

APPLICATION FOR ANIMAL USE

SECTION A - F

IRBNet Number:	
Previous IRBNet Number (If applicable):	

Sections A – F required for all protocols.

SECTION A: MAIN IACUC ADMINISTRATIVE PROTOCOL

Submission Notes: Please fill out all sections. Write N/A if the section is not applicable to your project.

A.1. PERSONNEL INFORMATION

Principal Investigator:

DU ID#:

Position/Title:

Department/College:

Office/Cell Phone #:

Email Address:

Credentials:

Protocol Title: (for this proposal)

Will this project be funded? Include internal funding, external funding, pending grants, and/or pending contracts? Yes (Submit Grant with this protocol) No

Grant Title: (if different from protocol):

Grant P.I.:

Funding Source:

If funded, please provide the Grant #:

A.2. EMERGENCY CONTACTS

A.2.1.

Choose the option that best describes the details of this protocol.

- None. This is a field observation study. No animal holding, housing, management, or control will occur under this protocol.
- This is a study where animals will be held, housed, managed, or controlled.

A.3. ROLE DELINEATION

NOTE: A [Personnel Qualification Form \(Section G\)](#) must be completed for every member of the research group listed on this protocol. The form should illustrate skills or training necessary for the roles specified below (e.g., surgeon, anesthetist, phlebotomist, breeder, provides husbandry, observer, etc.)

TABLE A.3.A. ROLE DELINEATION

To add additional names, please attach a separate document.

NAME	DU ID #	CONTACT PHONE # & EMAIL	ANIMAL HANDLING ROLE? YES/NO	ROLE IN PROJECT
			<input type="checkbox"/> YES <input type="checkbox"/> NO	
			<input type="checkbox"/> YES <input type="checkbox"/> NO	
			<input type="checkbox"/> YES <input type="checkbox"/> NO	
			<input type="checkbox"/> YES <input type="checkbox"/> NO	
			<input type="checkbox"/> YES <input type="checkbox"/> NO	

A.4. COLLABORATING (INCLUDES SUB-CONTRACTING) INSTITUTIONS

A.4.1.

Will any facilities other than the University of Denver be used for animal use activities (e.g., housing, experimentation, observation, or procedures)?

- No, all work will be performed at the University of Denver facilities
- Yes, this is a new protocol

A.5. RENEWAL PROTOCOLS

A.5.1.

Does this application renew an existing protocol?

- Yes, this is a renewal protocol No, this is a new protocol

A.6. IMPORTING & EXPORTING ANIMALS, TISSUES, OR ACTIVITIES

A.6.1.

Will you be EXPORTING animals, specimens, samples (tissues, blood, organ, etc.), or research products outside of the USA?

No

Yes. I commit to contact the University of Denver Export Controls at (303)871-4025 prior to exporting any items

The items I am exporting include:

A.6.2.

Will you be IMPORTING animals, specimens, samples (tissues, blood, organ, etc.), or research products outside of the USA?

No

Yes. I commit to contact the University of Denver Export Controls at (303)871-4025 prior to exporting any items

The items I am importing include:

A.7. SUPPLEMENTAL SECTIONS INCLUDED IN THIS APPLICATION

<http://www.du.edu/orsp/research-compliance/animal-welfare/forms-templates.html>

- Section G: Personal Qualifications Form (PQF) REQUIRED FORM
- [Section H: Hazardous Agent Use](#)
- Section I: Survival Surgery Procedures
- Section J: Non-Survival Surgery Procedures

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- Section K: Non-Surgical Procedures
- Section L: Field Capture and/or Field Studies
- Section M: Breeding Colony (including transgenetic/ko breeding and use)
- Section N: PI Managed Facility
- Section O: PI Managed Holding Facility Aquatic - Reptile Species
- Section P: Exemption from Animal Welfare Standards (Amendment)
- Section Q: Exemption from Animal Welfare Standards (New Protocol)

SECTION B: ANIMAL USE JUSTIFICATION

B.1. PURPOSE

B.1.1.

Describe in lay terms the purpose of this animal use study (250 words or less).

B.2. BENEFIT

B.2.1.

