Augustana College

Protocol for the Use of Live Vertebrate Animals for Research, Testing or Education

Date:_____ **Protocol #:** _____

__X__ **Initial Submission**
___ **Renewal**
___ **Amendment/Modification**

1A. Principal Investigator:

Dept: _____ Daytime phone #: _____ Emergency # for after hours: _____

2. Project Title: _____

3A. Please check below if your research protocol involves any of the following:

__ Antibody production/adjuvant use
__ Breeding
__ Ordering timed pregnant animals
__ Ordering animal(s) w/ litter
__X__ "D" and/or "E" Level study ("D" & "E" defined below)
__ Death (without appropriate euthanasia) as an experimental endpoint
__ Decapitation/cervical dislocation without anesthesia
__ Hazardous materials use *in vivo*
  __ a) Chemicals (highly hazardous chemicals & select toxins)
  __ b) Radioactive materials
  __ c) Biological agents & Recombinant DNA
__ Neuromuscular blocking agents
__X__ Surgery (survival, non-survival, and multiple)
__ Tumor induction/Viable cell injections
__ Transgenic/genetically modified animal use
__ Wild animal capture or field studies

3B. Identify <u>all personnel</u> in your laboratory who will handle animals.
If PI and or Co-PI is handling animals, he/she must be on list.

Name:

Name:

Name:

Name:

Name:

Summarize the experience and/or training of the personnel identified in Item 3B.

3C. The IACUC, in accordance with policies set forth by the USDA Animal Welfare Act and NIH/ OLAW, expects all individuals handling the animals to be experienced with the species, and that all individuals are fully trained in the procedures that they are required to perform.

Do you certify all personnel are suitably trained in the procedures of this protocol?

___ Yes
___ No

3D. Abstract: Please provide a brief statement of not more than 200 words, in **LAY TERMINOLOGY,** outlining the purpose of the experimental procedures of this protocol. [*Why you are doing this experiment and what you hope to learn.*] **Please do not use medical terminology**, so that it is easily understandable by a non-scientist.

3E. Animal Manipulations: Describe, in narrative form, the experimental procedures and manipulations that will be performed on the animals. *[Be brief and specific.]*

4. A. Level of Experiments (Indicate breakdown for same species for the pain experienced during procedures): Contact the IACUC or the ARC veterinarians for further explanation or help if needed.

Level B

Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes. Animals on a breeding specific protocol with no genotyping or other procedures being done, sentinel animals, animals on a blanket protocol where procedures are not performed and while awaiting transfer to a procedural protocol.

Level C
Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs. Animals undergoing procedures that are considered to cause only slight or momentary pain and/or distress, such as needle sticks for injections and blood withdrawals, should be placed in this category.

Level D
Numbers of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used. Animal procedures such as: surgery (survival and non-survival), prolonged restraint, genotyping, antibody production.

Level E
Number of animals upon which teaching experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, surgery, or tests. (An explanation of the procedures producing pain or distress in those animals and the reasons such drugs were not used must be attached to the report).

Enter each species, number needed for the **3-year term** of this protocol, and experimental level (use guide above). If same species is used at multiple levels, enter the number required on a separate row.

ANIMAL SPECIES	NUMBER REQUESTED	LEVEL

4B. Attach a COMPLETE OUTLINE OR FLOW CHART RELEVANT TO ANIMAL USE.
Provide a detailed outline description or graphic flow chart of what is planned for the animals from start to finish of this experiment. This should include any other procedures not previously described, such as administration/injection of non-hazardous agents (e.g., estrogen, anesthetics for sedation or restraint purposes). You must include route(s) of administration including maximum amounts and volumes. This description should indicate the number of test and control groups, the number of animals in each group, the sequence of the experimental manipulations in each group and the time between each manipulation. The numbers should also be reconciled with the numbers in sections 4A, 5E, and 10D.

4C. Answer all the Questions below for "D" and "E" level procedures.

If using B or C level only procedures, proceed to question #5.

