DIVISION OF RESEARCH & INNOVATION
Research Integrity & Compliance

Institutional Animal Care and Use Committee

Animal Care and Use Protocol Application

1. Administrative Information:

Filled out by IACUC Office Only: **Protocol #:** **Approval Date:** **Expiration Date:**	
Principal Investigator:	
Department:	
Telephone:	**Emergency Contact #:**
Email Address:	
Co-Principal Investigator/ Secondary Contact:	
Department:	
Telephone:	**Emergency Contact #:**
Email Address:	

2. Protocol Information:

☐ New ☐ Renewal: Previous Protocol #:
Title of Project:
Application Date (Please use MM-DD-YYYY Format):

If the Project is a renewal, please answer the following 3 questions:

2a. Progress Report:
Please include a brief summary of the progress made over the last 3 years

2b. Summary of Anticipated Changes:

2c. Unanticipated Results:
Describe any unanticipated results involving animal health

3. Funding Information:

Is this Application associated with a grant? ☐ Yes ☐ No

If yes, *list the title used on the Grant application to assure proper notification of the approval status to the funding agency. The grantee must be either the Principal Investigator or the Co-Investigator on the IACUC protocol. For federally funded projects, the PI must submit a copy of the vertebrate animal section of the grant with the IACUC application. Pending applications may be listed; however animal orders cannot be made until a pending grant application has been approved. An amendment to add the pending grant to the protocol must be submitted before animal orders can be placed. Please specify source for departmental or privately funded projects.*

Principal Investigator on Grant:		
Funding Agency or Fund Source (one per table):		
Grant Title/ Animal Project Title:		
Grant or Project Duration Dates:	Beginning:	Ending:
Contract/Grant Number:		
This application is (check one): ☐ New ☐ New Grant submitted to alternate funding agency* ☐ New Grant that involves monies for salary or equipment support only. No monies are requested for animal studies. ☐ Competitive Renewal * ☐ Addendum/Modification * ☐ Resubmission to funding agency* ☐ IACUC Required Three Year Review*		*** Previously Assigned Protocol:**

Principal Investigator on Grant:		
Funding Agency or Fund Source (one per table):		
Grant Title/ Animal Project Title:		
Grant or Project Duration Dates:	Beginning:	Ending:
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4. **Personnel** (Training & Qualifications)

Provide information regarding the qualifications for all personnel involved with the project (i.e., investigators, technical staff, student personnel, etc.) who may have direct or indirect contact with the animals. All personnel will need to meet the training requirements before being added to the protocol. These requirements are listed on the IACUC Website under Personnel Requirements.

Name *Degree, Certification, or Licensure*	**Title**	**Email Address**	Experience Summary Please describe your experience with the proposed animal model and manipulation

If an investigator, student, or technician listed in this protocol application is performing the procedure for the first time, describe the type of training (below) he/she will receive, the person(s) who will provide that training, and the qualifications of that person to provide such training.

5. Lay Summary of Project (Non-technical):

In the space below, provide a brief nontechnical (lay) description of this project. The language used should be understandable to a non-scientist with a 9th grade education. Avoid using medical/scientific terminology. Use language appropriate for release to the news media. '

This summary should include:

1) An introductory statement of the purpose of and need for the studies,

2) descriptions of the animal use from start to endpoint (with a statement explaining that the animals will be humanely euthanized by approved methods), and

3) The summary should include how discomfort, pain, or distress to the animals will be minimized.

There is no word limit; nevertheless, the summary should be succinct, informative, and complete to facilitate review by a broad audience.

USDA Classification

Classification B: Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes.

Classification C: Animals upon which testing, research, experiments, or tests will be conducted involving no pain, distress, or use of pain-relieving drugs.

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.

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.

6. Animal Numbers:

Please list animal numbers per species separately (Duplicate page if more than 3 species)
Please include animals used specifically for breeding within your totals (ie Breeders, Surplus, & Pups/Offspring). Animals used purely for breeding should be listed under category B.

	Species:				
Category	**B**	**C**	**D**	**E**	Total of animals per category

	Species:				
Category	**B**	**C**	**D**	**E**	Total of animals per category

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Category	**B**	**C**	**D**	**E**	Total of animals per category

	Species:				
Category	**B**	**C**	**D**	**E**	Total of animals per category

	Species:				
Category	**B**	**C**	**D**	**E**	Total of animals per category

	Species:				
Category	**B**	**C**	**D**	**E**	Total of animals per category

6a. Justification for Classification E Animals:

If you have Classification E animals, provide a justification below.

An explanation of the procedures producing pain or distress in these animals and the justification for not using appropriate anesthetic, analgesic or tranquilizing drugs must be provided. This information is required to be reported to the USDA, will be available from the USDA under the Freedom of Information Act, and may be publicly available through the internet via USDA's website. (NOTE: You do not need to provide this justification if you do not have Classification E animals.)

7a. Rationale for Study:

Include the overall rationale and purpose of the proposed use of animals. Include the significance for this project, such as the societal benefit for the study.

7b - Rationale for Animal Numbers:

Please provide justification for the number of animals requested. The number of animals should be statistically justified and be the minimum number required to obtain statistically valid results. Please consider:
-breeding animals (# of breeders, # of replacement breeders, # of surplus, # of offspring for experiments),
-animals used to maintain a colony size,
-animals used for developing and practicing techniques,
-animals for tissue collection, and
-for unforeseen circumstances.
If this is a funded project that extends past the three years, please briefly and clearly indicate the total number of animals needed for years 4 and 5

7c - Rationale for Species:

Provide a rationale for why the species selected is the most appropriate for the study, and explain why a species lower on the phylogenetic scale would not be equally (or more) appropriate.

8. Animal Model:

Species	Strain/Stock/Breed/ (If Other was selected, provide species as well)	Age	Weight	Sex M/F/Both
None				
None				
None				
None				
None				
None				
None				
None				
None				
None				
None				
None				
None				
None				
None				
None				
None				
None				
None				
None				
None				

8a. Wild or exotic species:

☐ **Yes** ☐ **No**

If exotics species are used, are permits required? ☐ **Yes** ☐ **No**

8b. Will animals be individually identified? (*microchip, ear tag, etc)*? ☐ **Yes** ☐ **No**

If yes, please describe method

_____

8c. Will animals be purchased by a UNT/HSC approved vendor? ☐ **Yes** ☐ **No**

If a non-traditional source will be used for acquiring animals, please identify the source and the reason for acquiring animals from an unapproved vendor.

9. Documentation/ Literature Search:

A literature search must be performed to prevent unnecessarily duplication of research projects/courses performed at this and/or other institutions, and to demonstrate that there are no alternatives (such as computer models, tissue culture, etc.) to the use of live animals.

At least two database sources should be searched for alternatives to rule out unnecessary duplication. The date of the search should be current with the application submission date. The years covered in the search should be at least the most recent ten years.

9a.Source	Source(Other)	Date of Search (MM-DD-YYYY)	Years Covered: Start Date (YYYY)	Years Covered:End Date (YYYY)
None				
None				
None				

9b.Keywords used (separated by comma):

Results of the Literature Search (Required of all protocols):
Provide a narrative description of the result of the literature search. **Include a Statement of Assurance that the literature was reviewed for non-animal or less sentient animal species to partially or fully replace animals (such as tissue culture, or insect model), and that this project is not unnecessarily duplicative of research projects/courses performed at this or other institutions.** This narrative should include adequate information for the IACUC to assess that a reasonable and good faith effort was made to determine the availability of alternatives or alternative methods. If the database search or other source identifies a valid alternative method (one that could be used to accomplish the goals of the animal use proposal), the written narrative should justify why this alternative was not used.

More Detailed Documentation Required for Classification D & E: If any procedures fall into USDA's Classification D or E, causing more than momentary or slight pain or distress to the animals, describe your consideration of alternatives and your determination that alternatives are not available. Delineate fully the methods and sources (7a-d above) used in the search. **Alternatives include methods that (a) refine existing tests by minimizing animal distress, (b) reduce the number of animals necessary for an experiment, or (c) replace whole-animal use with in vitro or other tests. When ascities production is used to produce antibodies, justification needs to be given** as to why in vitro systems cannot be used. You must certify that no valid alternative was identified to any described procedures which may cause more than momentary pain or distress, whether relieved or not.

9c. Please provide the results of the literature search in the box below:

10. Housing Location:

(If outside UNT Vivarium select Other and indicate the location in the free text) Other

10a. Special Housing/Husbandry Requirements

☐ Individual Housing*	☐ Metabolic Cages	☐ Special diet
☐ Treated Water	☐ Alternative Lighting	☐ Static Caging
☐ Sterilized Cages	☐ Radiated Feed/Bedding	☐ Other (explain): _____

10a1.*If Individual Housing, identify reason None Selected

10a.2.Justification for Special Housing/ Husbandry Requirements:

Please describe the special housing/ husbandry requirements, provide justification, and indicate who will be responsible for handling the special requirements. If animals are given a special diet, please indicate the source of the diet, where it will be stored, who is responsible for feeding, and if it is nutritionally balanced.

10b. Environmental Enrichment:

Will Animals receive Enrichment? ☐ **Yes** ☐ **No**

If enrichment needs to be withheld, please justify the need to withhold enrichment.

(IACUC SOP 02.09: Enrichment for Laboratory Animals)

10c. Animal Use Location:

Building/ Room	Reason (Check all that apply)	> 12 hrs outside of Housing (Y/N)
	☐ Nonsurgical Procedure ☐ Housed ☐ Survival Surgery ☐ Nonsurvival Surgery ☐ Euthanasia ☐ Behavioral Studies ☐ Other ______	
	☐ Nonsurgical Procedure ☐ Housed ☐ Survival Surgery ☐ Nonsurvival Surgery ☐ Euthanasia ☐ Behavioral Studies ☐ Other ______	
	☐ Nonsurgical Procedure ☐ Housed ☐ Survival Surgery ☐ Nonsurvival Surgery ☐ Euthanasia ☐ Behavioral Studies ☐ Other	
	☐ Nonsurgical Procedure ☐ Housed ☐ Survival Surgery ☐ Nonsurvival Surgery ☐ Euthanasia ☐ Behavioral Studies ☐ **Other**	
	☐ Nonsurgical Procedure ☐ Housed ☐ Survival Surgery ☐ Nonsurvival Surgery ☐ Euthanasia ☐ Behavioral Studies ☐ **Other**	
	☐ Nonsurgical Procedure ☐ Housed ☐ Survival Surgery ☐ Nonsurvival Surgery ☐ Euthanasia ☐ Behavioral Studies ☐ **Other**	
	☐ Nonsurgical Procedure ☐ Housed ☐ Survival Surgery ☐ Nonsurvival Surgery ☐ Euthanasia ☐ Behavioral Studies ☐ **Other**	
	☐ Nonsurgical Procedure ☐ Housed ☐ Survival Surgery ☐ Nonsurvival Surgery ☐ Euthanasia ☐ Behavioral Studies ☐ **Other**	

10d. Justification for animals transported from housing facility for greater than 12 hours (or overnight):

The facility/lab must meet animal facility requirements and will be inspected by an IACUC representative before housing may begin.

10e. How will animals be transported? (IACUC SOP 02.06: Standards for Animal Transport)

11. Food/water restriction:

Will food or water be restricted during the study? ☐ **Yes** ☐ **No**

11a. If yes, what will be restricted? ☐ **Food** ☐ **Water** ☐ **Both**

11b. How long will the Restriction last in hours?

11c. Provide a description and justification in the box below.

12. Restraint *(Other than while under surgical plane of anesthesia)*:

Species (If more than one)	Method (Manual, Device Type)	Duration	Frequency	Reason

12a. Explain procedure in text box below; include considered alternatives and the frequency of observation:

12b. How will the animal be acclimated to the restraint device?

12c. What interventions will be given if an animal fails to adapt to the restraint device? Explain in text box below:

12d. Prolonged restraint (restraint greater than 10 minutes) justification

13. Blood/fluid collection: (IACUC SOP 02.22: Blood Collection Guidelines)

Will blood and/or fluid need to be collected from live animals before euthanasia? ☐ **Yes** ☐ **No**

If yes, answer the questions below:

Species (If more than one)	**Fluid Collected**	**Method**	**Volume** (collected at one time)	**Frequency**

13a. Describe method below, and provide justification and replacement fluid if greater than 10% will be collected at one time.

14. Substance Administration:

Will you be administering any substances to the animals (such as anesthetics, analgesics, drugs, reagents, including adjuvants, dry substances, etc. ...)?

☐ **Yes** ☐ **No**

If yes, provide the following for each substance. Code names may be used for proprietary or unknown substances:

Species	Agent/Class	Route	Dose (mg/kg)	Frequency	Expected Results/ Complications	Pharmaceutical Grade (Y/N)

14a - Non-Pharmaceutical Grade: Adverse Reactions

(IACUC SOP 02.19: Use of Non-Pharmaceutical Grade Compounds in Animals)

Please address the consideration of adverse events related to the following points:

- Grade
- Purity
- Sterility
- pH Balance
- Pyrogenicity
- Psmolatity
- Stability
- Fomulation
- Compatibility of Components
- Pharmacokinetics

14b - Non-Pharmaceutical Grade Justification

OLAW and UDSA agree that pharmaceutical-grade substances must be used when available, however understand the necessary use of non-pharmaceutical grade substances to meet scientific research goals. If non-pharmaceiutical grade substances are used, please provide justification below.

15. Are Biological and/or Hazardous Agents Being Used?

If your work includes use of Recombinant or Synthetic Nucleic Acids, Biohazardous Materials, Chemicals, Radioactive Materials, or Lasers select Yes. ☐ Yes ☐ No

Provide the following for each substance. Code names may be used for proprietary or unknown sources

Species	Agent/ Class	Agent Type (Carcinogen, Radioisotope, Biohazard, Chemical, Other)	Agent Type(if Other)

15a. IBC Approval Numbers (for Bio-hazardous Use Only)

IBC Approval Number	Approval Date (as MM-DD-YYYY)

15b. Is the animal expected to survive exposure? ☐ **Yes** ☐ **No**

15c. Please indicate the Biosafety level required for housing, handling instructions, and length of time that animals/ environment considered hazardous:

15d - Maximum number of exposed animals that will be maintained at any one time

15e. Decontamination procedures required for equipment, personnel, housing areas:

15f. How will contaminated animals, feed, bedding and disposable supplies be handled?

16. Study and Humane Endpoint Criteria: **(IACUC SOP 02.11: Humane Endpoints and Methods of Euthanasia)**

16a. Identify and explain the study endpoint:

16b. Describe the humane endpoint criteria used for determining early experimental endpoints

16c. Describe the frequency of the animal observations:

16d. Describe the response required when the endpoint is reached:

☐ Euthanasia ☐ other:

17. Intervention for pain or distress:

Intervention for pain or distress can only be withheld for scientific reasons. Interventions may be needed for painful study procedure or for accidental injuries and infections. Please specify which interventions can and cannot be given. If one type is preferred over others, please explain in the text box below.

(IACUC SOP 02.12: Assessment and Treatment of Pain and Discomfort)

17a. Interventions are given:

☐ anesthesia ☐ analgesia ☐ euthanasia ☐ other: ☐ none

17b. Circumstances under which interventions are to be used:

☐ as stated in protocol ☐ as recommended by vet ☐ other:

17c. What interventions are withheld?:

☐ anesthesia ☐ analgesia ☐ euthanasia ☐ other: ☐ none

17d. If interventions are withheld, please provide an explanation below why intervention is inappropriate:

18. Euthanasia:

Methods must comply with the current recommendations of the AVMA Guidelines on Euthanasia and IACUC SOP 02.11: Euthanasia Guidelines. If an alternative is proposed, a justification is required.

Species	Agent	Dose	Route of Administration	Secondary Method

18a. Description of Euthanasia Method:

18b. Describe any post-euthanasia sample collection procedures and the samples being collected. Include any substances used to fixate the tissue

18c. If anesthesia will not be used prior to the physical method of euthanasia, please provide Justification:

18d. If euthanasia method is not in line with the AVMA Guidelines for euthanasia, please provide Justification:

19. Surgery:

Surgical Type: ☐ Survival ☐ Multiple Survival* ☐ Terminal ☐ None

Type of Survival Surgery: ☐ Major ☐ Minor

19a. Preoperative Care:

19a.1. Describe how the animal will be prepared for the surgical procedure. Include methods used to minimize microbial contamination to the surgical site, and a description of how the anesthetic depth will be confirmed.

19a.2. Check the boxes of the PPE the surgeon will wear during the procedure.

- ☐ **Clean Lab Coat**
- ☐ **Gown**
- ☐ **Clean Scrub Top**
- ☐ **Face Mask**
- ☐ **Surgical Cap**
- ☐ **Sterile Gloves**
- ☐ **Clean Exam Gloves (only for terminal surgeries)**
- ☐ **Other**

19a.3. Describe how surgical instruments and supplies will be sterilized prior to use. Include how instruments will be sterilized between animals, and the maximum number of animals used per surgical pack.

19b. Intraoperative Care:

Describe the surgical procedures, including the details of the procedure from incision to closure. Include any special techniques, and how the depth/ quality of anesthesia will be monitored throughout to ensure it is adequate.

19c. Postoperative Care:

Describe the post-operative care (For survival procedures only Include information regarding the use of pain-relieving drugs, monitoring of animals for normal recovery, and provision of supportive care.

19d. Incremental Doses:

Under what circumstances will incremental does of anesthetics / analgesics be administered? If none, state this. Otherwise, describe below.

19e. Neuromuscular Blocking Agents:

Will neuromuscular blocking agents be used? ☐ Yes ☐ No

If yes, describe below how and by whom animals will be monitored. Also, if neuromuscular blocking agents are used without general anesthesia, provide justification.

19f. Multiple Survival Surgeries:

Please provide justification for the need of multiple survival surgeries. In addition, include the name of the surgeries that will be performed in conjunction with each other on a single animal, the maximum number of surgeries a single animal will receive, and the time frame between surgeries.

20. Other procedures:

Please select, if any, additional procedures that will performed.

☐ **20a. Tumor & Biological Material Attachment**

20.a.1 Describe the procedure. Include the following: how the animal will be anesthetized, the injection/inoculation site, the tumor cell concentration used, how it will be administered, how the animal will be monitored afterwards.

20.a.2 Total number of inoculations/injections per animal:

20.a.3 If biological material induces tumors, tumors are expected to be: ☐ External ☐ Internal

20.a.4 Is metastasis or other potential side effects expected? ☐ Yes ☐ No

If yes, please describe

☐ **20b Breeding**

20.b.1Breeding Scheme:

☐ Trio Breeding ☐ Timed (hand) Mating ☐ Post-Partum Breeding

☐ Pair Breeding
(If Trio Breeding, please describe how PI will ensure multiple litters do not occur in one cage)

☐ Other
(If other, please describe method and give justification below)

20.b.2 Will animals be weaned within 21-28 days? ☐ **Yes** ☐ **No**
(If no, provide weaning dates and justification)

20.b.3Genetically Modified Animals (GMAs)

GMAs represent an increasingly large proportion of animals used in research. Resulting phenotypes are often unpredictable and may lead to outcomes that affect the animal's well-being or survival. The animals may require more frequent monitoring.

Will GMAs be produced and/or bred? ☐ **Yes** ☐ **No**

Are there any health concerns associated with the development of the phenotypes for the requested strains? ☐ **Yes** ☐ **No**

If yes to either, please detail phenotypes, associated health concerns, and special care required

20.b.4 Will genotyping be required?
(If yes, provide method, age of genotyping, and anesthesia used) ☐ **Yes** ☐ **No**

20.b.5 Please provide a justification for the necessity of breeding as well as what species will be bred:

☐ **20c. Behavior**

Behavior Test	Behavior Test (if Other)	Species	Maximum times animal performs test	Rest time between tests	Response if animal fails test
None					
None					
None					
None					
None					
None					
None					
None					
None					
None					
None					
None					
None					
None					
None					
None					
None					
None					
None					

20.c.1 Please describe the device(s) used in test(s), how the animal will be acclimated to the device,what happens if the animal does not acclimate to the device:

20.c.2 Please describe how the device(s) will be sanitized between animals:

☐ **20d. Imaging**

Imaging Procedure	imaging Procedure (if Other)	Species	Maximum times animal will be imaged	Will animal be restrained/ anesthetized?	Duration of imaging procedure
None				None	
None				None	
None				None	
None				None	
None				None	
None				None	
None				None	
None				None	
None				None	
None				None	
None				None	
None				None	

20.d.1 Provide a description of the imaging procedure, including if the animal will be restrained or anesthetized, how the animal will be monitored throughout the procedure, any substances administered (i.e., contrast agents) as part of the imaging procedure, the device used in the procedure, and how will the device be sanitized between animals

20e Include a Flowchart of all procedures, include animal number and cohort assignments as applicable:
(can include as an attachment if needed)

PRINCIPAL INVESTIGATOR ASSURANCES (Signify by initialing each box)

ALL ASSURANCES MUST BE INITIALED BY PRINCIPAL INVESTIGATOR BEFORE SUBMISSION TO IACUC

1. I have 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. ☐
2. The proposed work does not unnecessarily duplicate previous experiments, based upon search results described in question 7 ☐
3. All personnel involved in this project have been trained in the procedure to be used or will be training before performing procedures. ☐
4. I and all personnel on the project have read any pertinent safety information, IACUC requirements, and security procedures (See Vivarium Director) ☐
5. I shall be responsible for maintaining records of all animals used and the procedures carried out. ☐
6. Any discomfort, distress or pain that may be associated with this research will be held to the absolute minimum. ☐
7. Alternatives to any procedures that may cause pain or discomfort have been considered. ☐
8. **Controlled Substances** IACUC SOP 044: Controlled Substances ☐ ….Yes ☐ No
   If yes, please: I am responsible for procurement, storage, administration, and record keeping for all controlled substances ☐
9. **Non-pharmaceutical Grade Compounds** ☐ ….Yes ☐ No
   If yes, please initial: I have read and understand the IACUC's policy regarding the use of NPGC's in animals. NPGC's will only be used for projects with scientific justification, when acceptable pharmaceutical compounds are unavailable, and with prior IACUC approval ☐
10. I will purchase my animals from an approved vendor, or receive proper approvals from the AV ☐

As Principal Investigator and/or Co-Principal Investigator, I am aware that I have the ultimate responsibility, on a day-to-day basis, for the proper care and treatment of the laboratory animals. I agree to adhere to all federal, state and local laws and regulations governing the use of animals in teaching and research. I 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.

I will obtain formal approval of the Committee prior to implementation of any changes in this protocol.

_____

Principal Investigator

To Submit this protocol, please email this PDF to untiacuc@unt.edu, and use the subject line "IACUC Submission - New Protocol".
Please include any additional attachments required (Flow Chart, Hazardous Agent Risk Assessment Attachment, permits, funding docs, etc.).