Describe the potential scientific benefit of the proposed study with respect to human or animal health, the advancement of knowledge, or the good of society (250 words or less).

B.3. LITERATURE SEARCH FOR ALTERNATIVES TO POTENTIALLY PAINFUL PROCEDURES

NOTE: The University of Denver Libraries has a very good web site to assist with [Alternative Searches](#). The IACUC recommends use of this site.

B.3.1.

Does the study include procedures that have the potential for producing pain (see instructions)?

- Yes. There is potential for pain
- No. There is NO potential for pain

B.4. LOCATION OF ANIMAL HEALTH/WELL BEING RECORDS (NOT RESEARCH DATA RECORDS)

B.4.1.

Records documenting observation of animal health and well-being:

- Will not be kept by the research staff.

State reason:

- Will be kept with the animal (next to or near the housing location).

- Will be kept at the following location:

Building:

Room Number:

B.5. ANIMAL JUSTIFICATION (APPLIES TO ALL ANIMALS)

B.5.1.

The justification for using live vertebrate animals rather than alternative means of achieving the research goal is (check all that apply):

- The complexity of the processes being studied cannot be duplicated or modeled in simpler systems.

Explain:

- There is not enough information known about the processes being studied to design nonliving models.

Explain:

- Other

Explain:

B.6. SPECIES JUSTIFICATION (ADDRESS EACH SPECIES INDIVIDUALLY)

TABLE B.6.A. SPECIES JUSTIFICATION

To add additional species, please attach a separate document.

SPECIES	THIS SPECIES WAS SELECTED FOR THE STUDY BECAUSE OF THE FOLLOWING ATTRIBUTES (select all that apply)	OTHER ATTRIBUTES (if applicable)
	<input type="checkbox"/> A large database exists allowing comparisons with previous data.	<input type="checkbox"/> Other attributes:

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	<input type="checkbox"/> The anatomy or physiology is uniquely suited to the study proposed. <input type="checkbox"/> This is the lowest species on the phylogenetic scale that is suitable for the proposed study.	
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B.7. NUMBER JUSTIFICATION (ADDRESS EACH SPECIES INDIVIDUALLY)
TABLE B.7.A. NUMBER JUSTIFICATION

To add additional species, please attach a separate document.

SPECIES	THE NUMBER OF ANIMALS REQUESTED FOR THIS PROTOCOL IS BASED ON THE FOLLOWING (Check all that apply)	
	<input type="checkbox"/>	A statistical estimate of the number required to achieve statistical significance.
	<input type="checkbox"/>	The estimated minimum number necessary to achieve the goals of the study in the absence of a statistical estimate.
	<input type="checkbox"/>	The number necessary to obtain sufficient tissue or other material for testing or analysis.
	<input type="checkbox"/>	The number required to provide sufficient technical training or practice for the number of trainees expected.
	<input type="checkbox"/>	The expected or established mortality associated with this procedure.
	<input type="checkbox"/>	OTHER:

B.8. ANIMAL NUMBERS
Adult and/or juvenile (counted at first use) animals only:

NOTE: If this is a renewal protocol and there are animals remaining on the expiring protocol, the number of animals remaining on the expiring protocol (and transferring to the new protocol) must include in the number of animals requested under the new protocol. Animals on the expiring protocol will be transferred to the new protocol upon activation of the new protocol.

TABLE B.8.A. ANIMAL NUMBERS

To add additional species, please attach a separate document.

Species: Age or weight range:
--

Number required for 3-year protocol:

Distribution of above 3-year number of animals over USDA Categories: Attending Veterinarian MUST be consulted for Category D or E.

Category B: (breeding animals)

Category C: (Non-painful procedures)

Category D: (Procedures using anesthesia/analgesia)

Category E: (Painful or distressful procedures without anesthesia/analgesia)

Source of the animals:

NOTE: if transferred from another protocol, provide PI name and protocol number.

B.8.1.

Will embryonic and/or pre-weaning neonate animals be used at any time during this protocol?

No. Only post-weaning animals will be used

Yes. Embryos and/or pre-weaning neonates will be used

B.9. ANIMAL IDENTIFICATION (APPLIES TO ALL ANIMALS)

B.9.1.

Animal identification is:

NOT necessary for this protocol NECESSARY for this protocol

If Animal Identification is NECESSARY, list identification method below.

B.10. OVERVIEW OF EXPERIMENTAL DESIGN AND ANIMAL USE TIMELINES

B.10.1.

Provide a summary of the overall experimental design. The description should define animal groups, group sizes, anticipated or established mortality for these procedures, and how each group will be tested or used. The section should not include a detailed review of surgery or other activities, but should include the use of any unique drugs or practices:

B.10.2.

Describe the anticipated sequence of experimental events (timeline) such as breeding, preparation of animals, surgery, testing procedures, collection of tissues, euthanasia, etc.:

B.11. USE OF ANIMALS FOR PERSONNEL TRAINING

B.11.1.

Is personnel training the primary purpose of this protocol?

- No. This is not a training protocol. However, I may use small numbers of the approved experimental animals to train my research staff the procedures approved for this protocol
- Yes. Animals will be used for personnel training (students or others)

B.12. USE OF PHARMACEUTICAL GRADE CHEMICALS OR SUBSTANCES

NOTE: USDA (Policy #3) and [The Guide \(8th Edition\)](#) requires the use pharmaceutical-grade substances (medications, diluents, and extenders) **whenever they are available, even in acute procedures.**

NOTE: Non-pharmaceutical grade chemical compounds may be used in animals only after specific review and approval by the IACUC for reasons such as scientific necessity or non-availability of an acceptable veterinary or human pharmaceutical-grade product. Cost savings is not a justification for using non-pharmaceutical-grade compounds (exceptions for extraordinary costs of substances may be considered).

NOTE: The IACUC shall consider the grade, purity, sterility, pH, pyrogenicity, osmolality, stability, site and route of administration, formulation, compatibility, and pharmacokinetics of the chemical or substance to be administered, as well as animal welfare and scientific issues relating to its use when determining whether to approve the use of non-pharmaceutical grade products. Inclusion of this information will assist the Committee's review of your request for use of non-pharmaceutical grade material in animals.

B.12.1.

Will this protocol include the use of non-pharmaceutical grade substances for which there is a pharmaceutical grade substance?

- No. All chemicals and substances used on animals will be pharmaceutical grade. Complete table B.12.A
- Yes. Some or all chemicals and substances used on animals will be non-pharmaceutical grade. Complete table B.12.B

TABLE B.12.A. USE OF PHARMACEUTICAL GRADE CHEMICALS OR SUBSTANCES

To add additional spaces, please attach a separate document.

Pharmaceutical chemical or substance required	Describe why each Pharmaceutical grade chemical or substance is necessary.
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TABLE B.12.B. USE OF NON-PHARMACEUTICAL GRADE CHEMICALS OR SUBSTANCES

To add additional spaces, please attach a separate document.

Non-pharmaceutical chemical or substance required	Describe why each non-pharmaceutical grade chemical or substance is necessary.
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B.13. PHOTOGRAPHY/VIDEOS OF ANIMALS OR TISSUES:**B.13.1.**

Will images/video taken of live animals for scientific purposes/publication?

 No. Proceed to section C. Yes**B.13.2.**

Are animals (tissues) University of Denver-owned, Client-owned, or Free-ranging?

- Free-ranging. **NOTE:** No approvals are necessary for free-ranging animals.
- Client-owned. **NOTE:** The Client should provide approval to photograph the animals. No University of Denver approval required.
- University of Denver-owned. Please complete the following:

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Provide the name(s) of the photographer(s) and description of how images/videos will be secured/protected from unauthorized use:

Provide a description and purpose of the photographs/videos, including species (if not all listed in the protocol), and whether the photos are whole body, histologic/fresh/fixed tissues, or radiologic (e.g., CT, PET, MRI):

SECTION C: HOUSING & PROCEDURE ARRANGEMENTS

C.1. PI-MANAGED OR DU ANIMAL FACILITIES (DU-MANAGED) HOUSING

Check all that apply:

- No animal housing will occur at the University of Denver (also includes field studies, collaborating institutions, etc.)
- DU Animal Facilities (DU Managed) housing
- DU PI-Managed housing

TABLE C.1.A. PI-MANAGED OR DU ANIMAL FACILITIES (DU-MANAGED) HOUSING

To add additional species, please attach a separate document.

SPECIES:			
ACTIVITY		BUILDING	ROOM
PI Managed Housing/Holding. (Do NOT complete this row if housed in DU Animal Facilities)	Greater than 12 hours		
	Less than 12 hours		

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Survival Surgery	Pre-operative preparation		
	Surgery		
	Post-operative care		
Non-Survival Surgery	Pre-operative preparation		
	Surgery		
Non-Surgical procedures (including euthanasia)			
Hazardous Agent Use (location of animals while excreting agent)			
Breeding Colony Activities			

C.2. SPECIAL HUSBANDRY REQUIREMENTS
C.2.1.

Is approval requested for any special husbandry needs? Note that special husbandry needs that are approved must be implemented through direct arrangements with the Director of the Animal Facility.

Yes. There are special husbandry requirements No. There are no special husbandry requirements

C.3. END-OF-STUDY HOUSING
C.3.1.

While protocol planning which minimizes animals remaining as single animals for extended periods of time is preferred, on occasion, as experiments approach the end, a single animal may remain. Please answer the following:

- There may be end-of-study animal which will be maintained as single animals for a limited period of time. I confirm that I will provide an enhanced level of species-specific environmental enrichment for any end-of-study animal being housed.
- There will be no end-of-study animals maintained as single animals.

SECTION D: SPECIAL CONCERNS FOR ANIMAL USE
D.1. EXEMPTION FROM ANIMAL WELFARE STANDARDS
D.1.1.

Are there experimental or scientific reasons why any animal on this protocol should be exempted from animal welfare standards?

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- NO.
- YES. An exemption from Social Housing Standards is requested in [Section P](#).
- YES. An exemption from Cage Change Frequency Standards is requested in [Section P](#).
- YES. An exemption from Environmental Enrichment Standards is requested in [Section P](#).
- YES. An exemption from Radio / Sounds / Noise Standards is requested in [Section P](#).
- YES. An exemption from Environmental Conditions (temp, humidity, light, HVAC) Standards is requested in [Section P](#).
- YES. An exemption from Feed / Water Provision Standards is requested in [Section P](#).
- YES. An exemption from Housing Density Standards is requested in [Section P](#).
- YES. An exemption from Aquatics Water Quality Standards is requested in [Section P](#).
- YES. An 'OTHER' exemption is requested in [Section P](#).

Explain:

D.2. ETHER

NOTE: The use of ether presents serious animal and researcher safety concerns and requires compelling scientific justification.

D.2.1.

Will ether be used for euthanasia, anesthesia, or brief sedation?

- No. Ether will not be used.
- Yes. Ether will be used for scientific reasons.

D.3. CONTROLLED SUBSTANCE USE

D.3.1.

Will controlled substances be used for anesthesia, restraint, animal management, agent testing, or euthanasia?

- NO. Controlled substances will not be used.
- YES. Controlled substances will be used. I DO NOT have the registrations at present, but I am/will apply for controlled substance registration. I will have my registration sent to Research Compliance prior to beginning this research.
- YES. Controlled substances will be used. Other personnel will provide controlled substances for sedation, anesthesia, analgesia, and/or euthanasia.

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Please name:

YES. Controlled substances will be used. An [Individual Controlled Substance Registration](#) will provide controlled substances for sedation, anesthesia, analgesia, and/or euthanasia.

My controlled substance registrations are:

NOTE: The Registrant of the C.S. License / Registration **MUST** be listed in Protocol Section A-3 (Roles).

Registrant Name:

Colorado DHHS #:

Federal DEA #:

Location of C. S. Storage:

Building Name:

Room #:

D.4. PHYSICAL RESTRAINT

D.4.1.

Will the proposed research require the use of physical restraint (other than short-term hand-held) of awake animals?

NO. Physical restraint of awake animals will not exceed short-term hand restraint.

YES. Physical restraint must be used. I recognize and agree with the following:

Restraint devices shall not be considered a normal method of housing.

Restraint devices shall not be used as convenience in handling or managing animals.

Alternatives to physical restraint have been considered and cannot meet the requirements of my study.

The restraint period shall be the minimum required to accomplish my research objectives.

Animals shall be acclimated to the devices and personnel prior to actual research use.

Animals that fail to adapt shall be removed from the study.

Animals in restraint shall be observed at appropriate intervals, as described below.

Veterinary care shall be provided if lesions or illnesses associated with restraint are observed.

Clear explanation of the purpose of the restraint and its duration shall be provided to personnel involved.

Please address D4. 2-7 below.

D.4.2.

Briefly describe or identify the restraint device:

D.4.3.

Briefly describe the procedure for restraining the animal:

D.4.4.

State the duration of the restraint period:

D.4.5.

Describe the plan for observation of the animal during the period of restraint:

D.4.6.

Describe the plan for animal care and support during the period of restraint to ensure comfort and well-being:

D.4.7.

Describe the procedure for conditioning the animal to the restrain device and procedure so as to minimize potential animal distress during restraint:

D.5. WITHHOLDING OF ANESTHETICS OR ANALGESICS

D.5.1.

Does this protocol involve procedures that are expected to cause pain, but for which pain-relieving anesthetics and/or analgesics will not be provided?

NO. There are no painful procedures (i.e., no greater pain than would be expected from simple injections.)

NO. Anesthetics and/or analgesics will be provided for pain relief.

YES. This protocol includes painful procedures for which anesthetics and/or analgesics must be withheld. Please complete D5.A. and D5.B. below.

D.5.2.

Identify the treatment groups and specify the number of animals in each group that will not be provided with pain relief.

D.5.3.

Detail the scientific reason that requires the withholding of anesthetics and/or analgesics for pain relief.

D.6. ANIMAL WELL-BEING, HUMANE & EXPERIMENTAL ENDPOINTS.

According to [The Guide](#), researchers should consider the impact of their procedures upon the animals' well-being. Do you anticipate any animal health complications (e.g. local or systemic infection, physical or physiological impairment, heavy tumor burden, tumor necrosis, malnutrition, dehydration, etc.) arising from the experimental procedures or animal manipulations that are proposed in this protocol?

- NO. Animal health complications are NOT expected. **Skip to D6.4.**
 YES. Animal health complications MAY occur. **Please address D6.1-D6.3 below.**

D.6.1.

Describe the health complications that are anticipated:

D.6.2.

Describe the plan for detecting the development of complications and their routine management:

D.6.3.

If animals experience complications that are not resolved by the above management plan, specify the action(s) that will be taken (select all that apply).

- Euthanize the animal.
 Seek veterinary advice from the Attending Veterinarian.
 Withdraw the animal from the study for treatment and recovery according to the following plan (describe):

D.6.4.

According to The Guide, the Principal Investigator, with precise knowledge of both the objectives of the study and the proposed model, should identify, explain and include in the protocol a study endpoint that is both humane and scientifically sound.

The **experimental endpoint** of a study occurs when the scientific aims and objectives have been reached. The **humane endpoint** is the point at which pain or distress is prevented, terminated or relieved in an experimental animal. The use of humane endpoints contributes to refinement by providing an alternative to experimental endpoints that result in more severe animal pain and distress, including death. Please select the correct response.

- I anticipate that the experimental endpoints will be reached prior to the humane endpoints.
 I anticipate that humane endpoints will be reached prior to the experimental endpoints. Please explain in the space below.

This is necessary because:

D.6.5.

Other than euthanasia, is there the potential for adverse outcomes affecting the animals' well-being (inflammation, inappetence, etc.)?

- NO. Other than euthanasia, there is no potential for adverse outcomes affecting the animals' well-being.
 YES. Other than euthanasia, there is the potential for adverse outcomes affecting the animals' well-being.

If 'YES', please explain:

D.7. ACCLIMATION AND HABITUATION OF RESEARCH ANIMALS

According to [The Guide](#), habituating animals to routine husbandry or experimental procedures may assist the animal to better cope with a captive environment by reducing stress associated with novel procedures or people (see Policy on Acclimation). The type and duration of habituation needed will be determined by the complexity/novelty of the procedure.

D.7.1.

Please select the appropriate response below:

Acclimation upon arrival to the University of Denver:

- The [Policy on Acclimation](#) will be followed.
 I am unable to adhere to the [Policy on Acclimation](#). My justification is:

Habituation for Husbandry or Experimental Procedures:

- Habituation is not necessary. This protocol does not present the animal with novel procedures or people which would require habituation or training to assist the animal with coping.
 Habituation/training are performed as part of my research protocol. The methods I will use include:

SECTION E: EUTHANASIA & DISPOSITION**E.1. EUTHANASIA:**

E.1.1.

Please indicate the role of euthanasia in the proposed activity:

- Animals will be euthanized as part of the experimental protocol. (Specify method below.)
 Euthanasia is not planned, but will be performed to prevent animal distress. (Specify method below.)

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Euthanasia will not be performed. Federal, international, or local permits governing this work do not allow euthanasia.

E.1.2.

Please specify the method(s) of euthanasia below. Use a separate line for each species studied under this protocol.

TABLE E.1.A. GENERALLY ACCEPTABLE METHODS OF EUTHANASIA (SEE DROP-DOWN LIST FOR ACCEPTABLE OPTIONS)

To add additional species, please attach a separate document.

SPECIES	METHOD	ANESTHETIC OR INJECTABLE AGENT/DOSE/ROUTE OF ADMINISTRATION OR TRICAINЕ CONCENTRATIONS
	<input type="checkbox"/> CO2 inhalation chamber <input type="checkbox"/> Cervical dislocation under anesthesia <input type="checkbox"/> Decapitation under anesthesia <input type="checkbox"/> Exsanguination under anesthesia <input type="checkbox"/> Inhalant anesthetic gas (no ether) <input type="checkbox"/> Injectable euthanasia agent <input type="checkbox"/> Tricaine (MS-222) immersion <input type="checkbox"/> Tricaine (MS-222) applied to gills	

NOTE: If CO2 euthanasia was selected for any species, a secondary method to ensure non-recovery is required. Please select the secondary method(s) that will be used to ensure euthanasia:

- Bilateral thoracotomy
- Decapitation
- Tissue/organ collection
Specify tissues / organs:
- Other method to ensure death
Specify:

TABLE E.1.B. CONDITIONALLY ACCEPTABLE METHODS OF EUTHANASIA

(see drop-down list for acceptable options):

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To add additional species, please attach a separate document.

SPECIES	METHOD	SCIENTIFIC JUSTIFICATION FOR PROCEDURE WITHOUT ANESTHESIA
	<input type="checkbox"/> cervical dislocation without anesthesia <input type="checkbox"/> decapitation without anesthesia	

TABLE E.1.C. OTHER METHODS OF EUTHANASIA

(consistent with [AVMA Panel on Euthanasia](#) recommendations)

To add additional species, please attach a separate document.

SPECIES	METHOD (SPECIFY)	AGENT/DOSE/ROUTE OF ADMINISTRATION AS APPLICABLE

E.1.3.

Please explain the reason for performing euthanasia by a method other than those identified above as generally or conditionally acceptable:

E.2. FINAL DISPOSITION OF ANIMALS

E.2.1.

Indicate the method(s) of terminating responsibility for the live animals (select all that apply):

- Live animals may be transferred to other approved DU protocols to facilitate collaborative interactions and reduce overall animal usage and undue wastage. All transfers will be coordinated through the Director of the Animal Facilities.
- Live animals may be returned to production/breeding unit.
- Animals will be euthanized by methods specified in section E1 above (Euthanasia).
- Other (specify):

E.3. FINAL DISPOSITION OF TISSUES, FLUIDS, OR CARCASSES

E.3.1.

