**Policy Statement.**
Each institution that receives PHS support for activities involving vertebrate animals or is subject to the authority of the USDA Animal Welfare Act (AWA) must operate an animal care and use program with clear line of authority and responsibility. The program must include a properly constituted and functioning Institutional Animal Care and Use Committee (IACUC), procedures for self monitoring, an adequate veterinary care program, an occupational health and safety program, a personnel training program, an environment housing, and management program for animals, and appropriately maintained facilities for housing and support.

**Application of Policy.**
This policy applies to all new and existing laboratory personnel, animal care personnel, students, UNTHSC employees and IACUC members who are involved with animal care and use within the institution.

**Definitions.**
1. **Animal Welfare Act (AWA).** Federal law enforced by the United States Department of Agriculture (USDA) to protect certain animals from inhumane treatment and neglect. The act regulates the care and treatment of all warm-blooded animals bred for commercial sell, used in research, transported commercially, or exhibited to the public with the exception of farm animals used for food or fiber, rats, and mice.

2. **Chief Executive Officer (CEO).** The highest operating official of an organization.

3. **Institutional Animal Care and Use Committee (IACUC).** A federally mandated, self-regulation committee that is appointed by the institution to oversee and evaluate the institutions animal program, procedures, and facilities.

4. **Institutional Official (IO).** A senior administrator appointed by the CEO to oversee the IACUC.

5. **Principal Investigator (PI).** The person who directs a research project or program. The PI writes and submits the protocol application, oversees the scientific and technical aspects of the protocol, and has responsibility for the management of the research.

6. **Public Health Service (PHS) Policy.** Policies enforced by the Office of Laboratory Animal Welfare (OLAW) under the National Institute of Health (NIH) to provide requirements for animal care and use by institutions using animals in research, testing, and education that is funded by the NIH.
Procedures and Responsibilities.

1. The CEO shall appoint or shall delegate authority to an Institutional Official (IO) to appoint the members of the IACUC.

   Responsible Party: UNTHSC University President, Vice President of Research

2. The IACUC shall be composed of no less than five members and shall include at least one: Doctor of Veterinary Medicine with training or experience in laboratory animal medicine, a practicing scientist experienced in research involving animals, a member whose primary concerns are on a nonscientific area, and an individual unaffiliated with the university in any way other than as a member of the IACUC.

   Responsible Party: Vice President of Research

3. The IACUC is responsible for oversight and evaluation of the animal care and use program and its components. Its federally mandated functions include: inspection of the facilities and the evaluation of animal care programs and study areas no less than once every six months, submission of reports to responsible institutional officials, review of proposed uses of animals in research, teaching, and education, and review concerns involving the care and use of animals at the institution.

   Responsible Party: Members of the Institutional Animal Care Committee, IACUC Administrator

4. As a part of the semiannual program review, the IACUC will regularly review:
   a. Its responsibilities to meet changing needs within the institution, the scientific community, and society as a whole and expand its responsibilities, as necessary, to meet the requirements of new regulations and policies;
   b. The concerns of the public within our own community;
   c. The security of the animals and research facilities;
   d. Standard operating procedures;
   e. Policies and procedures for monitoring animal care and experimental procedures within the institution.

   Responsible Party: Members of the Institutional Animal Care Committee, IACUC Administrator

5. A quorum of the IACUC shall meet at least once every 6 months and as often as necessary to fulfill its responsibilities.
6. The IACUC shall establish procedures to ensure that: unnecessary pain or distress is avoided; anesthesia and analgesia are properly and effectively used where indicated unless proper scientific justification is given; painful studies requiring exemption from the use of either anesthetics or analgesia are subject to particular scrutiny, not only prior to approval, but during the experiment; postoperative care commensurate with current veterinary concepts is provided.

