Title: Governing Principles

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Approval/Date:

Jamie Peno
Director, Research Integrity and Compliance

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REVISION HISTORY

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PURPOSE
This Standard Operating Procedure (SOP) is to outline the guiding principles of the Institutional Animal Care and Use Committee at UNT.

SCOPE
The University of North Texas Institutional Animal Care and Use Committee (IACUC) is mandated by federal law to oversee components of the institution’s animal care and use programs. The IACUC assures that animal research conducted at the University of North Texas is in compliance with federal, state and local regulations in congruence with institutional policies.

DEFINITIONS AND ABBREVIATIONS
UNT- University of North Texas, Denton
IACUC- Institutional Animal Care and Use Committee
SOP/SOP’s- Standard Operating Procedure(s)
NIH- National Institutes of Health
PHS-Public Health Services
OLAW- Office of Laboratory Animal Welfare
USDA- Unites States Department of Agriculture
AWA- Animal Welfare Act
AVMA- American Veterinary Medicine Association
FDA- Food and Drug Administration
REGULATIONS
The National Institutes of Health (NIH) Public Health Services Office of Laboratory Animal Welfare (OLAW) has provided The Guide for Care and Use of Laboratory Animals, commonly referred to as “The Guide” to assist Institutions in caring for and using laboratory animals in research in an appropriate manner in line with the PHS Policy on Humane Care and Use of Laboratory Animals. This guide must be adhered to for Institutions receiving funding through any NIH programs that are required to abide by the PHS Policy.

1. The University of North Texas provides a programmatic Assurance to OLAW that is renewed with program changes and every 5 years. An annual update is submitted each year under said Assurance to OLAW.
   - UNT PHS Assurance #D16-00485/ A3841-01

The United States Department of Agriculture (USDA) enforces The Animal Welfare Act (AWA) which is the only federal law regulating the treatment of animals in research, exhibition, and transport. The AWA covers vertebrate species aside from the following: farm animals used for food or fiber (fur, hide, etc.); coldblooded species (amphibians and reptiles); horses not used for research purposes; fish; invertebrates (crustaceans, insects, etc.); or birds, rats of the genus Rattus, and mice of the genus Mus that are bred for use in research. Birds (other than those bred for research) are covered under the AWA but the regulatory standards have not yet been established.

2. The University of North Texas facilities and IACUC program are registered with the USDA and inspected annually and are held responsible for any noncompliance with federal standards. Annual reports for USDA covered species are reported to USDA annually.
   - UNT USDA Registration #74-R-0033

The American Veterinary Medical Association (AVMA) provides guidance in relieving pain and suffering of animals to members of the veterinary profession who carry out or oversee the euthanasia of animals. The UNT IACUC requires that methods of euthanasia in animal research protocols be a method approved by the AVMA for each species.

The Food and Drug Administration (FDA) has provided Regulations that pertain to non-clinical laboratory studies using animals in support of applications for research or marketing permits for products that are regulated by FDA.

3. The Good Laboratory Practices (GLP) regulations address such issues as quality assurance personnel and processes; validation of equipment and data change controls; documentation requirements; construction and maintenance of facilities; quarantine and isolation periods of animal subjects, disease diagnosis and treatment of animal subjects; animal subject identification; and caging and routine care of animal subjects.
• GLP studies require prior training and approval before protocol proposals can be submitted to the IACUC from UNT Research Integrity and Compliance and the Vice President for Research.

REFERENCES
1. PHS Policy
2. The Guide
3. The Animal Welfare Act
4. AVMA Guidelines
5. FDA 21 CFR part 58

APENDICES
IACUC Standard Operating Procedures