Colorado State University
Animal Care and Use Research/Teaching Protocol Review Form
Form A-100 (Rev 7/19/05)

ACUC approval of this protocol review form is necessary prior to animals being obtained, housed or manipulated for research or teaching purposes. ACUC approval of activities conducted on animals outside of CSU prior to their arrival to CSU is also necessary.

This form should be used for new protocols, and for renewing protocols at the end of every third approval period. Submit one signed original and 12 copies (double-sided preferred) to the Regulatory Compliance Office, 321 General Services Building. Please make sure that all required signatures are obtained on the final sheet of the form before submission.

Please answer each question. If the question does not apply to your research, respond with an "N/A."
Do not answer a question by referring to your response to another question; this form is designed to collect necessary information in a grouped format.

PART I—Basic Protocol Information

1. Investigator Information

a) Principal Investigator:
(PI must be faculty member, administrative professional, or permanent research associate)
b) Department: 4 -Digit Campus Zip Code:
c) Campus Phone:
d) E-mail:
e) Secondary Contact name/phone/email:
f) List researchers and staff qualified to carry out this protocol. If staff listed is involved with any **Protocol Procedures** please answer
g) **Training Record** of the A-100**,** for each staff member.

	NAME, Degree, Certification	**Training History***	**Experience**	**Protocols Procedures e.g. animal handling, injections, anesthesia, surgery, euthanasia**	**Individual species authorized to use on this protocol**	**Check here if the individual will be participating in administrative Duties e.g Ordering Animals**
PI						
Co-PI						
Staff Roster						

* List as many of the following that apply
a. Completed (course ID), surgery course
b. Obtained DVM degree
c. Has previous experience with this procedure. Provide a description.
d. Continuing Education e.g. in-service, seminars

Comments:

g) **TRAINING RECORD FOR:** _____

For each staff member provide the training and experience for the procedures listed for each species. Identify the required training for surgery* by listing one or more of the following requirements:
a. Completed (course ID), surgery course
b. Obtained DVM degree
c. Has previous experience with this procedure. Provide a description.
d. Continuing Education e.g. in-service, seminars

Please attach additional sheets as needed.

Procedures	Species	Method/Route	Experience	Training Required *
Injections	Mice/Rats			
	Other (specify)			
Blood Collection	Mice/Rats			
	Other (specify)			
Anesthesia	Mice/Rats			
	Other (specify)			
Euthanasia	Mice/Rats			
	Other (specify)			
Restraint and Handling (Specify devices or methods)	Mice/Rats			
	Other (specify)			
Surgery (List specific procedures in Methods column)	Mice/Rats			
	Other (specify)			

Animal ID (e.g. ear punch or tag, microchip, etc.)	Mice/Rats			
	Other (specify)			
Other (Describe procedure in the Methods column)	Mice/Rats			
	Other (specify)			

2. Project Information

a) Project/Course Title:
b) Project Pass Number:
c) Funding Agency:
d) Funding Agency Deadline:
e) Which is this application:

- ☐ For a new project
- ☐ A major amendment to an existing project. List ACUC number: - A_ -0
- ☐ A competing continuation. List ACUC number: - A_ -0
- ☐ A renewal/*non*-competing continuation List previous ACUC number: - A_ -0

3. Animal Information

Enter one **SPECIES/STRAIN** in each box and report vertically → (if more than 4, list on separate attachment) **Sex(s):**				
Age/weight range:				
NUMBER to be used in Year 1:				
NUMBER to be used in Year 2:				
NUMBER to be used in Year 3:				
TOTAL NUMBER for the lesser of 3 years or duration of project				
SOURCE of animals:				

