

Start with a dream. Finish with a future.



Application for Project Approval
Form Revised 12/14/11 10:00 a.m.
Central Connecticut State University
Institutional Animal Care and Use
Committee (IACUC)
Chair: Ruth Rollin, 860-832-2659,
rollin@mail.ccsu.edu

OFFICE USE ONLY
Project # _____
Approval Date _____
Expiration Date _____

PLEASE TYPE:

A. ADMINISTRATIVE DATA:

Project Director:

Department:

Telephone: Emergency: E-Mail:

Project Title:

Initial Submission [] or Renewal [] or Modification [] of Project Number

If a teaching project, what is course number:

If a research project, what is the funding source: Submission Deadline:

Proposed Project Start Date: Project End Date:

B. ANIMAL REQUIREMENTS:

Species: Age/Weight/Size: Sex:

Stock or Strain:

Source(s):

Housing Location(s)(If animals will be housed in lab or anywhere else outside the primary facility for more than 12 hours, provide building and room number.):

Animal Procedure Location(s):

Number of Animals:

Table with 5 columns: Year 1, Year 2, Year 3, =, TOTAL

C. SPECIAL CONCERNS OR REQUIREMENTS OF THE PROJECT: Yes No If no, go to Section D.

List any special housing, equipment, animal care (e.g., special caging, water, feed, bedding, temperature, humidity, light cycle, or waste disposal, environmental enhancement, housing social animals singly, etc.). Solid-bottom caging, with bedding is recommended for rodents. Housing rodents on wire requires scientific justification. If laboratory personnel are primarily responsible for animal care, provide a copy of the standard operating procedures.

D. TRANSPORTATION: Yes No If no, go to Section E.

Transportation of animals must conform to all institutional guidelines/policies and 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. Will live animals be returned to animal facilities?

E. PROJECT OBJECTIVES:

1. Briefly describe in non-technical terms the aim of the project and how the project may benefit human or animal health or advance scientific understanding of biological processes or educational objectives. (What do you expect it to achieve? Why is the project important?)
2. Only If Renewal. Briefly explain why more work needs to be done.

F. RATIONALE FOR ANIMAL USE:

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.
 - This is a new model.
 - This model has previously been used. Provide citation:
 - The results will be directly applicable to the health or care of this species.

3. Justify the number of animals to be used. (*Describe how the number of animals to be used was determined, and why that number is necessary to achieve the goals of this project. If possible, summarize this information in a table giving 1) the number of different experiments, 2) the number of groups per experiment, and 3) the number of animals per group. Whenever possible, justify the number of animals statistically.*) Note: All animals involved in the project must be included in the protocol and justified. This includes not only experimental animals, but also donor animals, breeding pairs, pregnant mothers, and offspring that cannot be utilized because of genotype/phenotype, sex, etc.

G. DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES:

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 project. Specifically address the following:

-
- **Animal Identification Methods** (*e.g.*, ear tags, tattoos, collar, leg band, cage card, implant, etc.)
 - **Injections or Inoculations** (substances, *e.g.*, infectious agents, adjuvants, etc.; dose, sites, volume, route, and schedules). Yes No
 - **Pharmaceutical-grade and Non-pharmaceutical-grade Compounds** Identify any drugs, biologics, or reagents that will be administered to animals. If these agents are not human or veterinary pharmaceutical-grade substances, provide a scientific justification for their use and describe methods that will be used to ensure appropriate preparation and administration. Yes No
 - **Blood Withdrawals** (volume, frequency, withdrawal sites, and methodology). Yes No
 - **Non-Survival Surgical Procedures** (Provide details of survival surgical procedures in Section I)
 Yes No
 - **Radiation** (dosage and schedule) Yes No
 - **Methods of Restraint** (*e.g.*, restraint chairs, collars, vests, harnesses, slings, etc.) Yes No
 - **Resultant Effects**, if any, the animals are expected to experience (*e.g.*, pain or distress, ascites production, etc.) Yes No
 - **Other potential stressors** (*e.g.*, food or water deprivation, noxious stimuli, environmental stress) **and procedures to monitor and minimize distress.** If a project is Category D, indicate any non-pharmaceutical methods to minimize pain and distress. Yes No
 - **Other Procedures** (*e.g.*, behavioral studies, tail biopsies, etc.) Yes No

- **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. Yes No

H. RECORDS:

Records should include animal or group identification, type of procedure (blood collection (amount, method), kind of surgery, euthanasia (method), administration of drugs (name, dose, route), *etc.*), initials of personnel, date, and observations relating to animal health and welfare. Describe your records or attach a copy for the IACUC to review:

I. **SURVIVAL SURGERY:** Yes No If no, go to Section J.

Minor Surgery (cut-downs, needle aspirations, tail biopsies) Specify.

Major Surgery (entering a body cavity or producing substantial impairment of physical or physiologic functions (such as laparotomy, thoracotomy, craniotomy, joint replacement, or limb amputation). Specify.

1. Identify and describe the surgical procedure(s) to be performed. Include preoperative procedures (*e.g.*, fasting, analgesic loading), and anesthetic monitoring (*e.g.*, corneal and pedal reflexes, heart and respiratory rates, *etc.*), and supportive care (ophthalmic ointment, methods to prevent dehydration and hypothermia, *etc.*) during surgery. Include the aseptic methods (*e.g.*, animal and human preparations, sterile instruments and field, *etc.*) to be utilized.
2. Who will perform surgery and what are their qualifications and/or experience?
3. Where will surgery be performed (Building and Room)?
4. Are paralytic agents used during surgery? If yes, please describe how ventilation will be maintained and how pain will be assessed.

5. If survival surgery, describe post-operative care required, including location, frequency of observation, consideration of the use of post-operative analgesics, and identify the responsible individual(s), and duration of survival after surgery. What impairment can be expected from the surgery and describe any post-operative complications that may develop and your plans to handle them
6. Has major survival surgery been performed on any animal prior to being placed on this project?
 Yes No
 If yes, please explain:
7. Will more than one major survival surgery be performed on an animal while on this project?
 Yes No
 If yes, please justify:

J. PAIN OR DISTRESS CATEGORY AND CONSIDERATION OF ALTERNATIVES

1. Pain or Distress Categories

Species (common name)	Category* A, B, C or D	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):					

*** Categories and Examples**

Category A: 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. 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.

Category B: 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 or catheterization of same, standard radiography, parenteral injections of non-irritating substances, restrictions of food/water intake for less than equivalent to periods of abstinence in nature.
- Euthanasia performed in accordance with the recommendations of the most recent AVMA Guidelines 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; less than 12 hours of physical restraint for an adapted animal.

Category C: 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.

Category D: 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.
- Physical restraint of animals not conditioned to the procedure for the time period used or in excess of 12 hours.

Note Regarding Category D: An explanation of the procedures producing pain or distress in these animals and the justification for not using anesthetic, analgesic or tranquilizing drugs must be provided below. For USDA (Animal Welfare Act) AWA-covered animals, this information is required to be reported to the USDA, will be available from USDA under the Freedom of Information Act.

1. Consideration of Alternatives

The project director must provide a written assurance that the activities do not unnecessarily duplicate research projects/courses and that there are no alternatives (such as less sentient animal species, computer models, tissue culture, *etc.*) to the use of live animals. 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 bonafide 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.

If any procedures fall into Categories C or D, causing more than momentary or slight pain or distress to the animals, 1) describe your consideration of alternatives and your determination that alternatives are not available and 2) involve the Attending Veterinarian in planning. Yes No

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. Note that you must certify in Section R.5. that no valid alternative was identified to any described procedures which may cause more than momentary pain or distress, whether relieved or not. Delineate the methods and sources used in the search. Database references must include databases (2 or more) searched, the date of the search, period covered, and the keywords used.

- Medline Agricola Biosis Embase AWIC CAB Abstracts
- CAB Vet & Medica Index Medicus Federal Research in Progress NML
- Science Citation Index Current Contents National Agricultural Library PubMed
- Periodicals:(names of periodicals or journals read on a regular basis)
- Meetings or conferences: (names and dates of meetings attended)
- Consultation with colleagues (names and credentials of colleagues (*i.e.*, M.D., Ph.D.), dates of consultations and nature of discussions)
- Other. Specify.

K. ANESTHESIA, ANALGESIA, TRANQUILIZATION PROJECT: Yes No If no, go to Section L.

For animals indicated in Section J, Category C, specify the anesthetics, analgesics, sedatives or tranquilizers that are to be used. Include the name of the agent(s), the dosage, route and frequency of administration. Describe tracking and security of controlled drugs (Drug Enforcement Agency requirements).

L. METHOD OF EUTHANASIA OR DISPOSITION OF ANIMALS AT END OF PROJECT

What will happen to the animals at the conclusion of the experiment or demonstration? Indicate the proposed method of euthanasia. If a chemical agent is used, specify the dosage range and route(s) of administration. If the method(s) of euthanasia include those not recommended by the AVMA Guidelines on Euthanasia (e.g., decapitation or cervical dislocation without anesthesia), provide scientific justification as to why such methods must be used. Indicate the method of carcass disposal if not described in Section M. below.

- Anesthetic injection overdose (state drug/dose per body weight/route of administration of drug).
- Exsanguination under anesthesia (state name/dose (per body weight)/route of administration of drug).
- Inhalation of carbon dioxide from a compressed gas cylinder.
- Cervical dislocation.
- Decapitation.
- Other. (Describe.)

Note: In some animals exposed to gas, heartbeat can be maintained after visible respiration has ceased, and the animal might eventually recover. A thoracotomy or other physical method is recommended to assure death of animals after gas exposure. At minimum, check for both respiratory and cardiac arrest prior to discarding the carcass. Describe how death is verified.

M. HAZARDOUS AGENTS IN ANIMALS Yes No If no, go to Section N.

Use of hazardous agents requires the approval of the institutional biosafety specialist. Registration Documents for the use of recombinant DNA or potential human pathogens may be attached at the discretion of the IACUC.

	YES	NO	List Agents & Registration Document # (if applicable)
Radionuclides	<input type="checkbox"/>	<input type="checkbox"/>	
Biological Agents	<input type="checkbox"/>	<input type="checkbox"/>	
Hazardous Chemicals or Drugs	<input type="checkbox"/>	<input type="checkbox"/>	
Recombinant DNA	<input type="checkbox"/>	<input type="checkbox"/>	

Project conducted at Animal Biosafety Level:

Describe the practices and procedures required for the safe handling and disposal of contaminated animals and material associated with this project. Also describe methods for removal of radioactive waste and, if applicable, the monitoring of radioactivity.

Additional safety considerations:

N. BIOLOGICAL MATERIAL/ANIMAL PRODUCTS FOR USE IN ANIMALS (e.g., cell lines, antiserum, etc.): Yes No If no, go to Section O.

1. Specify Material

2. Source Material Sterile or Attenuated Yes No

3. If derived from rodents, has the material been MAP/RAP/HAP tested?
 Yes (Attach copy of results) No

4. 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 Project Director.

O. TRANSGENIC AND KNOCKOUT ANIMALS: Yes No If no, go to Section P.

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

P. FIELD STUDIES AND WILD CAUGHT ANIMALS: Yes No If no, go to Section Q.

Indicate if Federal and/or state permits are required and whether they have been obtained. Describe how wild animals will be observed, any interactions with the animals, whether the animals will be disturbed or affected, and any special procedures. Include an estimate of the expected mortality for any capturing or sampling technique. In section L, include a method of euthanasia for animals found severely injured or sick.

Q. PERSONNEL:

List the name, status (student, staff, faculty, visitor) and qualifications for each person working with animals. Who will perform the procedures? Please include the number of years of experience working with the species listed in Section B. If the person needs to be trained, please indicate who will do the training.

Last Name	First Name	Middle Initial	Status	Experience, Procedures and Training

All live animal work conducted under teaching/classroom projects must be supervised at all times by University faculty or staff listed above. It is the Project Director's responsibility to assure that all participants are properly trained in animal handling and the procedures conducted as part of this project. Keep a list of all such participants with the protocol.

PROJECT DIRECTOR CERTIFICATIONS:

1. I certify that all personnel, including myself in this project will attend the IACUC training course.
2. I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research.
3. I certify that all individuals working on this project who are at risk are participating in the CCSU's Occupational Health and Safety Program.
4. I certify that the individuals listed in Section Q. are authorized to conduct procedures involving animals under this project, have attended the institutionally required investigator training course, and received training in: the biology, handling, and care of this species; aseptic surgical methods and techniques (if necessary); 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 (if necessary); and procedures for reporting animal welfare concerns.
5. For all Category C and Category D projects (see Section J): I certify that I have reviewed the pertinent scientific literature and the sources and/or databases (2 or more) as noted in Section J.2, and have found no valid alternative to any procedures described herein which may cause more than momentary pain or distress, whether it is relieved or not.
6. I certify that I will obtain approval from the IACUC before initiating any significant changes in this project.

7. I certify that I will notify the IACUC regarding any unexpected project results that impact the animals. Any unanticipated pain or distress, morbidity or mortality will be reported to the attending veterinarian and the IACUC.
8. I certify that copies of the approved protocol will be made available to all laboratory personnel.
9. I certify that I shall on a monthly basis monitor drugs used in my laboratory and shall insure that outdated drugs are promptly discarded.
10. I certify that I shall maintain complete, up-to-date, and accessible records of procedures for the animals used in this project.
11. I will comply with the procedures described in the 8th Edition of the Guide for the Care and Use of Laboratory Animals (Guide), NRC 2011, with PHS Policy, the Animal Welfare Act, and applicable University policies.

Project Director: Signature _____ Date _____

S. CONCURRENCES: PROJECT NUMBER:

For all projects housing animals:

Animal Facility Supervisor certification of resource capability in the indicated facility to support the proposed project.

Facility _____ Name _____ Signature _____ Date _____

COMMENTS:

For all Category C and Category D projects (see Section J):

Attending Veterinarian certification of review and concurrence.

Name _____ Signature _____ Date _____

COMMENTS:

For all projects using hazardous agents (see Section M):

Safety Representative certification of review and concurrence.

Name _____ Signature _____ Date _____

COMMENTS:

T. FINAL APPROVAL:

Certification of review and approval by the CCSU IACUC Chairperson.

IACUC Chairperson _____ Signature _____ Date _____