DIVISION OF RESEARCH & INNOVATION Research Integrity & Compliance	**Institutional Animal Care and Use Committee** **Standard Operating Procedures**

Title: Animal Use Protocol Submissions

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Approval/Date:

Jamie Peno — 12/22/2020

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REVISION HISTORY		
Date	**Section**	**Author**

PURPOSE

It is the responsibility of the UNT IACUC to assure that all animal use activity meets federal regulations, policies, and recommendations. The UNT IACUC must therefore review and approve all proposals for animal use and provide guiding documents for documentation and evaluation of each Animal Use Protocol (AUP) submission.

SCOPE

This SOP will delineate the responsibilities of the Principal Investigator (PI) to timely submit (see SOP 01.07 AUP Approval Methods) all proposals and modifications accurately and concisely, to a level that should be understandable to a non-scientist with a 9th grade education, to describe and give good justification for the aims and design of their study and the use of animals.

DEFINITIONS AND ABBREVIATIONS

UNT- University of North Texas, Denton
IACUC- Institutional Animal Care and Use Committee
SOP/SOP's- Standard Operating Procedure(s)
AUP- Animal Use Protocol
PI- Principal Investigator
Co-PI- Collaborating Principal Investigator
AWIC -The Animal Welfare Information Center
USDA Categories- United States Department of Agriculture Pain Scale Classification of Procedures
NPGC- Non-pharmaceutical Grade Compounds

PO- Oral Route of Drug Administration
IM- Intramuscular Route of Drug Administration
IV- Intravenous Route of Drug Administration
IO- Intraosseous Route of Drug Administration
SQ- Subcutaneous Route of Drug Administration

PROCEDURES

I. The AUP is broken into sections and must be filled out in its entirety, electronically, and signed and dated by the UNT Principal Investigator.

1. **Administrative Data-** is for the use of filing and documenting communication methods for the PI and includes key study identifying data such as:
   a) AUP number
   b) Study Title
   c) PI and campus contact information
   d) Funding Source Identification
2. **Personnel Training and Qualifications**- this section identifies those participating in study activities and gives their qualifications by documenting:
   a) Names
   b) Degree, Certifications, Licensures
   c) Contact Information
   d) Years of experience with the applicable species
   e) Years of experience with the applicable procedures
   f) Training information
3. **Peer Review**- ensures that projects requesting the use of USDA covered species or animals under USDA Category D and/ or E have been reviewed by a scientific peer or peer group in the field of study related to the protocol.
4. **Funding Information**- provides funding information to ensure the proposals have designated funding and that any grants and funding award proposals are congruent with what the IACUC is approving.
5. **Non-Technical Lay Summary**- provides a summary description, avoiding the use of medical or scientific terminology, of:
   a) the experiments purpose and need
   b) descriptions of animal use
      i. explanations of procedures
      ii. explanations of data collection methods and measures
      iii. timelines, tables, and charts to explain the study design
      iv. summarization of the methods that will be used to minimize discomfort, pain, and distress
      v. study endpoints and determinations
6. **Animal Numbers and USDA Classification**- this section provides the number of animals requested and categorizes them as B,C,D,or E based on the USDA pain scale.
   a) Justification- any animals being requested in Category E require explanation and justification for needing animals to fall under this category.
      i. Classification B: Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes.
      ii. Classification C: Animals upon which testing, research, experiments, or tests will be conducted involving no pain, distress, or use of pain-relieving drugs.
      iii. Classification D: Animals upon which experiments, teaching, research, tumor-bearing experiments, surgery, or tests will be conducted which have the potential to cause pain or distress to the animals and for which appropriate

anesthetic, analgesic, or tranquilizing drugs will be used to prevent this pain and distress.

iv. Classification E: Animals upon which teaching, experiments, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs will adversely affect the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests.

7. **Literature Search**- this section is used in order to prevent unnecessary duplication of research and to demonstrate that there are no alternatives addressing replacement, reduction, and/ or refinement to the proposed use of live animals.
   a) Date of search
      i. Should not be more than 90 days prior to submission of application
   b) Sources used for review of scientific literature
      i. The Animal Welfare Information Center (AWIC) is a good source for alternative options such as computer models, tissue culture, etc.
      ii. Medline or PubMed is a good source to search and rule out duplication of research
   c) Date range covered in search
   d) Keywords used in search
   e) Results of the search
      i. A description of the literature search results should include a statement of assurance that literature was reviewed and that the proposed study is not unnecessarily duplicative and that valid alternatives were either not found or justification as to why they will not be used.
      ii. More detailed documentation and justification will be required for Category D or E proposals and should fully explain considerations of alternatives and the determination that none are available.
8. **Animal Species**- this section should include the specifics of the desired animal model(s).
   a) Species
   b) Strain
      i. Use of transgenic animals should be specified
   c) Source
      i. can be a "UNT approved vendor" or should specify vendor name and contact information
      ii. If the animals will be transferred from another UNT approved AUP, the original source should be listed as well as the AUP # they are currently housed under.
   d) Age and/ or weight range requirements
   e) Gender requirements
9. **Special Requirements for Housing and Animal Care**- animals will assumedly be maintained according to facility standard operating procedures for the following unless specified:
   a) Dietary requirements
   b) Medications and treatments
   c) Quarantine and evaluation
   d) caging and bedding
   e) environment (light cycles, temperature, humidity, etc.)
   f) cleaning
   g) grooming and enrichment

10. **Animal Identification**- this section should describe how animals will be identified such as a microchip, ear notching, tattoo, tag, collar, etc.
11. **Location**- this section should identify where animals will be throughout the study. If animals will be kept outside of an IACUC approved facility for more than 12hours at a time, the facility will need to be inspected by an IACUC representative prior to use. Locations should be provided as applicable for the following time points:
    a) Housing
    b) Non-surgical procedures (data collections, blood draws, etc.)
    c) Surgical procedures- survival
    d) Surgical procedures- terminal
    e) Post-operative care
    f) Euthanasia
    g) Breeding
12. **Wild or Exotic Species**- when wild or exotic species will be used and permits are required, copies of permits should be attached for review. All permits should be obtained prior to submission of the protocol to the IACUC.
13. **Restraint**- restraint can often cause distress in animals, therefore any procedures that will require the animal be physically restrained must be listed with the following information:
    a) Method of restraint
        i. Manual
        ii. Device (ie. slings, stanchions, tethers, metabolic caging, etc.)
    b) Frequency of restraint
    c) Duration of restraint
    d) Observation periods during restraint
    e) Justification for restraint
    f) Methods for training
14. **Anesthesia and Analgesia**- when a procedure involving the use of sedation, anesthesia, analgesia, and/ or neuromuscular blocking agents is involved the following information is needed for each:
    a) Drug Name
    b) Dose (mg/kg) should be a range
    c) Route of Administration (ie. Orally (PO), Intramuscular (IM), Intravenous (IV), Intraosseous (IO) Subcutaneous (SQ), etc.)
    d) Frequency of Use
    e) Duration of Use
    f) Timepoint of Use (Non-Surgical Procedure, Pre-operatively, Intra-operatively, Post-operatively, etc.)
    g) Note- Neuromuscular blocking agents require reasonable justification and proven training and experience by personnel in the use of these agents in animals.
15. **Surgical Procedures**- This section should describe (at a 9th grade level) all survival and terminal surgical procedures and should include:
    a) Personnel performing invasive procedures
    b) Full description of proposed procedures from start to finish including:
        i. Equipment involved and methods of use
        ii. Description of surgical techniques to be used
        iii. Explanation of special techniques to be used
        iv. Use of any test or ancillary articles that will remain in the animal (ie. sutures, ligation clips, staples, graft materials, etc.)
    c) Description of post-operative care, as applicable

16. **Invasive Procedures**- this section should describe all invasive procedures aside from the surgical procedures listed in section 15 such as blood collection, catheterization, intubation, etc.
17. **Blood and/ or Fluid Collection**- this section refers to collections performed on animals prior to euthanasia and should include:
    a) Fluid collected
    b) Route and method of collection
    c) Frequency and timepoint of collections
    d) Volume collected at one time
18. **Food and Water Restrictions**- this section should provide details and justification of any food and/ or water restrictions, including fasting prior to anesthetic procedures.
19. **Interventions for Pain and Distress**- this section should plainly state what interventions (analgesia, sedation, anesthesia, euthanasia, etc.) will be used throughout the study for pain and/ or distress, and if/ when they will be withheld, should provide clear scientific justification.
20. **Treatment and Disposition Instructions**- this section delineates what steps are expected of personnel upon noting unexpected injury, illness or death in animal subjects.
    a) Upon noting signs of injury or illness, personnel should notify the PI, and/ or treat per the protocol as described, and/or terminate per the protocol as described.
    b) Upon early death, personnel should notify the PI, and/ or have a Necropsy performed, and/ or bag for proper disposal.
21. **Study Endpoints and Disposition**- this section identifies the planned study endpoint and disposition of animal subjects and should include at least:
    a) Assessment criteria for the desired study endpoint for each test system
    b) Plan and justification for disposition that is humane and scientifically sound ie.:
        i. Planned euthanasia
        ii. Protocol transfer
        iii. Adoption
        iv. Wildlife release
    c) Frequency of animal observations
    d) Trained personnel responsible for observations and assessing endpoints
    e) Methods of euthanasia via an AVMA approved method and method of assuring death (ie. decapitation, cervical dislocation,
    f) Trained personnel performing euthanasia
22. **Hazards**- this section should provide any known hazards that pertain to the study design (such as the use of radioisotopes, carcinogens, biohazards, etc.) to ensure appropriate precautions are taken and that any related programs or committees are involved or have been consulted (ie. Risk Management, Radiation Safety, Institutional Biosafety, etc.).
23. **Tissue Sharing**- to reduce the number of animals used in research, PIs are encouraged, when feasible, to share tissues or fluids with other researchers at UNT. This section should provide a short narrative of the tissues and fluids being shared, if any, and should include the timepoint and justifications.
24. **Summary**- this section should be a detailed description of the study as a whole and should at least include the following:
    a) Description of the objective and significance of the work
    b) Detailed description of all procedures that animals will be subjected to
    c) Justification for the species and the number of each requested
    d) Explanation of the experimental design and data to be obtained, including charts,

graphs or other illustrations to provide a clear understanding for reviewers.

25. **Assurances**- this section requires the PI to acknowledge and assure the following:
    a) PI has a working knowledge of the PHS "Guide for the Care and Use of Laboratory Animals" and the USDA "Title 9 Animal Welfare Act" and its revisions.
    b) The proposed work does not unnecessarily duplicate previous experiments, based upon search results described.
    c) All personnel involved in the project have been trained in the procedures to be used or will be training before performing procedures.
    d) The PI and all personnel on the project have read any pertinent safety information, IACUC requirements, and security procedures pertaining to their work.
    e) The PI shall be responsible for maintaining records of all animals used and the procedures carried out.
    f) Any discomfort, distress or pain that may be associated with this research will be held to the absolute minimum.
    g) Alternatives to any procedures that may cause pain or discomfort have been considered.
    h) The PI is responsible for procurement, storage, administration, and record keeping for all controlled substances.
    i) The PI has read and understands the IACUC's policy regarding the use of Non-pharmaceutical Grade Compounds (NPGC) in animals. NPGC's will only be used for projects with scientific justification, when acceptable pharmaceutical compounds are unavailable, and with prior IACUC approval.
    j) The Principal Investigator and/or Co-Principal Investigator are aware that they have the ultimate responsibility, on a day-to-day basis, for the proper care and treatment of the laboratory animals and agree to adhere to all federal, state and local laws and regulations governing the use of animals in teaching and research. They must further assure the University of North Texas IACUC that the minimal number of animals will be used for the project and that every possible step will be taken to minimize stress or pain to the animals.
    k) The PI will submit appropriate annual review forms for this project, and will obtain formal approval from the IACUC prior to the implementation of any changes to the protocol.

REFERENCES

1. The Guide for the Care and Use of Laboratory Animals
2. Institutional Animal Care and Use Committee Guidebook
3. Animal Welfare Act
4. PHS Policy on Humane Care and Use of Laboratory Animals
5. AVMA Guidelines for Euthanasia
6. The Animal Welfare Information Center (AWIC)
7. PubMed Literature Search Engine
8. MedLine Literature Search Engine
9. UNT IACUC Policies and Procedures
10. UNT IACUC Procedure 01.07- AUP Approval Methods
11. UNT IACUC Form 01-Animal Use Protocol Form

APENDICES

IACUC Standard Operating Procedures
UNT IACUC Form 01-Animal Use Protocol Form