



Policy Chapter: Chapter 13 Research and Innovations

Policy Number and Title: 13.001 Animal Care and Use

I. Policy Statement

This policy establishes responsibility for humane care and use of animals in research, research training, experimentation, and biological testing conducted at or supported by the University of North Texas (UNT).

II. Application of Policy

All University

III. Policy Definitions

A. Adequate Veterinary Care

“Adequate Veterinary Care” means the standards set forth in Adequate Veterinary Care by the American College of Laboratory Animal Medicine and the Animal Welfare Regulations (AWRs).

B. Animal

“Animal” means any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.

C. Animal Facility

“Animal Facility” means any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. A satellite facility is any containment outside of a core animal facility, centrally designated, or managed area in which animals are housed for more than 24 hours.

D. Animal Use Protocol Application

“Animal Use Protocol Application” means the form completed by a Principal Investigator describing the details of a proposed study that is submitted to the IACUC for formal review and approval prior to the ordering of animals or initiation of the study.

E. Animal Welfare Regulations (AWRs)

“Animal Welfare Regulations” means the regulations promulgated by the U.S. Department of Agriculture, pursuant to the authority in the Animal Welfare Act.

F. Assurance

“Assurance” means the Assurance of Compliance document filed with the National Institutes of Health’s Office of Laboratory Animal Welfare (OLAW) certifying that the UNT research program is in compliance with the Public Health Service Policy.

G. The Guide

“The Guide” means the National Research Council’s *Guide for the Care and Use of Laboratory Animals*, which serves as one of the sets of standards by which animal care and use programs are developed and assessed.

H. Institutional Animal Care and Use Committee (IACUC)

“Institutional Animal Care and Use Committee” mean the committee appointed to oversee UNT’s animal program, facilities and procedures, including the key function of reviewing and approving requests to use animals in research.

I. Institutional Official (IO)

“Institutional Official” means the UNT Vice President for Research and Innovation, as appointed by the University President, has the authority to sign the UNT Assurance, making a commitment on behalf of UNT that the requirements of the PHS Policy will be met.

J. PHS Policy

“PHS Policy” means the U.S. Public Health Service (PHS) *Policy on Humane Care and Use of Laboratory Animals*, revised 1986, reprinted 2000.

K. Principal Investigator (PI)

“Principal Investigator” means a UNT faculty member responsible for the conduct of an animal study in compliance with this policy, the Guide, the PHS Policy, and the AWRs, and who certifies acceptance of this responsibility by signing the Animal Use Protocol Application.

L. Principles

“Principles” means the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training*, Interagency Research Animal Committee, 1985.

M. Significant Change(s)

“Significant Changes” to a study are any changes or deviations from the approved protocol that substantially alters or affects the overall study objectives/rationale, specific approved procedures, or the potential for pain, distress and discomfort in the animals.

N. Study Area

“Study Area” means any building, room area, enclosure or other containment outside of the UNT animal facility in which animals are housed more than 12 hours (per AWR's).

IV. Policy Responsibilities

A. General Regulation

Federal law regulates the care and use of animals at the University of North Texas. All

animals used for research, training, teaching and any related activities by UNT faculty, staff, or students will be used and cared for in accordance with all applicable provisions of the Animal Welfare Act, the Animal Welfare Regulations, the Public Health Service Policy for the Humane Care and Use of Laboratory Animals, the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training, and the Guide for the Care and Use of Laboratory Animals.

1. Animal Welfare Assurance Statement

UNT has an approved Animal Welfare Assurance Statement on file with the National Institutes of Health – Office of Laboratory Animal Welfare (OLAW) which includes the following policy statements:

- a. UNT will comply with all applicable provisions of the Animal Welfare Act and other federal statutes and regulations relating to animals.
- b. UNT is guided by the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training
- c. UNT acknowledges and accepts the responsibility for the care and use of animals involved in activities covered by the Assurance.
- d. UNT will make a reasonable effort to ensure that all persons involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with the Assurance as well as applicable laws and regulations pertaining to animal use.
- e. UNT has established, and will maintain, a program for the activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals.

