUC will inform the investigator and COIAC of its determination.

K. Quality Improvement Program

The quality improvement activities include education, investigator outreach, and post-approval monitoring. All components of the Animal Care and Use Program have a responsibility to ensure a quality program. Areas for improvement may be identified during the semi-annual program review and inspection, through performance problems identified by the AV or animal care staff, or as a result of specific quality improvement activities conducted by the ORRP staff. Data obtained from monitoring and compliance activities are used by the IACUC to revise existing guidance, make recommendations to the IO, and direct future educational efforts.

L. Accreditation

To affirm that the Animal Care and Use Program is in compliance with applicable federal regulations and state laws, as well as institutional and academic best practices, The Ohio State University will maintain accreditation of its ACUP through the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). AAALAC accreditation is renewed every three years.