USDA PAIN CATEGORIES: A painful procedure is defined as any procedure that would reasonably be expected to cause more than slight or momentary pain and/or distress in an animal to which that procedure is applied. Animals exhibiting signs of pain, discomfort, or distress such as decreased appetite/activity level, decreased mobility, adverse reactions to physical contact, open sores/necrotic skin lesions, abscesses, lameness, conjunctivitis, corneal edema, and photophobia are expected to receive appropriate relief unless written scientific justification is provided in the A-100 protocol and approved by the ACUC. **Indicate which level(s) apply for each species. If listing more than one, indicate how many animals at each pain level. Example: B (20 mice) and C (15 mice). If an animal is used for multiple procedures, count it in the most painful category.** **Category B:** breeding, conditioning only, or holding colony. **Category C:** No more than momentary or slight pain or distress and no use of pain-relieving drugs; or no pain or distress. Examples: euthanized for tissues; observation under normal conditions; positive rewards; routine injections (not Freund's Adjuvant); tattooing, blood sampling. **Category D:** Pain or distress appropriately relieved with anesthetics, analgesics and/or tranquilizer drugs or other methods for relieving pain or distress. Examples: Needle biopsy, non-survival or survival surgeries, terminal cardiac blood collection; exposure of blood vessels for catheter implantation; induced infections or antibody production. **Category E:** Unrelieved pain or distress. Examples: toxicological or microbial testing or infectious disease research that requires continuation until clinical symptoms are evident or death occurs; application of noxious stimuli; prolonged restraint; use of paralyzing drugs for restraint; infliction of burns or trauma.				

If using animals from other protocols, identify the PI and protocol number, and briefly list the procedures the animals have undergone on the protocols; identify the individual animals by identification number if applicable:

4. Project Activity Duration

a) Start Date *(date you first expect to order/obtain animals)*:
(*Unless continuation,* ***start date should not be prior to ACUC review date***)
b) Stop Date *(date you expect to be finished using animals)*:

5. Project Summary *(Provide a summary of the project in <200 words, using lay language suitable, for example, for release to a newspaper. Include rationale and goals of the research project*):

6. To help ACUC streamline the review process, please answer the following about procedures involved in your protocol:

a) Deep anesthesia followed by euthanasia of animals and tissue harvest. No other procedures are conducted on animals..... ☐ Yes ☐No
b) Deep anesthesia followed by terminal surgery for research or teaching purposes. No other procedures are conducted on animals ..... ☐ Yes ☐No
c) Only minor procedures with minimal pain or discomfort of the animals (such as blood sampling) ☐ Yes ☐No
d) Only observation of field animals only..... ☐ Yes ☐No
e) Only clinical evaluation of animals during routine reevaluations in hospital ..... ☐ Yes ☐No
f) Involves the use of food animals on studies designed to improve production efficiency and do not involve surgery or other invasive procedures ..... ☐ Yes ☐No

g) Is this ACUC application solely for a breeding colony at CSU..... ..... ☐ Yes ☐No

7. Animal care:

a) Location of housing:

b) Location of procedures:

c) Will Lab Animal Resources provide the care .... ☐ Yes ☐No

c) Attending veterinarian (LAR or specify other):

d) Location of medical records:

e) Exercise/Enrichment:

Federal regulations and the ACUC require that exercise opportunities be provided to dogs and that species-specific enrichment be provided to other animals used in research. Environment enrichment is a component of animal husbandry that identifies and provides the environmental stimuli necessary for psychological and physiological well-being. If animals are to be exempt from these opportunities, please provide scientific justification:

8. Living animals are required for this project because:

a) Complexity of the processes studied cannot be duplicated/modeled using in vitro models..... ☐ Yes ☐No

b) Not enough information known about processes being studied to design non-living models . ☐ Yes ☐No

c) Pre-clinical studies in living animals are necessary prior to human testing .... ☐ Yes ☐No

d) This study requires tissue harvested from animals prior to in vitro testing .... ☐ Yes ☐No

e) Currently this is the best method to accomplish the required teaching objectives .... ☐ Yes ☐No

f) Populations are being studied in natural or semi-natural environments..... ..... ☐ Yes ☐No

g) Animal behavior is being studied .... ☐ Yes ☐No

h) Other (please specify):

9. To comply with USDA Policy 12, provide documentation of a literature search to certify that 1) alternatives to each potentially painful/distressful procedure contained in this protocol have been sought, 2) the work is not duplicative of previous studies and 3) the fewest number of animals will be used to obtain valid results.

a) For automated literature searches, provide answers to each question below:

Date search performed:

Keywords used:

Period covered by search:

Names of databases searched:

Did the search reveal applicable alternatives..... ..... ☐ Yes ☐No

If yes, please explain:

b) The Animal Welfare Act allows other means of conducting a search to certify the above. If you used an alternative search strategy, provide information on the strategy, methods and sources:

c) If this is a teaching protocol, please specify why there are no alternatives to using live animals:

10. This species has been selected because:

a) Anatomy, physiology, behavior or agent susceptibility of species uniquely suited to the study ☐ Yes ☐No

b) Lowest phylogenetic species providing adequate size, tissue, or anatomy for proposed study ☐ Yes ☐No

c) This species provides a particularly good model for the human or other animal disease or process .... ☐ Yes ☐No

d) Previous studies which form the background for this project used this species .... ☐ Yes ☐No

e) The objective of this study is to provide information about the target species .... ☐ Yes ☐No

f) Other (please specify):

11. The ACUC requires a power calculation be provided or an explanation why a power calculation is not feasible for this project. Complete one or more of the following to justify the number of animals you will use. For experimental designs with multiple groups/treatments, it is suggested that a table of animal numbers per group be provided. In addition make sure the animal numbers justified in # 11 agree with those mentioned in other sections of the A-100 (e.g. # 15 and # 23).

a) This is a pilot/feasibility study (a total of 12 or more animals typically indicate to the ACUC that the project is not a pilot); describe how numbers were estimated:

b) The group size was determined using a statistical package (For these calculations, specify the package, effect size(s), variation used, and power level expected. If multiple response variables are to be measured, the power calculation should be based on the most critical measures):

c) This is a teaching protocol (specify species, number of animals and number of students so that the ACUC can understand the relationships):

d) This study involves tissue or cells harvested from animals for *in vitro* studies (explain the number of animals requested for the amount of tissue needed to obtain a specified level of precision desired, or if an experiment involving the tissue samples will be conducted as part of this protocol, provide power calculations as described in *b* above):

e) This study involves breeding animals (list number of breeding adults used/number of offspring produced each year and describe how the animals are expected to be allocated to the subsequent experiment. Note these experiments will need to submit separate A-100s):

f) This is a study of feral or wild animals where animals will be captured and released attempting to maximize sample size within logistical constraints. Describe, and please suggest a level of precision necessary to obtain useful information and the sample size required to obtain this precision ..... ☐ Yes ☐No

g) This is an observational, non-manipulative study in that animal numbers will not be captured or their behavior will not be interfered with and animal numbers cannot be predicted: ..... ☐ Yes ☐No

h) Sample size are government driven or agency mandated (please provide appropriate referenced) ☐Yes ☐ No

i) **Other** (please describe in detail):

12. Is this a field study? ..... ☐ Yes ☐No

If no, move to question 13. If yes, please provide the following information:

a) Briefly describe the capture device (e.g. trap, net, electroshock, etc).

b) What is the maximum amount of time animals will spend in trap or net?

c) Is there a possibility lactating females will be captured?

d) How will animals spending time in capture device be shielded from harsh environmental conditions (e.g. heat, cold, rain, etc.)?

e) During what season and at what time of day will capture take place?

f) What method of marking animals will be used? In general, toe clipping is not acceptable.

g) What insulative bedding will be used?

PART II—Surgical and Other Manipulations

13. Will surgical procedures be involved (Y/N)?..... ☐ Yes ☐No

If no, move to question #19. If yes, complete question 13-18, below.

Will any individual animal undergo more than one operative procedure .... ☐ Yes ☐No

If yes, please justify:

14. Surgery will be:

a) Survival or Terminal:

b) Major or Minor:

Major surgery penetrates or exposes a body cavity or produces substantial impairment of physiological or psychological function (e.g. laparatomy, thoractomy, joint replacement, limb amputation).

15. Briefly describe operative procedure or provide ACUC approval number for SOP.

16. Pre-anesthetics, anesthetics, and/or sedatives

(Please provide the following information for each drug used. Complete question 22 below to provide information on analgesia.)

a) Drug:

b) Initial Dose (mg/kg):

c) Route:

d) Supplemental Dose (mg/kg):

Route:

Frequency:

17. Sterile Technique

a) Will sterile instruments be used..... ☐ Yes ☐No
If yes, explain method of sterilization: Autoclave
b) If multiple surgeries will be performed on the same day, how are instruments sterilized between uses?
c) Sterile gloves worn ..... ☐ Yes ☐No
d) Sterile drapes used..... ☐ Yes ☐No
e) Animal hair/fur/wool clipped..... ☐ Yes ☐No
f) Explain skin preparation (agent and prep): shave fur, Poviderm scrub, Poviderm solution
g) Sterile gown worn ..... ☐ Yes ☐No
h) Sterile mask worn ..... ☐ Yes ☐No
i) Head cover and foot cover worn ..... ☐ Yes ☐No

18. Describe anesthetic monitoring and post-operative recovery/care, including frequency and location of post-op monitoring:

19. Non-surgical manipulations (list the following information for each):

a) Agent:
b) Vehicle:
c) Route:
d) Volume:
e) Frequency:
f) Duration:

Experimental Diet..... ☐ Yes ☐No
describe):

Fluid collection ..... ☐ Yes ☐No
If yes, list following information for each:
Fluid:
Collection Site/Method:
Volume Collected:
Frequency:
Percent of total blood volume withdrawn:

20. Describe any adverse effects that may occur *secondary* to experimental agents, procedures or field manipulations: Rats are expected to reduce their food and water intake initially after surgery, but they should regain normal eating and drinking patterns by day two.

21. Methods to be used for monitoring animal well-being will include:

(Answer Y for all that apply)

a) Use of clinical scoring system ..... ☐ Yes ☐No
Attach or provide ACUC SOP number:
Frequency and Duration:
b) Observation for changes in behavior, posture and activity ..... ☐ Yes ☐No
Frequency and Duration:
c) Observation for pain and discomfort ..... ☐ Yes ☐No
Frequency and Duration:
d) Observation of procedural area for local irritation/infection..... ☐ Yes ☐No
Frequency and Duration:
e) Observation for decreased activity/inability to move ..... ☐ Yes ☐No
Frequency and Duration:
f) Assessment of daily food/water consumption..... ☐ Yes ☐No
Frequency and Duration:
g) Other (describe):

22. Analgesia

Will animals experience more than momentary pain/distress ..... ☐ Yes ☐No

(If yes, complete below. If no, move to question #23)

a) Analgesic Drug:
b) Dose (mg/kg):
c) Route:
d) Frequency:
e) Duration:

The ACUC requires animals receive analgesia for 72 hours post surgery. **If no analgesic will be used to eliminate a potentially painful or distressful condition, provide justification**:

23. Overview of procedures to be conducted with animals.

a) Will any of the following occur?

If any yes answer is given, describe under item f below

a) Physical restraint greater than holding or transporting animals ..... ☐ Yes ☐No
b) Use of paralytic drugs (must be scientifically justified) ..... ☐ Yes ☐No
c) Unusual housing conditions..... ☐ Yes ☐No
d) Food or water deprivation other than pre-surgery..... ☐ Yes ☐No
e) Extreme environmental conditions ..... ☐ Yes ☐No
f) Describe and justify any "yes" answer above:

b) Provide a brief description of experimental groups, key procedures, frequency and type of sampling, and endpoints. You can summarize if specific information is provided elsewhere, but *a response here is required.*

PART III—Training and approvals

24. Will animals or their wastes or experimental agents be, or possibly be:

a) Biohazardous (infectious agents or rDNA/transgenics) ..... ☐ Yes ☐No
If yes, identify agents or rDNA use, describe potential risk to personnel/environment and risk management steps you've taken. Cite IBC approval number.
See website http://www.research.colostate.edu/rcoweb/ib.htm for information on required approvals.
b) Radioactive..... ☐ Yes ☐No
See website http://www.ehs.colostate.edu/radiation/ or contact Jim Abraham, 491-3736 for information on required approvals.
c) Use of controlled drugs (including HCG and Ketamine) (Y/N) ..... ☐ Yes ☐No
If yes, list whose drug cabinet will be accessed.
See website http://www.research.colostate.edu/rcoweb/dr.htm for information.
d) Carcinogenic to humans or other animals (Y/N) ..... ☐ Yes ☐No
Contact CSU-Pueblo Biosafety Committe for information on required approvals.

25. Documentation of Training

a) CSU "Handbook for Investigators Using Laboratory Animals" read and provided to staff ... ☐ Yes ☐No
Details:
b) Specific or targeted training performed on site ..... ☐ Yes ☐No
Describe (who, by whom, topics, etc.):
c) PI has a written description of SOPs available ..... ☐ Yes ☐No
Specify location of SOPs related to the species used in this project:
d) Pertinent training/education of people handling animals..... ☐ Yes ☐No
e) Other (describe):

PART IV—Euthanasia

26. Will euthanasia be performed? ..... ☐ Yes ☐No

If yes, move to question 27. If no, complete following information to specify what will happen to animals at study end.

a) Adoption..... ☐ Yes ☐No

b) Transfer to other studies ..... ☐ Yes ☐ No
c) Sold at auction (hoof stock only) ..... ☐ Yes ☐ No
d) Released into home territory ..... ☐ Yes ☐ No

27. Describe experimental endpoints or clinical signs that will determine when euthanasia will be performed. (Death is not an acceptable endpoint unless extensively justified). Describe euthanasia method to be used should unanticipated complications arise and euthanasia becomes necessary.

28. Euthanasia method/agent:
Should be consistent with guidelines published by the AVMA Panel of Euthanasia. See http://www.avma.org/resources/euthanasia.pdf.

a) Species:
b) Agent/Method:
c) Dose (mg/kg):
d) Route:

29. I understand that changes in the approved protocol must be submitted in writing to the ACUC as a protocol amendment and approved by the ACUC prior to implementation. Such changes include, but are not limited to: species, animal numbers, animal-related procedures, animal restraint, food/water deprivation, euthanasia, PI, research staff, and the like. Minor changes can be emailed to annette.gabaldon@colostate-pueblo.edu for review by one or more ACUC members; significant changes (e.g. a large increase in animal numbers, adding an invasive procedure) usually require a new A-100 be submitted for review by the ACUC at its next regularly scheduled meeting.

Please read the following before you sign this form:

As Principal Investigator, I:

Assure that these studies do not unnecessarily duplicate previous experiments.

Will abide by all relevant portions of the Public Health Service Policy and the USDA Animal Welfare regulations and guidelines concerning activities involving animals. For full text, see http://www.research.colostate.edu/rcoweb .

Agree to furnish ACUC with any relevant information on animal use it requests.

Assume responsibility for the ethical conduct of this project to protect the welfare of the animals.

Agree to attend and have my key personnel attend appropriate ACUC training opportunities.

Assure that personnel conducting animal procedures will be appropriately qualified and trained in these procedures. Assure that all individuals performing surgery under this protocol have been authorized by the ACUC to do so, as required by ACUC.

Understand that my signature acknowledges that I have reviewed this form and am responsible for this project.

Principal Investigator signature _____ Date _____

As Department Head, I understand that my signature on this form acknowledges that I have read this application and approve of this research.

Department Head signature _____ Date _____
Note: Alternate faculty signature for Department Head must be specifically delegated to another faculty member by the Department Head in advance.

With your ACUC application, provide just ONE copy of the complete funding proposal. This is to meet federal requirements that each ACUC approval be verified to involve the research included in the funding proposal.