2. Institutional Official and Veterinarian

Federal laws and regulations require UNT to identify an Institutional Official who is ultimately responsible for UNT's program for the care and use of animals. The IO is required to promptly take appropriate action and promptly report violations and deviations, as required under federal regulations or funding agency(ies) guidelines. The IO has the authority to suspend a project in the event that it is deemed required for maintaining health and safety. The IO is also empowered to suspend a project if it finds violations of UNT policy, procedures, or animal welfare regulations. A veterinarian qualified in laboratory animal medicine must also be appointed by the IO and actively participate in the program. The Vice President for Research and Innovation is UNT's designated Institutional Official, and the UNT Attending Veterinarian is UNT's designated Institutional Veterinarian.

3. Institutional Animal Care and Use Committee

The Animal Welfare Act and the *PHS Policy* also require the institution to establish an Institutional Animal Care and Use Committee that is qualified through the training

and/or experience of its members to oversee the institution's animal care and use program, facilities, and procedures. The IACUC (and IO) is empowered to suspend a project if it finds violations of UNT policy, procedures, or animal welfare regulations. As mandated by federal guidelines, UNT's IACUC is composed of people qualified to evaluate the animal programs and proposals under review, and who represent several categories of interested people, including scientists, lay persons, and veterinarians concerned with humane animal care and use. Before any activity involving animals begins, an Animal Use Protocol Application must be prepared by the Principal Investigator and be formally reviewed and approved by the UNT Institutional Animal Care and Use Committee ("IACUC").

B. UNT Institutional Animal Care and Use Committee Responsibilities

1. Basic Functions

The UNT Institutional Animal Care and Use Committee (IACUC) is responsible for the oversight, evaluation, and assurance of compliance of the institution's animal care and use program consistent with all applicable federal requirements. The Committee's basic functions include:

- a. semiannual inspections of animal care and use facilities and evaluation of animal care and use programs;
- b. make recommendations to the Institutional Official for any corrections or modifications needed in program or facilities;
- c. review and approve, require modifications in, or withhold approval of proposed uses of animals in research, testing, or education;
- d. review and approve, require modifications in, or withhold approval of proposed changes regarding the use of animals in ongoing activities;
- e. suspend animal use activities that are not in compliance with applicable standards;
- f. review concerns involving the care and use of animals at UNT;
- g. keep records and maintain the confidentiality of committee proceedings and activities; and
- h. submission of reports to the Institutional Official.

2. Requirements for Approval

The Chair, committee members, and UNT Staff Veterinarian will review submitted Animal Use Protocol Applications and related submissions in accordance with the UNT OLAW Assurance and UNT IACUC Procedures. In order to approve proposed research projects or proposed significant changes in ongoing research projects, the IACUC shall confirm that the research project will be conducted in accordance with the Animal Welfare Act, the *Guide*, and the UNT OLAW Assurance, and meets the following

requirements:

- a. procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design;
- b. procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator;
- c. animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure or, if appropriate, during the procedure;
- d. the living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and non-medical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied;
- e. medical care for animals will be available and provided as necessary by a qualified veterinarian;
- f. personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures; and
- g. methods of euthanasia used will be consistent with the recommendations of the [American Veterinary Medical Association \(AVMA\) Guidelines on Euthanasia](#), unless a deviation is justified for scientific reasons in writing by the Principal Investigator and approved by the committee.

3. Written Notices & Reviews

The IACUC will provide written notice of its decision on protocols reviewed to the Principal Investigator. Many funding agencies require the Principal Investigator to submit verification of IACUC approval, typically within 60 days after the proposal was submitted to the agency. IACUC approval of an Animal Use Protocol Application will be for a maximum period of three years. The Principal Investigator is responsible for contacting the IACUC annually to report on the status of the project. If no significant change in the protocol has occurred, IACUC approval may be extended for one year. At any time during the course of the project, a proposed significant change in the protocol requires prior approval by the IACUC. Any project that remains active after expiration of three years requires a complete review of a new Animal Use Protocol Application by the IACUC.

4. IACUC Composition

An adequate number of members shall be appointed to carry out the required responsibilities of the IACUC. An individual who meets the requirements of more than one of the below categories may fulfill more than one requirement. In no event may

the committee consist of less than five members appointed by the UNT Vice President for Research and Innovation, who shall designate one of the members as the Chair of the IACUC. The Committee shall include at least one:

- a. Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at UNT;
- b. practicing scientist experienced in research involving animals;
- c. member whose primary concerns are in a nonscientific area; and
- d. individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution.

5. IACUC Meetings

The IACUC shall meet as often as necessary to fulfill its responsibilities, but at a minimum shall meet at least once every six months.

C. *Principal Investigator Responsibilities*

Although institutional policies are designed to provide IACUCs and Institutional Officials responsible for animal welfare the necessary resources to assure compliance, a significant burden of responsibility rests with the Principal Investigator. The regulations and guidelines that affect the use of animals in research, teaching and testing programs are numerous. The Principal Investigator is required to comply with these regulations and this policy.

1. Working Knowledge of Regulations Necessary

A working knowledge of the applicable regulations is necessary to ensure that proposals for funding contain necessary information and to verify that all research projects are conducted in compliance with the requirements of the regulatory and funding agencies.

2. U.S. Government Principles

The U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training identify responsibilities of Principal Investigators whose animal use activities are subject to oversight by the IACUC. In summary, these Principles expect Principal Investigators to:

- a. design and perform procedures on the basis of relevance to human or animal health, advancement of knowledge, or the good of society;
- b. use the appropriate species, quality, and number of animals to obtain valid results;
- c. avoid or minimize discomfort, distress, and pain in concert with sound science;

- d. use appropriate sedation, analgesia, or anesthesia;
- e. establish experimental endpoints;
- f. provide appropriate animal husbandry directed and performed by qualified persons; and
- g. conduct experiments on living animals only under the close supervision of qualified and experienced persons.

3. Duties of the Principal Investigator

Not only is the Principal Investigator charged with completing the proposal for funding in accordance with the requirements of the funding agency, but he or she must also assure the project is performed in accordance with the funded proposal and the IACUC approved Animal Use Protocol.

4. Animal Use Protocol Application

It is the Principal Investigator's responsibility to ensure that IACUC approvals have been obtained by completing and submitting an Animal Use Protocol Application, ensuring applicable annual updates to the IACUC have been submitted in a timely manner for approved studies, and ensuring any changes to the approved protocol have been communicated and approved by the IACUC in advance. The Animal Use Protocol Application and related forms are available from Research Integrity and Compliance through the IACUC website. The protocol, at a minimum, shall contain the following information:

- a. identification of the species and approximate number of animals to be used;
- b. rationale for involving animals, and for the appropriateness of the species and justification of the numbers to be used;
- c. identification and qualifications of personnel handling animals and/or performing procedures on animals;
- d. a complete description of the proposed use of the animals;
- e. a description of procedures designed to assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals; and
- f. a description of any euthanasia method to be used.

D. UNT Attending Veterinarian Responsibilities

The UNT Attending Veterinarian is UNT's designated Institutional Veterinarian. The Institutional Veterinarian's responsibilities include:

1. ensuring the provision of adequate veterinary care to all animals housed in the UNT animal facilities;
2. ensuring that the day-to-day operation of the UNT animal facilities complies with federal requirements;
3. ensuring that all animal care personnel demonstrate acceptable skills in performing duties with the species of animal for which they are responsible;
4. providing guidance in handling and restraint, anesthetics, analgesics, and methods of euthanasia;
5. serving as a member of the IACUC;
6. monitoring Principal Investigators to ensure that all animal use activities are performed consistent with the approved protocols; and
7. making regularly scheduled visits to the UNT animal facilities and related animal use areas.

E. Recordkeeping

1. Three-Year Records

UNT will maintain the following records for at least three (3) years:

- a. a copy of the Institutional Assurance and any modifications thereto, as approved by PHS;
- b. minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations;
- c. records of Animal Use Protocol Applications and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld; and
- d. records of semiannual IACUC reports and recommendations as forwarded to the Institutional Official.

2. Duration-of-Activity Records

UNT will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity.

3. Inspection of Records

All records shall be accessible for inspection and copying by authorized Office of Laboratory Animal Welfare (OLAW) or other U.S. Public Health Service representatives at reasonable times and in a reasonable manner.

F. Reporting Requirements

1. OLAW Report

At least once every 12 months, the IACUC, through the Institutional Official, will report in writing to the Office of Laboratory Animal Welfare (OLAW). If there are not any changes to report, UNT will provide OLAW with written notification that there are no changes. The report will include:

- a. any change in status (e.g., if UNT becomes accredited by AAALAC or AAALAC accreditation is revoked);
- b. any change in the description of the UNT program for animal care and use as described in the Assurance;
- c. any changes in IACUC membership; and
- d. notification of the dates that the IACUC conducted its semiannual evaluations of the UNT program and facilities and submitted the evaluations to the Institutional Official.

2. Prompt Notice to OLAW

The IACUC, through the Institutional Official, will provide prompt notice to OLAW with a full explanation of the circumstances and actions taken with respect to:

- a. any serious or continuing noncompliance with the PHS Policy;
- b. any serious deviations from the provisions of the Guide; or
- c. any suspension of an activity by the IACUC.

3. Minority Views

The reports forwarded to the Institutional Official and to OLAW will include any minority views filed by members of the IACUC.

G. Reporting Suspected Animal Abuse

All such reports will be referred to the IACUC for review and, if warranted, an investigation to determine if corrective action is appropriate. Suspected abuse of animals on the UNT campus should be reported to any of the following:

1. UNT Research Integrity and Compliance, at oric@unt.edu;
2. UNT Attending/ Institutional Veterinarian,
3. Institutional Animal Care and Use Committee, at untiacuc@unt.edu;
4. [University Compliance and Ethics](#); or
5. UNT Trust Line, at the University Compliance and Ethics Office, at 1-877-606-9187.

H. Media or Public Inquiries

1. Parties Responsible for Media Inquiries

Members of the media or the public may contact UNT to make inquiries about the conduct of research involving animals. All such inquiries are to be directed to the Office of University Relations, Communications and Marketing as well as Research Integrity and Compliance.

2. Audio/Video Production for Research Purposes

Audio/visual production of animal research activities is prohibited without express permission. Recordings may only be taken when approved in a UNT Animal Use Protocol for justifiable research purposes and must not document any of the following:

- a. identifiable locations (includes room #s, building names/ #s, etc.),
- b. identifiable personnel, and
- c. animal housing/caging.

3. Audio/Video Production for Non-Research Purposes

Audio/visual recordings of animal research activities that are for non-research purposes are prohibited without express permission of Research Integrity and Compliance and the Principal Investigator(s) whose research may be involved, if any of the following are to be included:

- a. identifiable locations (includes room #s, building names/ #s, etc.);
- b. identifiable personnel;
- c. animal housing/caging; or
- d. research animals.

V. References and Cross-References

Animal Welfare Act, 7 U.S.C. 2131 *et seq.*

Animal Welfare Regulations, U.S. Department of Agriculture, 9 C.F.R. Subchapter A, Parts 1-3

Policy on Humane Care and Use of Animals, U.S. Public Health Service

Guide for the Care and Use of Laboratory Animals, National Academy of Sciences, Institute of Laboratory Animal Resources

U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training, Interagency Research Animal Committee

VI. Revision History

Policy Contact:	Associate Vice President of Research and Innovation
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