

Care and Use of Animals in Research

Academics and Research – Research

EWU Policy 302-03

Authority: EWU Board of Trustees

Effective: May 10, 2019

Proponent: Provost and Vice President for Academic Affairs

Purpose: This policy prescribes standards for the ethical treatment, and use of animals in all research, testing and instruction conducted at Eastern Washington University.

History: This policy revises the previous version adopted by the EWU Board of Trustees on June 22, 2011. It was approved by the Board of Trustees on May 10, 2019.

Scope: This policy applies to all faculty, staff, and students of EWU, and to any persons engaged in teaching or research activities that involve live vertebrate animals at Eastern Washington University.

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CHAPTER 1 – ANIMAL CARE AND USE

1-1. Introduction

The following general guidelines and principles are applicable to all research, laboratory instruction, or research training conducted at or sponsored by Eastern Washington University (EWU), involving the use of live vertebrate animals.

1-2. Authority & Responsibilities

a. EWU follows the provisions of the Animal Welfare Act, regulations of the U.S. Department of Agriculture and the Health Research Extension Act of 1985, Public Law 99-158 (HREA) for proper care and treatment of animals. In addition, externally funded activities will abide by specific regulations of the granting agency.

b. EWU's President appoints the Provost or designee as the Institutional Official (IO). The IO represents senior administration and bears ultimate responsibility for the Animal Care and Use Program. The IO has authority to support and provide resources to ensure compliance with federal and state requirements.

c. As mandated by the Animal Welfare Act, the University has established an Institutional Animal Care and Use Committee (IACUC), which is appointed by the IO, to assess and review the University's animal program, facilities, and procedures. Any research, laboratory instruction, or research training conducted at or sponsored by EWU that involves the use of live vertebrate animals must be approved in advance by IACUC as set forth in chapter two below.

d. EWU has a consulting veterinarian available to provide oversight and consultation as needed in accordance with the terms of this policy.

e. The director of animal facilities is responsible for the general care, use, and management of EWU's animal care facilities.

1-3. Adoption of U.S. Government Principles for the Humane Treatment of Animals

Any research, laboratory instruction, or research training involving the use of live vertebrate animals must comply with all applicable federal laws, regulations, guidelines, and policies, including, but not limited to:

a. Procedures involving animals should be designed and performed with due consideration of their relevance to human and animal health, the advancement of knowledge, or the good of society.

b. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered.

c. Projects using live animals must be conducted to avoid or minimize discomfort, stress and pain to the animals consistent with sound scientific practices. In general, investigators should be cognizant that procedures that cause pain or distress in human beings may cause pain or distress in other animals. Procedures that may cause an animal more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

d. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Animals should be housed in a manner that facilitates the expression of species-typical behavior and minimizes stress induced behaviors. The housing, care, and feeding of animals must be in accordance with the National Institute of Health's Office of Laboratory Animal Welfare (OLAW) regulations, and overseen by properly trained

staff who are supported and affirmed by a qualified veterinarian.

e. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.

f. An investigator may request an exception from a particular requirement of this section from IACUC. The IACUC must consider the federal principles before granting an exception and shall not grant an exception. Such exceptions should not be made solely for the purposes of teaching or demonstration.

1.4 Use of Live Vertebrate Animals in Teaching and Research Activities

a. IACUC approval must be obtained prior to the start of any project using live vertebrate animals for research, laboratory instruction, or research training, and for any field project using vertebrate animals in which the proposed activity is likely to alter, influence the activity of the study animals, or that involves capture, handling, confinement, transportation, anesthesia, euthanasia, or invasive procedures. This applies to all projects which are conducted through or on the EWU campus or affiliate, associated with any teaching degree program at EWU, or financed by any internal or external funding administered by EWU.

b. All research, research training, tests and experiments involving live vertebrate animals must have an IACUC approved protocol on file. Protocols will include a detailed description of the proposed use of animals in research and provide a detailed rationale and purpose for their proposed use.

c. Protocols are reviewed in accordance to the following guidelines:

1. Protocols must describe the species and number of animals requested.
2. The availability or appropriateness of the use of less invasive procedures
3. Projects must describe the use of appropriate sedation to avoid or minimize unnecessary discomfort, distress, or pain to animals. Procedures that may cause more than momentary or slight pain or distress to animals must: continue only for the necessary period of time, be performed with appropriate sedatives, analgesics, or anesthetics unless withholding such agents is justified for scientific reasons; involve consultation with the attending veterinarian; not include the use of paralytics without anesthesia; and allow euthanasia to avoid severe or chronic pain or distress.

4. Projects must not unnecessarily duplicate previous work. Necessary duplication may include teaching lab activities, student research projects that provide significant opportunities for learning, and research projects where duplication is an essential part of the project.
5. Animals' living conditions must be appropriate for their species.
6. Medical care for animals must be available and provided as necessary by a qualified veterinarian.
7. Individuals conducting procedures on animals must be appropriately qualified and trained in those procedures.
8. Projects involving surgery must include provision for pre-operative and post-operative care of the animals in accordance with established veterinary practices.
9. No animal may be used in more than one major operative procedure from which it is allowed to recover, unless: it is justified for scientific reasons; it is required as routine veterinary procedure or to protect the health or well-being of the animal; or in other special circumstances.
10. Protocols must include a description and rationale of anticipated or selected endpoints.
11. Protocols must also include method of euthanasia, plan for disposition of animals, including planning for care of long-lived species after study completion if applicable. Euthanasia must involve humane expiration of an animal accomplished by a method that produces rapid unconsciousness and subsequent death without evidence of pain or distress, or a method that utilizes anesthesia produced by an agent that causes painless loss of consciousness and subsequent death.

1-5. Facilities Oversight and Management

a. EWU has a consulting veterinarian available to provide oversight and consultation as required by this policy. In addition, the animal facilities director is responsible for daily animal care and use and management of animal research facilities.

b. Research projects using live animals must be performed by or under the supervision of a qualified scientist or veterinarian and in accordance with an approved protocol. Faculty sponsors are responsible for ensuring that student projects are conducted in accordance with the approved Protocol and in accordance with federal regulations. Graduate students may work with live vertebrate animals independently and with indirect faculty supervision after they have received training consistent with Section 1-6 of this Policy. Students at any level are permitted to perform procedures on deceased animals. If procedures are to be done outside regularly scheduled class times, the instructor must provide assurance that students are supervised and/or are adequately trained consistent with Section 1-6 of this policy.

c. The animal facilities director or designated animal caretaker may not provide live vertebrate animals to instructors or investigators unless there is a currently approved Protocol. The animal facilities director will maintain a file of all approved animal care and use protocols within the facilities to ensure compliance.

d. The Animal Care and Use Program will adhere to the University's occupational health and safety program to ensure the safety of personnel and students working in laboratory animal facilities and who have frequent contact with animals.

1-6. Training

The Animal Welfare Act regulations, 9 C.F.R. section 2.32, specifies that it is the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians and other personnel involved in animal care, treatment, and use are qualified to perform their duties. As such, all such personnel must receive adequate training and instruction as follows:

a. All personnel involved in the care and use of animals must be adequately trained and/or qualified in basic principles of laboratory animal science to help ensure high quality science and animal well-being. Training must be made available with sufficient frequency to ensure that individuals are adequately trained.

b. Training must include guidance in at least the following areas: humane methods of animal maintenance and experimentation; methods for limiting animal use and minimizing animal distress; proper use of anesthetics, analgesics, and tranquilizers; methods for reporting deficiencies in animal care and treatment; methods for euthanasia; and utilization of library resources on methods of animal care and use, alternatives to the use of live animals that could prevent unintended and unnecessary duplication of research involving animals (e.g. previous experimental results with live animals), and the requirements of the Animal Welfare Act. The specific components of the training program presented to each individual including students are dependent on the nature of that individual's activities.

c. All personnel who participate in federally funded research will be required to take the appropriate training modules that are offered through the Collaborative Institutional Training Initiative (CITI).

1-7. The Office of Grant and Research Development

To ensure compliance, the Office of Grant and Research Development (OGRD) is the responsible unit that coordinates IACUC activities.

The OGRD coordinates and schedules meetings and provides member notification, maintains and distributes attendance records, minutes of committee activities and deliberations and inspection records.

A database is maintained within the OGRD that includes all IACUC records of the animal care and use program. Records include but are not limited approved protocols, and any modifications or suspensions as well as expired protocols, facility reviews and inspection reports.

The OGRD also maintains training records for Federal awards.

The Office is also responsible, with collaboration with the IACUC, chair to complete all required reports and submit them to the proper authority. The OGRD also ensures that all reports are submitted to the IO.

CHAPTER 2 – INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

2-1. Membership

The IACUC is responsible for the assessment and oversight of EWU's Animal Care and Use program, including routinely evaluating the program components and facilities.

The IACUC is composed of at least five members, including one veterinarian with training or experience in laboratory animal science and medicine with direct or dedicated program responsibility for activities involving research animals at the University; one practicing scientist; one nonscientist; and one person not affiliated with the institution and not an immediate family member of a person who is affiliated with the facility. Members must be qualified through experience and expertise to assess the animal program, facilities, and procedures.

Each spring, the IACUC members will elect a chairperson at the for the next academic year. The chairperson must be an employee of EWU. The term of office is one year. There is no limit to the number of terms the chairperson may serve.

2-2. Role

At least twice a year, the IACUC will:

- a. Review EWU's animal care and use program. Utilizing the OLAW standard checklist, the IACUC performs an operational review that examines the animal care and use program, disaster planning and emergency procedures, IACUC protocol review, membership and functions, training, records and reporting requirements, veterinary care, personnel qualifications and training, occupational health and safety of personnel, personnel security, and investigating and reporting of animal welfare concerns;
- b. Perform an inspection of all animal facilities. All facilities and laboratories are inspected utilizing the OLAW standard checklist to ensure compliance with all federal and state laws and

- regulations, occupational health and safety and animal wellbeing, as well as adherence to reviewed protocols;
- c. Preparing reports of IACUC evaluations and submit them to the IO. Reports must:
1. Be updated at least once every six months upon completion of the required semiannual evaluation;
 2. Be maintained in accordance with records retention requirements and made available to OLAW or the United States Department of Agriculture upon request;
 3. Contain a description of the nature and extent of the institution's adherence to the regulations of the United States Department of Agriculture, OLAW's Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, the *Guide for the Care and Use of Laboratory Animals* (8th ed.), and this policy. It must describe any departures from the policies and the *Guide*.
 4. Distinguish between significant and minor deficiencies. A significant deficiency is one that, in the judgment of the IACUC and the IO, may be a threat to the health and safety of animals or humans. If program or facility deficiencies are noted, the report must contain a plan to correct each deficiency;
 5. If facilities are accredited by another accrediting body recognized by PHS, the report should identify those facilities as such;
 6. Review concerns involving the care and use of animals;
 7. The IACUC will make recommendations to the IO regarding the animal program, facilities, or personnel training;
 8. Review and approve, require modifications in, or withhold approval of proposed activities related to the care and use of animals; review and approve, require modifications, or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities;
 9. Suspend ongoing activities involving animals if the activities are not being conducted in accordance with the description of that activity provided by the user and approved by the IACUC.
- d. If a deficiency is found during an inspection, the IACUC must specifically identify it and set a specific compliance date. The deficiency must be designated as significant or minor. The IACUC will decide by a majority vote if the deficiency is significant. A second inspection must be conducted soon after the compliance date. If the deficiency has not been corrected by the compliance date the IACUC must notify, through the IO, OLAW, APHIS and any federal agency which is funding the project in writing within 15 business days.

- e. An inspection report must be signed by a majority of IACUC members. The inspection report is placed within the Office of Grant and Research Development, and copies are distributed to the IO and the animal facilities director.

Any IACUC member may add a minority view to the inspection report. If any minority views are added, they must be included in the final report.

2-3. Review of Protocols by the IACUC

a. Approvals

1. As stated in 1-4 (a), IACUC approval must be obtained prior to the start of any project using live vertebrate animals for research, laboratory instruction, research teaching, or testing, and for any field project in which the proposed activity is likely to alter, influence the activity of the study animals, or that involves capture, handling, confinement, transportation, anesthesia, euthanasia, or invasive procedures involving animals.
2. A Protocol Review Form (PRF) must be submitted to the IACUC for each project involving vertebrate animals. The PRF must address the criteria outlined in Section 1-4(c) and include justification for the selection of the methods used on animals, and the method of euthanasia if applicable.

b. Approval Process

1. Prior to a review, each IACUC member will be provided with the proposed research projects that will be reviewed. Written descriptions of research projects that involve the care and use of animals shall be available to all IACUC members, and any member of the IACUC may obtain, upon request, full committee review of those research projects.
2. Generally, protocols are reviewed on an ongoing basis using a designated member review (DMR) process unless a member calls for a full committee review (FCR). The IACUC Chair will appoint members to review proposed research projects. The DMR will consist of a primary reviewer, a scientist, a non-scientist member and the IACUC Veterinarian.
3. If full committee review is requested, approval of those research projects may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present.
4. No member may participate in the IACUC review or approve of a research project in which the member has a conflict of interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflict of interest contribute to the constitution of a quorum.

5. During the review process, IACUC members may request revisions or modifications from the investigator to ensure that the protocol is appropriate.
6. When IACUC members, including the veterinarian, have approved a protocol and there are no calls for a full committee review, the approved protocol is made available to the investigator and then research may begin.
7. The IACUC may defer or table the review of a proposed protocol if it requires further clarification, if committee members with certain expertise are not present, if the IACUC wish to seek external consultation, or if any other reason that prevents the IACUC from completing a review.
8. The IACUC may invite consultants to assist in the review of complex issues arising during the review of proposed activities. Consultants may not approve or withhold approval, prevent the IACUC from conducting the review and may not vote unless they are members of the IACUC.
9. Applications and proposals that have been approved by the IACUC may require additional review and approval by EWU officials. However, those officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC.

c. Withhold Approval

1. If the IACUC decides to withhold approval of a project, it must send written notification to the instructor or principal investigator which includes a statement of the reasons for the decision, and gives the instructor/investigator an opportunity to respond in person or in writing.
2. The IACUC may reconsider its decision, with documentation in IACUC minutes, in light of the information provided by the instructor/investigator.

d. Notification

The IACUC will notify investigators and the OGRD in writing of its decision to approve, or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval. If the IACUC decides to withhold approval of an activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

e. Suspension

1. The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the *Guide*, the institution's Assurance, or IV.C.1.a.-g. of PHS Policy or if it determines that the project is not being conducted in

accordance with the description of that project provided by the user and approved by the IACUC.

2. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and the suspension must be approved by a vote of a majority of the quorum present.
3. If the IACUC suspends an activity, the IO in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW, APHIS and any federal agency funding the project promptly if it has not been approved by the IACUC.

f. Modifications

1. Changes to an approved protocol may be made after it is approved by IACUC. All changes or modifications must be approved before they may be implemented. Some changes may require either an administrative update, consultation with the IACUC Veterinarian and/or IACUC Chair.
2. Protocols requesting significant changes to an approved protocol must be submitted to the IACUC for a review and must be approved before the changes occur. Significant changes may include but are not limited to: changes in the objectives of the study, changes in personnel, increase or decrease in animal numbers, changes in animal housing, changes in species or approximate numbers of animals used, changes in the degree of invasiveness of a procedure or discomfort to animals, changes in anesthetics or analgesia, methods of euthanasia, or type or number of procedures performed on animals.

g. Post Approval Monitoring and Review of Protocols

PHS Policy requires a de novo review of animal protocols at least every three years. An annual review is required for animal protocols that utilize USDA covered species. The annual review may include but not limited to annual monitoring and will include reporting by the faculty/investigator.

Ongoing protocols and activities will be checked periodically (at least annually) and reviewed for compliance and frequency of adverse or unanticipated events (e.g. animal illness or deaths not related to approved experiments) by the EWU animal facilities director (and/or members of the IACUC). In the event of non-compliance issues or adverse events, the animal facilities director will notify the IACUC Chair and the investigator will be given notification to immediately return to protocol adherence or submit an amendment to the IACUC Chair, as necessary. Failure to comply will result in suspension of the activity due to non-compliance.

2-3. Reporting Deficiencies in Animal Care and Treatment

- a. Deficiencies in animal care and treatment may be reported to any IACUC member or to the IO. A complainant may request anonymity. People who wish to report a deficiency may contact the Office of Grants and Research Development for contact information for an IACUC member or the IO.
- b. The IACUC is obligated to investigate all reported concerns involving the care and use of animals at the research facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees. Investigations should follow Eastern Washington University Guideline 401-01 (Investigations).
- c. No individual may be retaliated against or be subject to any reprisal for reporting possible violations of any animal research regulations or standards.
- d. Methods for reporting deficiencies in animal care and treatment must be included in the training program for all individuals receiving training on animal care and use through EWU.
- b. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations;
- c. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld;
- d. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official; and
- e. Records of accrediting body determinations

All records shall be maintained for at least six years; records that relate directly to applications, proposals, and proposed significant changes in ongoing activities reviewed and approved by the IACUC shall be maintained for the duration of the activity and for an additional six years after completion of the activity. All records shall be accessible for inspection and copying by authorized APHIS, OLAW or other PHS representatives, or funding federal agency representatives at reasonable times and in a reasonable manner.

2-4. Violations

Violations of this policy may result in one or more of the following university actions:

- a. Suspension of the research until a corrective action plan is approved by the IACUC and IO and put in place;
- b. When the research is funded by a federal agency, any violation or activity that is not being conducted in accordance with the Animal Welfare Act, the Guide or this policy will be reported to OLAW, APHIS and/or any federal agency funding the project. The IACUC, through the IO, is responsible for notifying the federal agency.
- c. Cancellation of the research;
- d. Suspension of the person's ability to engage in animal research in the future and/or;
- e. Principal Investigator, faculty, staff, and/or student discipline, up to and including possible termination or expulsion, dismissal from the university in the case of flagrant noncompliance resulting in a lack of disregard for the protection of animals, other faculty, staff and students and research participants, visitors, the general public.

2-5. Records

EWU will maintain all required records in OGRD. The records shall include:

- a. Assurance that has been approved by the PHS, if applicable;

Whenever the U.S. Department of Agriculture or any other official of the Animal and Plant Health Inspection Service (APHIS) to whom authority has been delegated in his/her stead notifies Eastern Washington University in writing that specified records shall be retained pending completion of an investigation or proceeding under the Animal Welfare Act, those records shall be retained until their destruction is authorized in writing by the APHIS Administrator of any person authorized to act for the APHIS Administrator.

The animal facilities director will maintain a file that includes approved protocols detailing proposed activities involving animals. The animal facilities director's file must be accessible to a federal funding agency representative(s) upon request at reasonable times.

2-6. PHS Requirements

- a. [PHS Policy](#) requires the institution to verify, before award, that the IACUC has reviewed and approved those components of grant applications and contract proposals related to the care and use of animals.
- b. EWU will obtain and maintain an OLAW-approved Animal Welfare assurance for all PHS grant and contract funded activities involving live vertebrate animals.
- c. Projects conducted at an institution assured under the Public Health Service Policy and receiving IACUC approval from that institution need not be reviewed by the IACUC at Eastern Washington University. In such cases, there must be a written agreement between the institutions delineating respective responsibilities.
- d. At least once every twelve months, the IACUC, through the IO, shall provide reports to OLAW or APHIS or any other regulatory body as required.

References

- Animal Welfare Act (AWA), 7 U.S.C. §§ 2131-2159
- Health Research Extension Act of 1985, Public Law 99-158, § 495. Animals in Research
- National Institutes of Health Revitalization Act of 1993, Public Law 103-43, § 205. Plan for Use of Animals in Research
- 9 CFR PART 2, SUBPART A, C
- Office of Laboratory Animal Welfare (OLAW) Animal Care and Use Committee Guidebook, 2nd Edition, 2002
- Public Health Service Policy (PHS) on the Care and USE of Laboratory Animals, 2015
- Guide for the Care and USE of Laboratory Animals 8th Edition, (*the Guide*)
- AVMA Guidelines for Euthanasia of Animals, 2013 Edition