

OFFICE USE ONLY

IACUC LOG # _____

Approval Date _____

Expiration Date _____

WESTERN CONNECTICUT STATE UNIVERSITY
Institutional Animal Care and Use Committee (IACUC)
PROTOCOL FOR RESEARCH WITH VERTEBRATE ANIMALS

NOTE: You **must** attach a copy of your certificate of successful completion of online training (available at <https://www.citiprogram.org>) to this form. Send the completed form with appropriate attachments to: Office of Sponsored Research for Administrative Services c/o Gabrielle Jazwiecki (jazwieckig@wcsu.edu). The form will be logged in and forwarded to the IACUC for review. The required signatures will be obtained if the protocol is approved.

PLEASE TYPE:

A. ADMINISTRATIVE DATA:

Principal Investigator/Project Director: _____

Department: _____

Address signed form should be sent to: _____

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, list 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:

			=	
Year 1	Year 2	Year 3	=	TOTAL

C. SPECIAL CONCERNS OR REQUIREMENTS: ____ Yes (If yes, attach response) ____ No (If no, go to Section D.) List any special housing, equipment, animal care (*e.g.*, special caging, water, feed, or waste disposal, environmental enhancement, *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 (If yes, attach response.) ____ 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, *e.g.*, what do you expect it to achieve? Why is the project important? (Attach response.)
2. Only If Renewal. Briefly explain why more work needs to be done. (Attach response.)

F. RATIONALE FOR ANIMAL USE:

1. Explain your rationale for animal use. (*The rationale should include reasons why non-animal models cannot be used.*). (Attach response.)
2. Justify the appropriateness of the species selected. (Attach response.)
3. Justify the number of animals to be used. (Attach response. *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.*)

4. 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

- **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 (See J: **Pain or Distress Category and Consideration of Alternatives** for a description of categories), 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 symptomology, 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 symptomology 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. (Attach response.)

5. 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. (Attach response.)

6. SURVIVAL SURGERY: ____ Yes (If yes, attach response.) ____ 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 (If yes, attach response.) _____ No
7. Will more than one major survival surgery be performed on an animal while on this project?
 _____ Yes (If yes, attach response justifying procedure.) _____ No

7. 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 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; 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. (Attach response.) 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.

2. 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. (Attach response.)

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: _____

8. ANESTHESIA, ANALGESIA, TRANQUILIZATION PROJECT: Yes (If yes, attach response.)
 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). (Attach response.)

9. 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? Techniques for euthanasia must follow the guidelines established by the latest report by the AVMA Panel on Euthanasia. Deviations must be justified for scientific reasons and approved by the IACUC. If euthanasia will be used, provide details: the proposed method, and if a chemical agent is used, specify the dosage and route of administration. Indicate the method of carcass disposal if not described in Section M. below. (Attach response.)

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			
Biological Agents			
Hazardous Chemicals or Drugs			
Recombinant DNA			

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. (Attach response.)

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 Principal Investigator/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. (Attach response.)

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

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 and/or state permits are required and whether they have been obtained. (Attach response)

Q. PERSONNEL:

List the name(s), title(s) and qualifications for each research 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	Title	Procedures

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.

R. 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 WestConn’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 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 *Guide for the Care and Use of Laboratory Animals* (National Academy of Sciences, 1996), with PHS Policy, the Animal Welfare Act, and applicable University policies.

Principal investigator's/Project Director's Signature

Date

If this is a student research project, both the student and the supervising faculty member must sign.

Supervising Faculty Member

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: _____

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Checklist for attachments (as appropriate):

_____ OLAW training certificate(s) **Note:** If this is a student research project, both the student's and the supervising faculty member's certificates **must** be attached

_____ Attachment C

_____ Attachment D

_____ Attachment E (#1 or #2)

_____ Attachment F (#1, #2, #3)

_____ Attachment H

_____ Attachment I (Minor Surgery) or

_____ Attachment I (Major Surgery, #1, #4, #5, #6 if your answer is yes, #7 if your answer is yes)

_____ Attachment J (Category 1.D., Category 2)

_____ Attachment K

_____ Attachment L

_____ Attachment O

_____ Attachment P

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T. FINAL APPROVAL:

Certification of review and approval by the Western Connecticut State University IACUC Chairperson:

Signature

Date