Indicate the method(s) of disposing of the carcasses and surplus tissues or fluids (select all that apply):

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- Carcasses of non-biohazardous dead animals will be disposed of by the PI according to EH&S policy.
- Non-radioactive/non-biohazardous tissues or fluids will be disposed of by the PI.
- Radioactive carcasses, tissues, or fluids will be disposed of with consultation with DU EH&S.
- Other (specify):

E.4. SHARING OF TISSUES, FLUIDS, OR CARCASSES

NOTE: This section **ONLY APPLIES** to animals which are dead prior to collecting the tissues, fluid, or carcasses. Any collection of tissues or fluids from animals which are alive **requires** specific protocol approval for the collection of tissues or fluids.

E.4.1.

Indicate below if you anticipate sharing tissues, fluids, or carcasses post-euthanasia from this protocol:

- I may share tissues, fluids, or carcasses from my euthanatized animals with DU researchers.
- I may share tissues, fluids, or carcasses from my euthanatized animals with non-DU researchers.

NOTE: Prior to shipping off campus, check with the Director of the Animal Facilities and EH&S for requirements of biological specimen shipment.

SECTION F: PRINCIPAL INVESTIGATOR AGREEMENT

F.1.1.

Check each box that is applicable. A checked box indicates agreement by the PI for the statement checked. The agreement may be signed electronically as part of this form or a printed copy may be signed, scanned, and attached.

- I will conduct the project in accordance with the PHS Policy on Humane Care and Use of Laboratory Animals, USDA regulations (9 CFR Parts 1, 2, 3), the Federal Animal Welfare Act (7 USC 2131 et. Seq.), and the *Guide for the Care and Use of Laboratory Animals*.
- I have determined that the research proposed is not unnecessarily duplicative.
- I confirm that all individuals working on this protocol have been assessed for health risks and are participating in an appropriate Occupational Health & Safety Program. (Note: The DU Animal Handler Questionnaire is located at <http://www.du.edu/ehs/forms/index.html>; participation in an Occupational Health Program is mandatory).
- I authorize individuals listed on this application to conduct procedures involving animals and I accept responsibility for their oversight in the conduct of this proposal.

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I confirm that all individuals listed on this protocol as working with animals have completed the [Occupational Health Review Form](#) or will be required to do so before being permitted to begin work with animals. Further, I certify that those individuals are properly trained, or will receive such training prior to working with animals, in all areas relevant to their assigned work with animals (e.g., biology, handling, and care of the species used; aseptic surgical methods and techniques; the concept, availability, and use of research or testing methods that limit the use of animals or minimize distress; the proper use of anesthetics, analgesics, and tranquilizers; and procedures for reporting animal welfare concerns).

For animals held in a DU operated facility or used on the DU campus, I understand that in cases of necessary medical treatment, the Attending Veterinarian is authorized to provide any treatment required to sustain life; or if necessary, humane euthanasia to prevent distress and/or pain. I recognize that the veterinary staff will contact me as soon as possible using the emergency contact information that I provide in this application, but I understand that such contact may not always be possible prior to providing treatment or performing euthanasia.

I will notify the IACUC regarding unanticipated outcomes of animal use; including protocol and non-protocol disease or injury. Unanticipated outcomes are generally defined as negatively impacts to animal welfare. This includes animals at DU or animals residing at collaborating institutions where DU grant funds are used for support or experimentation of the animals.

I recognize that veterinary consultation must occur when pain or distress is beyond the level IACUC approved in this protocol, or when my staff are unable to provide interventional control (e.g., euthanasia, immediate removal from the study). For animals held in a DU operated facility or used on the DU campus, I will notify the Attending Veterinarian when unanticipated pain or distress, unexpected morbidity, or unanticipated mortality occurs with animals approved for use under this protocol.

I will obtain approval from the IACUC before initiating any change in the study design or procedures by submitting a request for minor or significant change as appropriate. I understand that work performed without IACUC approval cannot be published with certification of IACUC approval and may result in federally-required reporting of non-compliance.

For all USDA Category D (anesthesia / analgesia provided to relieve potential pain) and USDA Category E (pain not relieved by anesthesia / analgesia) animal use procedures, I certify that I have reviewed the pertinent scientific literature and the sources and/or databases noted in this application and found no scientifically acceptable alternative to any of those procedures that would result in less pain or distress.

PI Name:

DU ID#:

Animal Handling Role: Yes No

Project Title:

Principal Investigator Signature: