



ANIMAL CARE AND USE PROGRAM

I. Purpose

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

II. Mission Statement

The mission of the ACUP is to promote the proper care and use of vertebrate animals in activities conducted on behalf of the university by adhering to the Public Health Service Policy, *Guide for the Care and Use of Laboratory Animals*; *Animal Welfare Act*; *Guide for the Care and Use of Agricultural Animals in Research and Teaching*; and other applicable regulations.

III. Scope of the Animal Care and Use Program

The ACUP is defined as providing oversight for the research, testing and teaching activities conducted by and at the Institution that have a direct impact on the well-being of animals, including animal and veterinary care, policies and procedures, personnel and program management and oversight, occupational health and safety, Institutional Animal Care and Use Committee (IACUC) functions, and animal facility design and management.

IV. Program Management Responsibility and Authority

Effective leadership in and collaboration among the three federally mandated components (Institutional Official (IO), Attending Veterinarian (AV), and the IACUC) are necessary. A Program that establishes a balance among these has the best chance of efficiently using resources while attaining the highest standards of animal well-being and scientific quality. Communication of activities between these components as well as other support units in the ACUP is necessary to ensure efficient ACUP operation. The following outlines the roles, authorities, and responsibilities of each component of the ACUP at The Ohio State University.

A. Institutional Official

The IO for the university's ACUP is the Vice President for Research, appointed by the President of The Ohio State University and reports to the Executive Vice President for Enterprise for Research, Innovation, and Knowledge (ERIK). The IO bears the ultimate responsibility for the Program, although overall Program direction is a shared responsibility among the IO, AV, and IACUC. The IO has the responsibility and authority for:

- Resource planning and ensuring alignment of Program goals of high quality animal care and use with the institution's mission;

- Communicating the importance of animal welfare across The Ohio State University;
- Assuming the role of providing the Assurance for the ACUP 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 ensure the Program's overall effectiveness;
- Appointing individuals to the IACUC and ensuring that these individuals are protected from coercion or undue influence while serving in this capacity;
- Appointing a Chair and Vice-Chair to provide leadership to the IACUC;
- 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; and
- Communicating with and advising other senior administrative officials on ACUP issues as necessary.

B. Institutional Animal Care and Use Committee

The IACUC has the responsibility for the assessment and oversight of the Institution's Program components and facilities. The IACUC is comprised of at least 5 members that meet specific criteria described in federal regulations, including an individual with scientific experience, a veterinarian with designated program responsibilities, a non-scientist and a non-affiliated individual representing community interests. To fulfill its oversight responsibilities, the IACUC has the responsibility and authority to:

- Review and approve or require modifications to secure approval, or disapprove proposed animal use (i.e. protocol review) and significant changes to animal use;
- Conduct regular inspections of facilities and animal use areas;
- Review the overall Program and assess animal care and use;
- Establish a mechanism for receipt and review of concerns involving the care and use of animals at the Institution;
- Evaluate ethical merit as it relates to the welfare and use of the 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;
- Establish protocol and amendment review processes as described by federal regulations and guidance;
- Develop policies for the use of animals at The Ohio State University;
- Solicit input from stakeholders in the ACUP regarding ACUP operations;
- Make written recommendations to the IO regarding any aspect of the Program;
- Ensure that an occupational health and safety program is in place for individuals working with or regularly exposed to animals; and
- Verify that IACUC activities are compliant with regulatory requirements and OSU policies (records retention and disposal).

Note: Proposals approved by the IACUC may be subject to further appropriate review and approval by officials of the Institution. However, 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.

C. Attending Veterinarian

The Attending Veterinarian is responsible for the health and well-being of all animals used at the institution for research, teaching, agricultural, or clinical studies. The AV 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 has the responsibility and authority for:

- Managing the program of veterinary care, environmental enrichment, and zoonotic disease prevention;
- Overseeing other aspects of animal care and use such as husbandry and housing to ensure that the ACUP complies with the regulations;
- 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;
- Staying abreast of current regulatory requirements as they relate to the ACUP at The Ohio State University;
- Serving 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;
- Communicating program issues including facility 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;
- Assisting institutional health officials to establish and monitor an occupational health program including biohazard control policies/procedures for ACUP activities and personnel;
- Providing veterinary consultation during protocol development for procedures that may cause more than momentary or slight pain or distress to animals; and
- Helping to ensure animals are not used for multiple major surgeries without IACUC approval.

V. Principal Investigator Responsibilities

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

- Obtain IACUC approval prior to conducting animal use activities
- Ensure that all personnel involved in animal use are listed on the applicable IACUC protocol prior to initiating work with animals
- Ensure that all personnel in their laboratory are trained in and familiar with the conduct of activities as described in the IACUC protocol
- Promote proper animal care and handling of animals in their studies

VI. 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 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 report to the Vice President for Research include the IACUC Support Office, University Laboratory Animal Resources (ULAR), Office of Sponsored Programs (OSP), and Office of Research Compliance (ORC).

B. IACUC Support Office

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

- Receiving and screening of all protocols submitted for IACUC review;
- 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 that 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;
- Serving as the point of authority on IACUC protocol review processes;
- Facilitating post-approval monitoring, 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 offices 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; and
- Providing administrative support to the Institutional Biosafety Committee (IBC), which is an ancillary component of the ACUP.

C. Dedicated ACUP Housing Facilities

Dedicated animal housing facilities support 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, Agricultural, and Environmental Sciences facilities including Ohio Agricultural Research and Development Center (OARDC) and Agricultural Technical Institute (ATI) in Wooster OH, OARDC outlying agricultural research stations, Stone Laboratory, and Columbus campus animal units. Personnel overseeing 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 of the regulatory requirements and animal health may be impacted
- Notifying the AV staff when veterinary care is 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 on a regular basis 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), Occupational Health and Wellness, and Student Health Services.

OEHS is responsible for:

- Evaluation of the occupational risk for animal users as needed
- Conducting Hazard Assessment reviews for all Principal Investigator's using hazardous agents 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 module as part of the animal care and use training

Occupational Health and Wellness 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 bio-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
- Reviewing work using radioactive materials in animals prior to IACUC approval
- 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, 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 IACUC Support Office 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 and manages the financial conflict of interest program. 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.

J. Conflict of Interest Approval Committee

The Conflict of Interest Approval Committee (CAC) 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. The results of a CAC review of conflicts involving clinical research studies involving animals, including any proposed management plans are communicated to the investigator and as needed to the Institutional Official.

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 IACUC Support Office 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.

VIII. Accreditation

To affirm that the Animal Care and Use Program is committed to responsible animal care and use and is in compliance with applicable federal regulations and state laws, as well as institutional and academic best practices, The Ohio State University maintains accreditation of its ACUP through AAALAC, International. AAALAC is a voluntary, private, nonprofit accrediting organization. Accreditation is reviewed every three years.