

Oklahoma State University Policy and Procedures

CARE AND USE OF ANIMALS IN RESEARCH, TESTING, AND TEACHING	1-0505 GENERAL UNIVERSITY January 2022
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PURPOSE

1.01 The purpose of this policy is to formalize the obligation of Oklahoma State University (OSU) to adhere to laws, regulations, and regulatory agency standards pertaining to the care and use of live, non-human vertebrate animals involved in research, research training, teaching, and testing activities. The University recognizes the significance of using animals to fulfill its teaching, research, and service missions and acknowledges the accompanying ethical obligation to advance knowledge for the benefit of society. As such, the University accepts responsibility for the humane care and use of live, non-human vertebrate animals in all activities at OSU. Toward this effort, the University has established Institutional Animal Care and Use Committees (IACUCs), which are mandated by the Animal Welfare Act (AWA) and the Health Research Extension Act (HREA). OSU IACUCs serve as self-regulating, institutional bodies charged with federally mandated oversight responsibilities for the proper care, use, and humane treatment of live, non-human vertebrate animals.

1.02 This policy is established to ensure:

- A. compliance with applicable laws, regulations, and regulatory agency standards,
- B. compliance with applicable University policies and funding agency requirements, and
- C. ethical care and humane use of live, non-human vertebrate animals at OSU.

Federal Laws and Regulations

2.01 The Animal Welfare Act (AWA) of 1966 (Public Law 89-544), including implementing regulations and subsequent amendments, established standards for the care, use, and transportation of animals, as defined in the AWA. The standards were originally promulgated, and are periodically revised, by officials of the United States Department of Agriculture (USDA). Certain OSU campuses are subject to AWA regulations and are required to register facilities with the USDA for activities involving animals, as defined in the AWA. In accordance with the AWA, these campuses are required to operate an animal care and use program which includes a duly constituted IACUC. AWA regulations cover OSU campuses using USDA-regulated animals in research, research training, teaching, and experiments (e.g., testing). OSU campuses subject to the AWA are required to submit an annual report of animal usage to the USDA.

2.02 Public Health Service Policy on Humane Care and Use of Laboratory Animals implements the Health Research Extension Act of 1985 (Public Law 99-158). To receive funding from a Public Health Service (PHS) agency or National Science Foundation (NSF), an institution must file an

Animal Welfare Assurance with the National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW), which is responsible for monitoring compliance with the PHS policy. No PHS support for an activity involving a live, vertebrate Animal will be provided to an individual unless said individual is affiliated with or sponsored by an institution which assumes responsibility for compliance with the PHS Policy on Humane Care and Use of Laboratory Animals (PHS policy). OSU campuses receiving funding, including grants, contracts, or cooperative agreements, from the PHS or NSF for activities involving live, vertebrate Animals must abide by the PHS policy and have an Animal Welfare Assurance on file with the PHS. OSU campuses receiving funding from PHS entities and/or the NSF are required to follow the most recent edition of the *Guide for the Care and Use of Laboratory Animals* (the *Guide*.) or the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* (the *Ag Guide*). In accord with federal law, the Chief Executive Officer (CEO) of an institution possessing an Animal Welfare Assurance, serving as the Institutional Official (IO), is responsible for 1) oversight of the animal care and use program and 2) appointing members of an IACUC. The law gives the CEO the option to delegate this authority in writing.

Statement of Principles

3.01 OSU is committed to the highest standards of animal care and use.

3.02 The use of Animals, as defined in Section 4.01 of this policy, by OSU scientists and educators, places moral, legal, and ethical responsibilities on the University. Individual faculty members and other employees, as well as students, are obligated to use Animals with sensitivity (i.e., avoiding all unnecessary pain, unnecessary distress, or inappropriate use) and comply fully with all laws, regulations, standards, and University policies pertaining to the care and use of Animals.

3.03 All OSU animal programs and facilities will be maintained and operated in accordance with applicable federal, state, and local laws, regulations, and regulatory standards.

3.04 OSU adheres to the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training.

Definitions

4.01 *Animals*: Any living, non-human, vertebrate animal (i.e., amphibians, birds, fish, mammals, and reptiles) used or intended for use in research, research training, teaching, and testing, except for:

- Animals presented as patients at the College of Veterinary Medicine's Boren Veterinary Medical Teaching Hospital and not otherwise subject to those activities falling within IACUC purview;
- Animals presented as patients at the Oklahoma State University-Oklahoma City Veterinary Technology Program and not otherwise subject to provisions of the Animal Welfare Act; and

- Animals submitted for diagnosis to the Oklahoma Animal Disease Diagnostic Laboratory (OADDL) and not otherwise subject to provisions of the Animal Welfare Act or PHS Policy.

Animals used exclusively for agricultural purposes are exempt from this policy in accordance with §2132 of the Animal Welfare Act. Agricultural Animals used for teaching or being raised or held for future use in teaching, testing, or research are covered under this policy. Regulations for administering the Hatch Act of 1887 require IACUC approval of animal use in agricultural research.

4.02 *Animal Welfare Assurance (Assurance)*: The principal document between an OSU campus and the Public Health Service's Office of Laboratory Animal Welfare (OLAW) defining the relationship between the entities in terms of the campus' animal care and use program. The respective campus IO signs the *Assurance*, which commits the campus to adherence to the PHS policy. An *Assurance* may be renewed every four years.

4.03 *Attending Veterinarian (AV)*: An appropriately trained and qualified individual who is delegated the authority and responsibility to oversee the adequacy of veterinary care in order to ensure proper care and treatment of Animals and to ensure the program meets germane standards. Each AV must be appointed to serve as a voting member of his/her respective campus IACUC.

4.04 *Institutional Animal Care and Use Committee (IACUC)*: Committee responsible for overseeing campus animal care and use programs, monitoring the care, use, and treatment of Animals used in research and instructional activities, and ensuring compliance with applicable laws, regulations, standards; and University policies pertaining to the care and use of Animals.

4.05 *Institutional Officials (IO)*: At OSU campuses with an IACUC, this is the individual who, as a representative of senior administration, bears ultimate responsibility for the Program and is responsible for resource planning and ensuring alignment of Program goals with the institution's mission. The IO is authorized to legally commit the campus to the requirements of the Animal Welfare Act and/or the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS policy). Each OSU IACUC reports to its campus IO.

APPLICABILITY AND SCOPE

5.01 This policy applies to all OSU campuses.

5.02 This policy shall be reviewed and modified as needed at least once every four (4) years.

5.03 OSU IACUCs shall not allow any IACUC member to participate in the initial or continuing review of any project in which the member has a conflict of interest, except to provide information requested by the respective IACUC. For information on financial conflict of interest, see the university's Conflict of Interest in Sponsored Programs Policy (4-0130).

5.04 Each IACUC is responsible for reporting to the appropriate IO any noncompliance with the requirements and determinations of the IACUC. IOs are responsible for making all reports to appropriate federal entities required by law or regulation.

5.05 IACUC Authority

A. OSU IACUCs are authorized to establish policies and procedures designed to foster compliance with applicable regulations, standards, and guidelines pertaining to the care and use of live, vertebrate Animals in research, research training, teaching, and testing activities.

B. Each IACUC reports to the respective OSU campus IO, who is responsible for providing sufficient resources to ensure compliance with regulations and policies germane to activities involving Animals. Therefore, on behalf of the respective OSU campus, the IO will ensure the following:

- IACUC has meeting space and sufficient staff to support the IACUC's mandate including program review, protocol review, and recordkeeping duties.
- The AV has sufficient authority, personnel, equipment, and supplies to maintain an adequate program of veterinary care.
- Sufficient resources are provided to maintain animal facilities in accordance with federal regulations and standards.
- Appropriate training is provided to all personnel involved in the animal care and use program.
- An occupational health and safety program is in place for all personnel with exposure to regulated Animals.

C. On a semiannual basis, each campus IACUC shall provide a report on the animal care and use program and animal facilities to its IO. Reports shall include information on the status of campus compliance with applicable regulations and standards; plans for addressing identified deficiencies; and recommendations regarding the campus' animal care and use program, animal facilities, personnel training, and occupational health program.

5.06 Federally Mandated Functions of the IACUC

A. Review, at least once every six months, the campus' program for humane care and use of Animals in compliance with the *Guide*, and when appropriate the *Ag Guide* and updated versions of the animal standards referenced in *Appendix A* of the *Guide*.

B. Inspect, at least once every six months, all campus' animal facilities in compliance with the *Guide*, and when appropriate the *Ag Guide* and updated versions of the animal standards referenced in Appendix A of the *Guide*, and when appropriate USDA's animal welfare regulations. Inspections may be performed without advance notice to a facility director/manager.

C. Prepare reports of IACUC evaluations and submit reports to the IO.

D. Review concerns involving the care and use of Animals at the campus.

- E. Make written recommendations to the IO regarding any aspect of the campus' animal program, facilities, or personnel training.
- F. Review and approve, require modifications in order to secure approval, or withhold approval of those components of proposed activities related to the care and use of Animals, with subsequent review conducted as required per germane regulations [i.e., once per year (USDA) or once every three years (PHS)].
- G. Review and approve, require modifications in order to secure approval, or withhold approval of proposed significant changes regarding the care and use of Animals in ongoing activities.
- H. Conduct continuing review of each previously approved, ongoing activity at appropriate intervals in accordance with pertinent regulations.
- I. Suspend an activity involving Animals if it determines the activity is not being conducted in accordance with the description provided by the investigator or instructor, as approved by the IACUC, and/or in compliance with pertinent regulations or guidelines (e.g., specifications in IV.C.6 of PHS policy, the AWA regulations, the *Guide*, the *Ag Guide*, updated versions of the animal standards referenced in *Appendix A* of the *Guide*, and the campus' Animal Welfare Assurance). A temporary suspension may be implemented immediately by the AV until the full IACUC can convene to act on the concern. A permanent suspension may be implemented only after review of the matter at a convened meeting of a quorum of the IACUC and a vote for suspension by the majority of the quorum present. The IO, in consultation with the IACUC, shall review the reasons for the suspension, take appropriate corrective action, and report the action with a full explanation to the OLAW and/or the USDA, and any agency or sponsor funding the activity, as appropriate. Activities covered by this policy previously approved by an OSU IACUC may be subject to additional review and approval or disapproval by officials of the University (e.g., President, Vice President for Research, college deans, department heads), as nothing in the federal regulations prohibits an IO, or another authorized official, from unilaterally terminating, suspending, or imposing sanctions on an activity involving live, vertebrate Animals previously approved by an IACUC. Nonetheless, an IO or other campus officials and committees may not approve animal activities or reinstate animal activities previously suspended by an IACUC. Additionally, the institution, its officials, or other institutional committees may not override a decision by the respective OSU IACUC to disapprove a protocol.
- J. Evaluate campus compliance with the PHS policy, the AWA regulations, *The Guide*, the *Ag Guide*, OLAW standards, USDA policies, and University policies.
- K. Report any serious or continuing noncompliance, any serious deviations from provisions of the *Guide*, and any suspension of an IACUC approved activity to the OLAW and the USDA, when appropriate, via the IO.

5.07 Animal Care and Use Protocol Review

- A. Any use of Animals as defined in Section 4.01 shall be approved by the respective campus IACUC in advance of actual use. Consequently, a protocol for the proposed activity must be submitted to the IACUC for review and approval prior to initiating the activity with Animals.
- B. The IACUC may take one or more of the following actions during review of a protocol:
 - 1. Approve a protocol as submitted.
 - 2. Require modifications to the protocol to secure approval.
 - 3. Withhold approval of ACUP.
- C. Evaluations of protocols by the respective campus IACUC shall be guided by the AWA as amended; the PHS policy on Humane Care and Use of Laboratory Animals; the *Guide*; and when appropriate the *Ag Guide* and updated versions of the animal standards referenced in *Appendix A* of the *Guide*; OLAW guidance; USDA policies; as well as current scientific knowledge and community standards.

5.08 Preparation of Reports

- A. Collation of animal welfare data required for regulatory reports shall be the responsibility of the respective campus AV.
- B. Information required for preparation of animal welfare reports shall be furnished to the respective campus AV by those using Animals, without unnecessary delay, and shall ordinarily be submitted within 14 days of receipt of a request for the information.

PROCEDURES

6.01 Organization - Animal Program

- A. Stillwater Campus (OSU-Stillwater)
 - 1. At OSU-Stillwater, all activities involving the use Animals are subject to IACUC oversight and must be approved by the IACUC prior to initiating the activity.
 - 2. The animal program is comprised of a centralized program in the Division of the Vice President for Research, Animal Resources, and investigator-managed satellite facilities. A veterinarian with the title “Director of Animal Resources” who is also the AV shall be responsible for management of the centralized animal program. The AV and Animal Resources’ faculty and staff shall provide or assist in arranging veterinary medical care, including diagnostic services as needed for the care of live, vertebrate Animals. The AV shall also provide training to faculty, staff, and students as requested on animal techniques such as husbandry, restraint, sample collection, anesthesia, euthanasia, etc. The AV reports to the Vice President for Research (VPR) in close coordination with his or her department chair.

