COLORADO COMMUNITY COLLEGE SYSTEM
ANIMAL STUDY PROPOSAL

Leave Blank
Proposal #:

Approval Date:

Expiration Date:

PLEASE TYPE

A. ADMINISTRATIVE DATA

College
Department:

Principal Student
Investigator:

Mailing Address:

Telephone: Fax: Email:

Project Title:

Initial Submission ☐ Renewal ☐ or Modification ☐

List the names of all students authorized to conduct procedures involving animals under this proposal

B. ANIMAL REQUIREMENTS

Genus: *[e.g., Mus]* Species: *[e.g., musculus]*

Strain, subspecies, or breed: *[e.g., C57BL]* Common name: *[e.g., black laboratory mouse]*

Approximate age, weight or size:

Sex:

Bacteriological status: *[e.g., germfree (axenic), defined flora (gnotobiotic), specific pathogen free, conventional]*

Viral status: *[e.g., simian immunodeficency virus, simian retrovirus]*

Source(s): *[e.g., name of vendor or breeder, bred in-house]*

Primary housing location(s): *[Facility manager must certify below that facility has the resource capability to support the study. If animals will be housed in lab or anywhere else outside central facility for more than 12 hours, provide building and room number.]*

Location(s) where manipulation will be conducted:

Number of Animals to be Used:
Year 1: Year 2: Year 3:
Total:

C. TRANSPORTATION

Transportation of animals must conform to all federal regulations. If animals will be transported on public roads or out of state, describe efforts to comply with USDA regulations. If animals will be transported between facilities, describe the methods and containment to be utilized. If animals will be transported within a facility, include the route and elevator(s) to be utilized.

D. STUDY OBJECTIVES

Briefly explain in language understandable to a layperson the aim of the study and why the study is important to human or animal health, the advancement of knowledge, or the good of society.

E. RATIONALE FOR ANIMAL USE (Use additional sheets if necessary.)

1) Explain your rationale for animal use. *[The rationale should include reasons why non-animal models cannot be used.]*

2) Justify the appropriateness of the species selected. *[The species selected should be the lowest possible on the phylogenetic scale.]*

3) Justify the number of animals to be used. [The number of animals should be the minimum number required to obtain statistically valid results.]

F. DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES

(Use additional sheets if necessary.)

Briefly explain the experimental design and specify all animal procedures. This description should allow the IACUC to understand the experimental course of an animal from its entry into the experiment to the endpoint of the study. Specifically address the following:

- **Experimental injections or inoculations** (substances, e.g., infectious agents, adjuvants, etc.; dose, sites, volume, route, and schedules).
- **Blood withdrawals** (volume, frequency, withdrawal sites, and methodology).
- **Radiation** (dosage and schedule)**.**
- **Methods of restraint (**e.g., restraint chairs, collars, vests, harnesses, slings, etc.). Include how animals are restrained for routine procedures like blood withdrawals. Prolonged restraint must be justified with appropriate oversight to ensure it is minimally distressing. Describe any sedation, acclimation or training to be utilized.
- **Animal identification methods** (e.g., ear tags, tattoos, collar, cage card, implant, etc.).
- **Other procedures** (e.g., survival studies, tail biopsies, etc.).
- **Resultant effect**s, if any, that the animals are expected to experience (e.g., pain or distress, ascites production, etc.).
- **Other potential stressors** (e.g., food or water deprivation, noxious stimuli, environmental stress) **and procedures to monitor and minimize distress**. If a study is USDA Classification E, indicate any non-pharmaceutical methods to minimize pain and distress.
- **Experimental endpoint criteria** (e.g., tumor size, percentage body weight gain or loss, inability to eat or drink, behavioral abnormalities, clinical symptomatology, or signs of toxicity) must be specified when the administration of tumor cells, biologics, infectious agents, radiation or toxic chemicals are expected to cause significant symptomatology or are potentially lethal. List the criteria to be used to determine when euthanasia is to be performed. Death as an endpoint must always be scientifically justified.
- **Veterinary care** (indicate desired plan of action in case of animal illness, e.g., initiate treatment, call investigator prior to initiating treatment, euthanize).

G. PAIN OR DISTRESS CLASSIFICATION AND CONSIDERATION OF ALTERNATIVES

1. Pain or Distress Classification

Species (common name)	**USDA Classification* B, C, D or E**	**Number of animals used each year**			**3 year total number of animals**
		Year 1	**Year 2**	**Year 3**	
Total number of animals (should equal total from Section B):					

*** USDA Classifications and Examples**

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

- Breeding colonies of any animal species (USDA does not require listing of rats, mice, birds) that are held in legal sized caging and handled in accordance with the *Guide* and other applicable regulations. Breeding colony includes parents and offspring.
- Newly acquired animals that are held in proper caging and handled in accordance with applicable regulations.
- Animals held under proper captive conditions or wild animals that are being observed.

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

- Procedures performed correctly by trained personnel such as the administration of electrolytes/fluids, administration of oral medication, blood collection from a common peripheral vein per standard veterinary practice (dog cephalic, cat jugular) or catheterization of same, standard radiography, parenteral injections of non-irritating substances.
- Euthanasia performed in accordance with the recommendations of the most recent AVMA Panel on Euthanasia, utilizing procedures that produce rapid unconsciousness and subsequent humane death.
- Manual restraint that is no longer than would be required for a simple exam; short period of chair restraint for an adapted nonhuman primate.

Classification D: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will be used.
Examples:

- Surgical procedures conducted by trained personnel in accordance with standard veterinary practice such as biopsies, gonadectomy, exposure of blood vessels, chronic catheter implantation, laparotomy or laparoscopy.
- Blood collection by more invasive routes such as intracardiac or periorbital collection from species without a true orbital sinus such as rats and guinea pigs.
- Administration of drugs, chemicals, toxins, or organisms that would be expected to produce pain or distress but which will be alleviated by analgesics.

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.

Examples:

- Procedures producing pain or distress unrelieved by analgesics such as toxicity studies, microbial virulence testing, radiation sickness, and research on stress, shock, or pain.
- Surgical and postsurgical sequella from invasion of body cavities, orthopedic procedures, dentistry or other hard or soft tissue damage that produces unrelieved pain or distress.
- Negative conditioning via electric shocks that would cause pain in humans.
- Chairing of nonhuman primates not conditioned to the procedure for the time period used.

NOTE REGARDING CLASSIFICATION E: 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 on **Attachment 1**. This information is required to be reported to the USDA, will be available from USDA under the Freedom of Information Act, and may be publicly available through the Internet via USDA's website.

2. Consideration of Alternatives

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 the methods and sources used in the search. Database references must include databases searched, the date of the search, period covered, and the keywords used. Alternatives include methods that (1) refine existing tests by minimizing animal distress, (2) reduce the number of animals necessary for an experiment, or (3) replace whole-animal use with in vitro or other tests. When ascites production is used to produce antibodies, justification needs to be given as to why in vitro systems cannot be used. Note that you must certify in Section Q.5. that no valid alternative was identified to any described procedures which may cause more than momentary pain or distress, whether relieved or not.

H. ANESTHESIA, ANALGESIA, TRANQUILIZATION, OTHER AGENTS

For animals indicated in Section H.1., Classification D, specify the anesthetics, analgesics, sedatives or tranquilizers that are to be used. Include the name of the agent(s), the dosage, route and schedule of administration. If information is provided in Section G. above, please cross-reference. Describe tracking and security of controlled drugs (Drug Enforcement Agency requirements).

I. METHOD OF EUTHANASIA OR DISPOSITION OF ANIMALS AT END OF STUDY

Indicate the proposed method of euthanasia. If a chemical agent is used specify the dosage and route of administration. If the method(s) of euthanasia include those **not** recommended by the AVMA Panel Report on Euthanasia (e.g., decapitation or cervical dislocation without anesthesia), provide scientific justification why such methods must be used. Indicate the method of carcass disposal if not described in Section K. below.

Additional safety considerations:

J. BIOLOGICAL MATERIAL/ANIMAL PRODUCTS FOR USE IN ANIMALS
(e.g., cell lines, antiserum, etc.)

1. Specify Material:

2. Source: Material Sterile or Attenuated: Yes ☐ No ☐
If derived from rodents, has the material been MAP/RAP/HAP tested*? [MAP - Mouse Antibody Production; RAP - Rat Antibody Production; HAP - Hamster Antibody Production]*

Yes ☐ (Attach copy of results) or No ☐

3. I certify that the MAP/RAP/HAP tested materials to be used have not been passed through rodent species outside of the animal facility in question and/or the material is derived from the original MAP tested sample. To the best of my knowledge the material remains uncontaminated with rodent pathogens.

☐ **Initials of Principal Investigator.**

K. TRANSGENIC AND KNOCKOUT ANIMALS

Describe any phenotypic consequences of the genetic manipulations to the animals. Describe any special care or monitoring that the animals will require.

L. EXEMPTIONS FROM ENVIRONMENTAL ENHANCEMENT FOR NONHUMAN PRIMATES OR EXERCISE FOR DOGS

1. For nonhuman primates, are you seeking an exemption for scientific reasons from the institution's plan for environment enhancement? Yes ☐ or No ☐ If yes, provide the basis of the request.

2. For dogs, are you seeking an exemption for scientific reasons from the institution's plan to provide dogs with the opportunity for exercise? Yes ☐ or No ☐ If yes, provide the basis of the request.

M. FIELD STUDIES

If animals in the wild will be used, describe how they will be observed, any interactions with the animals, whether the animals will be disturbed or affected, and any special procedures anticipated. Indicate if Federal permits are required and whether they have been obtained.

N. SPECIAL CONCERNS OR REQUIREMENTS OF THE STUDY

List any special housing, equipment, animal care (e.g., special caging, water, feed, or waste disposal, environmental enhancement, etc.).

O. PRINCIPAL INVESTIGATOR CERTIFICATIONS

1. I certify that I have attended the institutionally required investigator training course.
   Year of Course Attendance: Location:
2. I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research.
3. I certify that I will obtain approval from the IACUC before initiating any significant changes in this study.
1. I certify that I will notify the IACUC regarding any unexpected study results that impact the animals. Any unanticipated pain or distress, morbidity or mortality will be reported to the attending veterinarian and the IACUC.
2. I certify that I am familiar with and will comply with all pertinent institutional, state, and federal rules and policies.

Principal Investigator:

Name: Signature: Date:

Q. CONCURRENCES

PROPOSAL NUMBER _____ (leave blank)

Faculty Supervisor:

Name: Signature: Date:

Safety Office/Committee Certification of Review and Concurrence:
(Required of all studies utilizing any hazardous agents.)

Name: Signature: Date:

Veterinarian certification of resource capability in the indicated facility to support the proposed study:

Facility:	Name:	Signature:	Date:
Facility:	Name:	Signature:	Date:

Comments:

Attending Veterinarian certification of review and consultation on proper use of anesthetics and pain relieving medications for any painful procedures:

Name: Signature: Date:

R. FINAL APPROVAL:

Certification of review and approval by the Institutional Animal Care and Use Committee:

Name: Signature: Date:

List any attachments here:

Attachment 1

Explanation for USDA Classification E

(This report is required to accompany USDA Form 7023 to support any USDA Classification E listings.)
This document must be typed.

Name of investigator:

Animal Study Proposal Title:

Species and number of animals listed in Classification E for each year:

Species:
Number of animals:
year 1 -
year 2 -
year 3 -
Total:

Description of project including reason(s) for species selection:

Provide a scientific justification to explain why the use of anesthetics, analgesics, sedatives or tranquilizers during and/or following painful or distressing procedures is contraindicated:

Signature of investigator:
Date:

Signature of IACUC Chairperson:
Date: