



Eastern Kentucky University

Policy and Regulation Library

Academic Regulation: 4.4.13ACR

Responsible Office(s): Office of the Provost

Effective: January 26, 2011

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Humane Care and Use of Animals in Research and Teaching Activities

Statement

It is the policy of Eastern Kentucky University to ensure the proper care, use, and humane treatment of animals used in research and teaching activities and to maintain an animal care and use program that is managed in accordance with applicable local, state, and federal laws and regulations. In doing so, the University complies with applicable provisions of the Animal Welfare Act (AWA) and other state and federal statutes and regulations relating to animals. The University is guided by the "United States Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training," and the University's animal care and use program is based on the *Guide for the Care and Use of Laboratory Animals (Guide)*.

This policy is applicable to all research, training, experimentation, biological testing, teaching, and related activities at EKU involving animals, regardless of whether the activities are supported by externally sponsored agreements or University funds. This policy is also applicable to such activities occurring at another institution as a consequence of subgranting or subcontracting from EKU.

Entities Affected

- Deans
- Chairs
- Faculty and staff responsible for animals or participating in activities involving animals
- Students participating in activities involving animals
- Subrecipients participating in activities involving animals
- Sponsored Programs staff
- Institutional Animal Care and Use Committee (IACUC) members

Background

The University acknowledges and accepts responsibility for the humane care and use of animals involved in research, training, experimentation, biological testing, teaching and related activities. As partial fulfillment of this responsibility, the University makes a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this policy as well as all other applicable laws and regulations pertaining to animal care and use.

The University has established an Institutional Animal Care and Use Committee (IACUC), which is qualified through the experience and expertise of its members to oversee the University's animal program, facilities, and procedures. As partial fulfillment of this responsibility, the University relies on the IACUC to represent society's concerns regarding the welfare of animals used in projects associated with the University. The purpose of this policy is to outline the University's accountability with regard to the care and use of animals in research, training, experimentation, biological testing, teaching and related activities. The policy explains the responsibilities of individuals involved in such activities and of the IACUC.

Criteria

The following criteria are requirements for IACUC approval of projects involving animals:

1. The principal investigator has conducted a thorough literature search for options to address the following three elements:
 - a. Reduction (i.e., use of innovative statistical tests/packages requiring fewer animals)
 - b. Replacement (i.e., use of an animal considered lower/lowest on the sentience scale)
 - c. Refinement (i.e., use of minimally invasive or stressful procedures; use of analgesia)
2. The principal investigator has provided written assurance that the activities do not unnecessarily duplicate previous experiments.
3. Procedures involving animals, including use of restraints, will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
4. The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and has provided a written narrative description of the methods and sources used to determine that alternatives were not available.
5. Procedures that may cause more than momentary or slight pain or distress to the animals will:
 - a. be performed with appropriate sedatives, analgesics, or anesthetics, unless withholding such agents is justified in writing by the principal investigator for scientific reasons and will continue for only the necessary period of time;

- b. involve, in their planning, consultation with the attending veterinarian; and
 - c. not include the use of paralytics without anesthesia.
6. Alternatives to animal use have been considered, such as the use of computer models or non-vertebrate species.
 7. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized after the procedure or, if appropriate, during the procedure.
 8. Methods of euthanasia used are in accordance with the American Veterinary Medical Association (AVMA) Panel on Euthanasia (Journal of the American Veterinary Medical Association (JAVMA), 2001, Vol. 218, No. 5, pp. 669-696) unless an alternate method is justified in writing by the principal investigator for scientific reasons and specifically approved by the IACUC.
 9. The animals' living conditions will be appropriate for their species and contribute to their health and comfort. Food or fluid restrictions must be justified in writing by the principal investigator for scientific reasons and specifically approved by the IACUC.
 10. Medical care for animals will be available and provided as necessary by a qualified veterinarian.
 11. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
 12. Activities that involve surgery include appropriate provision for pre-operative and post-operative care of the animals in accordance with established veterinary medical and nursing practices and in compliance with AWA regulations and the *Guide*.
 13. No animal will be used in more than one major operative procedure from which it is allowed to recover unless scientifically justified by the researcher and specifically approved by the IACUC.

Procedures

Selecting the Institutional Animal Care and Use Committee (IACUC)

The ECU IACUC consists of, at a minimum, five members to include: a Veterinarian who is certified in or has training or experience in laboratory animal science and medicine, at least one practicing scientist with experience in research involving animals, at least one member whose primary concerns are in non-scientific areas, and at least one member who is not affiliated with the University in any way other than as an IACUC member and who is not a member of the immediate family of a person who is affiliated. The Director of Sponsored Programs shall also serve as non-voting advisory member. The Associate Vice President for Research shall serve as the Institutional Official responsible for providing IACUC compliance assurances to federal agencies.

Submission of Protocols for IACUC Review

Principal Investigators are responsible for completing the IACUC application form and all applicable attachments and obtaining IACUC approval prior to the initiation of any activity involving animals.

Review and Approval of Protocols

Upon receipt of an IACUC application, Sponsored Programs will assign a protocol number and forward the application to IACUC members for review. In a timely manner, IACUC members will review the protocol and return completed evaluation sheets to Sponsored Programs. Any IACUC member who wishes to do so may request a convened meeting of the full committee prior to the approval of the protocol. If a full committee review is not requested, the protocol will be reviewed via the designated reviewer method. If the IACUC requests additional clarification on any aspect of the application, the principal investigator is responsible for promptly responding to the request prior to the issuance of an approval. If the majority of IACUC members approve the protocol during a convened meeting with a quorum of members present or if designated reviewers approve the protocol unanimously, the Chair will issue an approval letter to the principal investigator.

Amendments to Approved Protocols

Investigators may request IACUC approval to amend previously approved protocols. IACUC approval must be granted prior to the implementation of the changes. Amendment requests shall be submitted in writing to the IACUC and shall include a complete description of the purpose or rationale for the amendment and the specific changes (IACUC Form A). Amendments shall be distributed to IACUC members for review, and any member may request a convened meeting of the full committee to review the request. If a full committee review is not requested, the amendment will be reviewed via the designated reviewer method. If the majority of IACUC members approve the protocol during a convened meeting with a quorum of members present or if designated reviewers approve the protocol unanimously, the Chair will issue an approval letter to the principal investigator.

Continuing Review of Approved Protocols

Protocols will be approved for a period of not more than three years, and all approved protocols are subject to continuing review and must be approved on an annual basis. If no adverse events are noted on the Continuation Review form (IACUC Form C), formal IACUC review is not necessary, and the IACUC Chair may issue the approval notification for the continuation of the previously approved activity. If adverse effects are noted, the continuation protocol will be forwarded to the IACUC for formal review prior to approval. Any changes to the protocol must be submitted as an amendment and may not be implemented until IACUC approval has been granted. If an activity is to continue for more than three years from the date of the initial IACUC approval, a new application must be submitted for review. A final report is required within 30 days of the activity's end date (IACUC Form F).

Review of University's Program for Humane Care and Use of Animals

At least once every six months, the IACUC shall review the University's program for humane care and use of animals using the *Guide* as a basis for evaluation. This review includes an inspection and evaluation of the animal care facilities.

Reporting

The IACUC will submit semi-annual reports of its evaluation of the University's animal care and use program, including its inspection of the animal care facilities to the Institutional Official.

The Institutional Official shall submit annual reports to OLAW. The reports shall include any change in the status of the institution, any change in the description of the University's program for animal care and use, and any changes in IACUC membership. The reports shall also provide notification of the date on which the IACUC conducted its semi-annual evaluations of the institution's program and facilities.

The Institutional Official shall provide prompt notification to appropriate authorities of the circumstances and actions taken with respect to any serious or continuing noncompliance, any serious deviations from the provisions of the Guide, or any suspension of an activity by the IACUC.

Records

The following records related to the use of animals in research and teaching activities shall be maintained by the University:

- Copy of the Assurance of Compliance with Public Health Service (PHS) on Humane Care and Use of Laboratory Animals
- Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations
- Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was granted or withheld
- Records of semi-annual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official
- Records of accrediting body determinations

The University shall maintain IACUC records for a period of three years. Records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC will be maintained for the duration of the activity and for an additional three years following the completion of the activity.

Training

All IACUC members shall complete appropriate training programs as detailed in the University's PHS Assurance. All investigators and other individuals engaging in animal activities are required to complete an appropriate training program prior to initiating any activities involving animals and prior to the IACUC granting approval for protocols submitted for review. IACUC records shall document appropriate training for all investigators and other involved individuals. Training certificates shall be valid for a period of three years, at which time individuals are required to renew their training certifications. In addition, principal investigators are responsible for providing and documenting protocol-specific training for their employees and students who participate in activities involving animals.

Definitions

- **Animal:** Any living vertebrate, excluding humans.
- **Animal Facility:** Buildings, rooms, areas, enclosures and vehicles (including satellite facilities in which animals are housed for more than 24 hours) that are used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation.
- **Animal Welfare Act:** The Act passed by Congress to insure humane care and treatment of animals used in research and during transportation in commerce and to prevent the sale and use of stolen animals.
- **Attending Veterinarian:** Veterinarian who is certified in or has training or experience in laboratory animal science and medicine and serves as a voting member of the IACUC.
- **Euthanasia:** Humane death for an animal accomplished by a method that produces rapid unconsciousness and subsequent death without pain or distress, or a method that utilizes anesthesia produced by an agent that causes painless loss of consciousness and subsequent death.
- **The Guide:** The Guide for the Care and Use of Laboratory Animals
- **IACUC:** Institutional Animal Care and Use Committee: the governing body responsible for overseeing the University's animal care and use program, facilities, and procedures
- **Institutional Official:** The Associate Vice President for Research: the individual with the authority to provide compliance assurances to federal agencies and other for issuing other official documentation on behalf of the University.
- **OLAW:** Office of Laboratory Animal Welfare: The Office of Laboratory Animal Welfare (OLAW) provides guidance and interpretation of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals and monitors compliance with the Policy by Assured institutions and PHS funding components to ensure the humane care and use of animals in PHS-supported research, testing, and training.
- **PHS Assurance:** Public Health Services Assurance: The University's animal welfare assurance, which describes the animal care and use program at the University and has been approved by the PHS
- **Quorum:** A simple majority of the voting members of the IACUC
- **Subrecipients:** Institutions to whom the University subgrants or subcontracts on a sponsored project

Responsibilities

- Attending Veterinarian
 - Participate in semi-annual review of University's program for humane care and use of animals
 - Be on call for the University's animal care program, including the provision of treatment in emergency situations
 - Maintain a written veterinary care program that addresses, at a minimum, the following components:
 - a. Preventive medicine
 - b. Surveillance, diagnosis, treatment, and control of disease
 - c. Management of protocol-associated disease or disability
 - d. Anesthesia and analgesia
 - e. Surgery and postsurgical care
 - f. Assessment of animal well-being
 - g. Euthanasia
 - Be available to serve as a consultant during protocol planning and implementation
 - Provide medical care to specified animal subjects in need of medical attention or approve medical care for designated species
 - Serve in an advisory capacity as a voting member of the IACUC in the areas of laboratory animal medicine and care and the appropriate use of animals in research

- Department Chairs
 - In applicable academic areas, facilitate faculty awareness of the animal care and use policy and IACUC submission procedures
 - Review IACUC protocols from faculty within their departments and recommend them for submission to the IACUC

- Division of Sponsored Programs
 - Provide administrative support to the IACUC, including the processing of application and reporting forms for review by the IACUC and the maintenance of applicable records
 - Ensure that activities proposed for external support have been reviewed and approved by the IACUC prior to the release of any awarded funds
 - Provide support for the review and investigation of animal care and use concerns and complaints from all sources
 - Provide support to the Institutional Official in preparing annual reports to OLAW
 - Provide support to the Institutional Official in promptly notifying appropriate authorities of the circumstances and actions taken with respect to any

serious or continuing noncompliance, any serious deviations from the provisions of the Guide, or any suspension of an activity by the IACUC.

- Graduate Thesis Advisors
 - Maintain current training for the care and use of animals from an educational program acceptable to the IACUC
 - Provide guidance to advisees on the submission of protocols for IACUC review
 - Ensure that students participating in animal activities have been properly informed of any risks and have received training on animal care and safety issues related to the activity
 - Monitor and supervise graduate students to ensure the appropriate care and use of animals at all times
 - Ensure that IACUC reporting requirements are followed for each protocol

- Institutional Animal Care and Use Committee
 - EKU's Institutional Animal Care and Use Committee (IACUC) is responsible for overseeing the institution's animal program, facilities, and procedures. The following are specific responsibilities:
 - Complete semi-annual review of University's program for humane care and use of animals
 - Inspect the University's animal facilities at least once every six months
 - Prepare reports of the IACUC evaluations and submit to Institutional Official describing the nature and extent of the institution's adherence to the Guide and the PHS Policy
 - Make written recommendations to Institutional Official regarding any aspect of the University's animal care and use program, facilities, or personnel training based on the semi-annual review of the program and/or other IACUC deliberations
 - Review and approve, require modifications to, or withhold approval of activities related to the care and use of animals
 - Review and approve, require modifications to, or withhold approval of proposed changes to previously approved activities
 - Notify investigators and the University in writing of its decision to approve or withhold approval of protocols for activities or changes to previously approved activities
 - Conduct continuing review of each previously approved activity on an annual basis and a complete review at least once every three years
 - Review and investigate animal care and use concerns and complaints from all sources
 - Suspend activities for failure to comply with the Animal Welfare Act, the Guide, or the University's policy

- Institutional Official
 - Facilitate the review and investigation of animal care and use concerns and complaints from all sources
 - File annual reports with OLAW
 - Provide prompt notification to appropriate authorities of the circumstances and actions taken with respect to any serious or continuing noncompliance, any serious deviations from the provisions of the Guide, or any suspension of an activity by the IACUC.

- Principal Investigators
 - Prepare protocol and submit to the IACUC for approval prior to the initiation of any activity involving animals
 - Obtain prior approval for the use of facilities in the Department of Biological Sciences animal quarters
 - Maintain current training for the care and use of animals from an educational program acceptable to the IACUC
 - Provide protocol-specific training to all personnel and students participating in activities involving animals
 - Adhere to applicable federal, state and University policies and guidelines in the conduct of all activities involving animals
 - Notify the IACUC immediately and seek prior approval for any proposed changes to approved protocols
 - Complete, on an annual basis, the continuing review form for ongoing projects
 - File a final report with the IACUC within 30 days of the activity's end date

Violations of the Policy

Individuals who fail to comply with this policy may face consequences imposed by the IACUC. Such ramifications include project suspension or termination and ineligibility to publish research results of activities for which prior IACUC approval was not granted, including professional publications. Student theses and dissertations subject to this policy will not be published in the institutional archive or other online repositories without IACUC approval.

Statutory or Regulatory References

- [The Animal Welfare Act](#)

Relevant Links

- [The Guide for the Care and Use of Laboratory Animals](#)
- [Institutional Animal Care and Use Committee \(IACUC\) Application Materials](#)
- [Office of Laboratory Animal Welfare](#)

- [United States Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training](#)
- [United States Department of Agriculture's Animal Welfare Information Center](#)

Regulation Adoption Review and Approval
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Regulation Revised

<u>DATE</u>	<u>ENTITY</u>	<u>ACTION</u>
October 18, 2024	University Counsel	Editorial Revision
January 26, 2011	Board of Regents	Adopted
December 13, 2010	President Whitlock	Approved
November 3, 2010	Provost Council	Approved
September 20, 2010	Faculty Senate	Approved

Regulation Issued

<u>DATE</u>	<u>ENTITY</u>	<u>ACTION</u>
June 7, 2010	President Whitlock	Extended Interim Expiration Date
June 4, 2009	President Whitlock	Adopted Interim