   Responsible Party: Members of the Institutional Animal Care Committee, IACUC Administrator

7. The IACUC shall establish and implement policies which will provide for a system of animal care that meet the needs of the UNTHSC and include:
   a. The requirement that all animal care and experimentation is conducted within the guidelines as set out in the AWA and PHS policies, and any other federal, state, or institutional regulations that may be in effect;
   b. Ensuring adequate numbers of animal care personnel are present, and that animal users and animal care personnel are qualified to perform their duties. All individuals shall receive training in the humane care and use of animals;
   c. Ensuring that facilities and equipment meet the standards of all applicable regulations and policies.
   d. Providing standards of husbandry and veterinary medical care that meet or exceed regulatory mandates;
   e. Ensuring that all activities and procedures that involve animals are carried out humanely and that analgesics, anesthetics, and tranquillizing drugs are used to minimize pain;
   f. Ensuring proper methods of euthanasia, with appropriate guidelines for timely euthanasia to minimize pain and suffering.

   Responsible Party: Members of the Institutional Animal Care Committee, IACUC Administrator

8. The IACUC shall assure that all animal users have the opportunity to become familiar with all federal, state, city, and institutional requirements that may apply to their work.

   Responsible Party: Members of the Institutional Animal Care Committee, IACUC Administrator

9. The IACUC shall ensure appropriate care of animals in all stages of their life. Adequate veterinary care must be available at all times for all animal species used by UNTHSC.
10. The IACUC shall ensure the living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding and nonmedical 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.

11. The IACUC shall ensure that no research, testing project, teaching program, or any other study (including field studies) involving animals be commenced without prior IACUC approval of a written Animal Use Protocol Application; further, no animals shall be acquired before such approval. This includes internally-funded projects.

12. The IACUC shall review the animal care and use components of proposed research projects to ensure that procedures and practices are in compliance with the Guide, Act, NIH Assurance Statement, and any other regulations or policies which apply. When necessary, the IACUC will require further supportive information from the investigator or meet with the investigator to assure that all members of the review committee understand the procedures to be used on the animal. If there is any variance with the guidelines noted above, the IACUC will require justification for the variance on scientific grounds.

13. The animal use protocol must include the following information:
   a. Project title (including course number if a teaching program.)
   b. Principal Investigator name
   c. Names, qualifications, and training of all Research Staff and other authorized personnel.
   d. Departmental affiliation, mailing address, phone number(s), and lab location.
   e. Proposed start date, proposed end date.
   f. Funding agency.
   g. An indication of the use of any hazardous material including infectious agents and other biological hazards, toxic or carcinogenic chemical agents, and radioactive materials.
h. Rationale and purpose of the proposed use of animals and the scientific goals of the research.
i. Species and number of animals to be used with scientific justification; the number of animals used should be justified statistically.
j. An indication of the categories of discomfort and the classification of research based on primary use.
k. Methods of anesthesia and analgesia, including dosages and methods of use.
l. The methods of euthanasia, if necessary.
m. A description detailing the procedures that are carried out in the animals.
n. Written assurance that the activities do not unnecessarily duplicate previous experiments.
o. Assurance that procedures with animals will avoid or minimize discomfort, distress, and pain to the animals consistent with sound research design.
p. Written assurance that 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.
q. Assurance that all 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.
r. Assurance that animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanatized at the end of the procedure or, if appropriate, during the procedure.
s. Assurance that more than one major survival surgical procedure will not be performed on an animal unless justified for scientific reasons and approved by the IACUC.
t. Assurance that adequate pain relieving drugs and pre- and post-surgical care will be provided by trained personnel.
u. Assurance that the methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.
v. Description of possible clinical signs of illness or distress exhibited by the experimental animals and mode of treatment.
w. Unusual housing and husbandry requirements.
x. Any other information considered important or necessary and pertinent.
y. All information must be presented in a form that all members of the IACUC can readily understand.

Responsible Party: Members of the Institutional Animal Care Committee, IACUC Administrator
14. The IACUC must be aware of all modifications to protocols. When these involve major changes in animal utilization, new protocols must be submitted.

**Responsible Party:** Members of the Institutional Animal Care Committee, IACUC Administrator

15. The Committee shall review all protocols at least once every three years, with annual confirmation that the studies have not been changed since the commencement of the project. Protocols require renewal with full submission every three years.

**Responsible Party:** Members of the Institutional Animal Care Committee, IACUC Administrator

16. The IACUC may invite consultants to assist in the review of complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also members of the IACUC.

**Responsible Party:** Members of the Institutional Animal Care Committee, IACUC Administrator

17. Prior to Protocol review, IACUC members shall be notified of proposed research projects submitted for review. 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. If full committee review is not requested, at least one member of the IACUC, designated by the IACUC Administrator or Chairperson, and qualified to conduct the review, shall review those research projects and have the authority to approve, require modifications in (to secure approval) or request full committee review of those research projects.

If full committee review is requested, approval of those research projects may be granted only after review at a convened, quorum meeting of the IACUC and with the approval vote of the majority present. No member may participate in the IACUC review or approval of a research project in which the member has a conflicting interest except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.

**Responsible Party:** Members of the Institutional Animal Care Committee, IACUC Administrator

18. The IACUC shall notify investigators and the institution 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.

**Responsible Party:** Members of the Institutional Animal Care Committee, IACUC Administrator

19. Applications and proposals that have been approved by the IACUC may be subject to further appropriate review and approval by officials of the institution. However, those officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC.

**Responsible Party:** Members of the Institutional Animal Care Committee, IACUC Administrator

20. The IACUC shall ensure that all use of animals has “scientific merit.” In many instances, the Committee will primarily rely on the review process by scientific funding agencies, such as the NIH. However, for those projects that will not be subject to external peer review for scientific merit, the IACUC may require that such be obtained externally; or alternately, the Committee may choose, if qualified, to assess the protocol for scientific merit itself. In such cases, the Committee may invite other UNTHSC scientists knowledgeable in the field of research indicated by the protocol to assist in the internal review.

**Responsible Party:** Members of the Institutional Animal Care Committee, IACUC Administrator

21. Other general functions of the IACUC include:
   a. The IACUC will maintain liaison with federal and state authorities where applicable.
   b. The IACUC will develop and maintain liaison with the public and foster an “open door” policy, as appropriate.
   c. The IACUC will sponsor from time to time seminars or workshops on research animal science and the ethics of experimentation.
   d. The IACUC shall achieve and maintain a high profile within the institution and in the community in order to allay some public concerns regarding animal experimentation.
   e. The IACUC shall be responsive to the needs and concerns of the research and animal care community at the UNTHSC and work toward a harmonious relationship with those it serves. At the same time, the Committee, must, in all cases, retain its ability to be objective so that it fulfills its responsibilities as the overseer of the animal care and use program.

**Responsible Party:** Members of the Institutional Animal Care Committee, IACUC Administrator
22. Additional or revised standard operating procedures and policy-related actions relevant to the appropriate care and use of animals may be added by the IACUC as needed and will be posted on appropriate UNTSHC web sites.

   Responsible Party: Members of the Institutional Animal Care Committee, IACUC Administrator

23. All new and existing laboratory personnel, animal care personnel, students, IACUC members, and UNTHSC employees who are engaged in research with animals within the institution shall comply with all policies, IACUC-Approved protocols, and all procedures promulgated under this policy.

   Responsible Party: Members of the Institutional Animal Care Committee, Laboratory personnel, animal care personnel, students and UNTHSC employees engaged in research with animals within the institution

References and Cross-references.
The PHS Policy on Humane Care and Use of Laboratory Animals
The Animal Welfare Act
The Guide for the Care and Use of Laboratory Animals

Forms and Tools.
UNTHSC IACUC Animal Care and Use Policy Manual
Animal Use Protocol Application
Animal Use Amendment Form
Animal Use Annual Review Form, for one or two species
UNTHSC Animal Welfare Assurance
UNTHSC IACUC website: http://www.hsc.unt.edu/IACUC/
IACUC Protocol Database: https://www.hsc.unt.edu/applications/IACUC/IACUC.html

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