3. Veterinarians providing care to regulated Animals other than the AV and Animal Resources faculty and staff are required to coordinate with the AV and Animal Resources' veterinary faculty and staff and provide timely access to complete veterinary records for the care provided.
4. Compliance with animal welfare laws, regulations, regulatory standards, regulatory agency policies, and OSU policies is the responsibility of all individuals (administrators, faculty, staff, and students) involved with the animal care program. Any individual who is aware of a known or potential compliance concern is responsible for reporting their concern through the procedures posted in animal facilities. Periodic monitoring for compliance is performed by the IACUC through the semi-annual inspection process. Compliance monitoring following protocol approval is conducted by the Post-Approval Monitor who reports to the IACUC Manager.
5. Operation of all animal programs shall be consistent with the *Guide*, and when appropriate shall be consistent with the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* (the *Ag Guide*), and/or with nontraditional animal standards as referenced in the *Guide* in *Appendix A*, including updated versions of those referenced standards, and/or USDA regulations when appropriate.

All animal housing outside IACUC approved facilities requires advance approval by the IACUC.

6. The University President/Chief Executive Officer (CEO) has delegated authority for oversight of the IACUC to the Vice President for Research (VPR). This authority grants the VPR responsibility for the campus animal care and use program as the Institutional Official (IO). The IO shall appoint an IACUC which is duly constituted in accordance with applicable federal laws and regulations and is responsible for ongoing oversight of the animal care and use program. The IACUC shall be comprised of representatives of user groups, a practicing scientist experienced in research involving Animals, a non-scientist, a member drawn from the Stillwater community who is not otherwise affiliated with OSU, and the University Attending Veterinarian. The IO will designate the IACUC chairperson and vice chairperson, who must be members of the faculty.
7. All protocols involving the use of transgenic animals or live, vertebrate animals and the use of biohazardous material, as defined by the Institutional Biosafety Policy, are subject to additional review by the Institutional Biosafety Committee (IBC). Both IACUC and IBC approval must be in place prior to the initiation of any covered work.
8. All protocols involving the use of live, vertebrate Animals and the use of radioactive material and/or X-ray devices are subject to additional review by the Radiation Safety Committee (RSC). Both IACUC and RSC approval must be in place prior to the initiation of any covered work.

9. All protocols involving the use of live, vertebrate Animals and the use of Class 3B or Class 4 lasers are subject to additional review by the Laser Safety Officer (LSO). Both IACUC and LSO approval must be in place prior to the initiation of any covered work.
 10. All protocols involving the use of live, vertebrate Animals and the use of chemical hazards are subject to additional review by Environmental Health and Safety (EHS) personnel before the IACUC will approve the ACUP. Consequently, IACUC approval of a protocol involving the use of live, vertebrate animals and chemical hazards is contingent upon EHS approval.
- B. Oklahoma City Campus (OSU-OKC)
1. At OSU-OKC, all activities involving the use of *Animals* are subject to IACUC oversight and must be approved by the IACUC prior to initiating the activity.
 2. Compliance with animal welfare laws, regulations, regulatory standards, regulatory agency policies, and OSU policies is the responsibility of all individuals (administrators, faculty, staff, and students) involved with the animal care program. Any individual who is aware of a known or potential compliance concern is responsible for reporting their concern through the procedures posted in animal facilities.
 3. The OSU-OKC President has ultimate responsibility for the campus animal care and use program and serves as the Institutional Official (IO).
 - a. The IO shall appoint an IACUC which is duly constituted in accordance with applicable federal laws and regulations and is responsible for ongoing oversight of the animal care and use program.
 - b. The IO will designate the IACUC chairperson and vice chairperson, who must be members of the faculty or administration on the OSU-OKC campus.
 - c. The IACUC shall be comprised of representatives to include a veterinarian experienced in research involving Animals, a non-scientist, a member drawn from the local community who is not otherwise affiliated with OSU, and the AV. The AV will serve on the committee as a voting member.
 4. The use of biological agents, radiation, radioactive materials, or lasers with animals may require additional reviews.
 5. The animal program is comprised of a Veterinary Technology (VT) component and a general University component. The VT program director, with the title of Veterinary Technology Department Head, shall be responsible for operation of the VT animal programs.

6. The AV shall be responsible for technical oversight of all animal programs associated with the OSU-OKC campus. The AV shall provide or assist in arranging veterinary medical care, including diagnostic services as needed for the care of live, vertebrate Animals. The AV shall also provide training to faculty, staff, and students as requested on animal techniques such as husbandry, restraint, sample collection, anesthesia, euthanasia, etc. The AV reports to the IO on matters pertaining to animal care.
 7. Evidence of noncompliance shall be reported to the OSU-OKC IACUC Chair and IO, or his/her designee when he/she is not available, in accordance with applicable reporting requirements.
 8. Operation of all animal programs shall be consistent with the most recent version of USDA/APHIS/Animal Care *Code of Federal Regulations (CFR), vol.9, Subchapter A, Parts 1 through 4*; otherwise known as “The Animal Welfare Act” as well as the *Guide* and the *Ag Guide*.
- C. Center for Health Sciences Campus (OSU-CHS)
1. At OSU-CHS, all activities involving the use of *animals* are subject to IACUC oversight and must be approved by the IACUC prior to initiating the activity.
 2. Compliance with animal welfare laws, regulations, regulatory standards, regulatory agency policies, and OSU policies is the responsibility of all individuals (administrators, faculty, staff, and students) involved with the animal care program. Any individual who is aware of a known or potential compliance concern is responsible for reporting their concern through the procedures posted in animal facilities.
 3. The OSU-CHS President has delegated responsibility for the campus animal care and use program to the Director of Regulatory Compliance who serves as the Institutional Official (IO). The IO shall appoint an IACUC which is duly constituted in accordance with applicable federal laws and regulations and is responsible for ongoing oversight of the animal care and use program. The IACUC shall be comprised of representatives of user groups, a practicing scientist experienced in research involving Animals, a non-scientist, a member drawn from the local community who is not otherwise affiliated with OSU, and the AV. The IO will designate the IACUC chairperson and vice chairperson, who must be members of the faculty.
 4. All protocols involving the use of transgenic animals or live, vertebrate animals and the use of biohazardous material are subject to additional review by the IBC. The IBC must approve the use of the biohazardous material or transgenic animals before the IACUC will approve the protocol. Consequently, IACUC approval of a protocol involving the use of transgenic Animals or live, vertebrate Animals and biohazardous material is contingent upon IBC approval.

5. All protocols involving the use of live, vertebrate Animals and the use of chemical hazards, radioactive material and/or X-ray devices are subject to additional review by the Chemical Hygiene and Radioisotope Use Committee (CHRUC) before the IACUC will approve the protocol. Consequently, IACUC approval of a protocol involving the use of live, vertebrate Animals and chemical hazards, radioactive material and/or X-ray devices is contingent upon CHRUC approval.
6. The acquisition of all Animals used on an OSU-CHS research, research training, teaching, and/or testing protocol, including Animals raised in breeding colonies, shall be coordinated with the AV and Animal Facility Management (AFM) prior to placing an order or assigning an animal to a protocol to ensure the planned animal use is in compliance with OSU policy and federal regulations. The number of feral Animals trapped/captured per year shall also be reported to the AV and AFM at least once a year.

REFERENCES

Animal Welfare Act. 1966 (Public Law 89-544).

CFR (Code of Federal Regulations). Title 9 (Animals and Animal Products), Subchapter A (Animal Welfare). Washington, D.C.: Office of the Federal Register.

USDA Animal Care Policies

Guide for the Care and Use of Agricultural Animals in Research and Teaching. 2010 (or current version). The Federation of Animal Science Societies. Champaign. Ill.

Guide for the Care and Use of Laboratory Animals (2010 or current version). Washington, D.C. Institute of Laboratory Animal Resources. National Academy Press.

Health Research Extension Act of 1985 (Public Law 99-158).

National Institutes of Health: Public Health Service Policy on Humane Care and Use of Laboratory Animals. Public Health Service. 1996. Washington, D.C.: U.S. Department of Health and Human Services.

OLAW Guidance Documents

Revised:

February 1978

May 1986

April 2004

May 2011

June 2013

April 2016

January 2022

Approved:

Dr. Boger, May 1986

E-Team, June 2013

E-Team, April 2016

E-Team, January 2022