(4C1) **the nature of the impairment or discomfort**:

(4C2) **how and by whom the animals will be monitored**:

(4C3) **will additional criteria, other than those described in the Quantitative Assessment for Pain and Distress Chart (see Appendix A), be used to evaluate the animals? If yes, describe the criteria**:

(4C4) **Discuss the steps taken to minimize the impairment or discomfort – how will pain be controlled:**

(4C5) **if using the Quantitative Assessment for Pain and Distress Chart, what score will you use as evidence that the animal should be euthanized? Is it possible that some animals might exhibit a severe impairment (a single score of three in any independent variable)? If yes, describe the nature of the impairment. Will these animals be immediately euthanized? If no, explain how this will impact your assessment score:**

(4C6) **is death the end point for this study?**

___ Yes
___ No

Death as an endpoint is determined when there is no humane intervention and the animal becomes moribund and the PI is not able (due to experimental design) to euthanize the animal.

(4C7) For E-Level protocols only:

Annual reports to USDA require a statement of justification for E-Level procedures for USDA covered species. For all UTMB protocols involving death endpoints and/or animal manipulations without the use of anesthetics, analgesics, or tranquilizers, you must provide a statement of scientific justification. ***NOTE: This statement will be included in the annual report to USDA***. At a minimum, these statements should address the following:

- A complete description of the procedures(s) producing pain and/or distress in the animal(s). The explanations should include, as appropriate, the name of the test, the reference from the CFR if the test is mandated by federal regulations, or other relevant guidelines.
- A complete explanation for withholding drugs for relieving pain and/or distress. For example, provide scientific justification that such drugs would adversely affect the test/study results, or cite all regulations(s) and/or federal agency policies that prohibit the use of these drugs.

5. Animal Requirements for entire project:

If more than two species are being requested for use, please duplicate this page.

	Species 1	**Species 2**
5A. Species		
5B. Age(s) or weight(s)		

5C. Sex

5D. Strain(s)/breed(s)

5E. Number to be used for entire project (justify in 10D)

5F. Are the animals immunocompromised?	___ Yes ___ No	___ Yes ___ No
5G. Genetic status: transgenic/knockout?	___ Yes ___ No	___ Yes ___ No

5H. Does the transgene or knockout affect the physiology? Are there expected health complications?
(for more info, consult the Transgenic Mouse Core Facility webpage at http://www.utmb.edu/scccb/mouse)

___ Yes

___ No

___ N/A

5I. Do your procedures require food/water deprivation (other than normal pre-surgical restriction) or prolonged physical restraint?

___ Yes

___ No

If yes, please indicate the extent or duration respectively, and the precautions that will be taken to assure the comfort and health of the animals. NIH guidelines request a daily record of fluid intake and recording of body weight at least once weekly to ensure a suitably balanced diet, since food intake may decrease with a decrease in fluid intake.

6. Anesthesia/Analgesia:

6A. Pre-anesthetic drug

Route & dose mg/kg

Frequency

6B. Anesthetic drug

Route and dose mg/kg

Frequency

6C. Post-procedure analgesic

Route and dose mg/kg

Frequency

Note: Current opinion on the usage of Buprenorphine post-surgically is that the frequency should be twice daily, rather than once daily. Simultaneously, it is felt that fewer days are acceptable. Example, bid Buprenorphine for 2 or 3 days, prn.

7. Euthanasia:

A. Euthanasia method:

B. Name of drug:

Route and dose mg/kg:

7C. Death will be assured by:

___ Open chest

___ Decapitation

___ Cervical dislocation

7D. Scientific justification is required for decapitation or cervical dislocation without anesthesia; Please provide justification if this method is used.

7E. Euthanasia will be performed by:

___ PI or PI's staff

___ Other _____

8. Controlled Substances:

If your protocol uses any controlled substances, under whose DEA registration will you be obtaining/using these agents? **Please note** that if an ARC veterinarian is listed as the certificate holder's name, only ARC staff will administer controlled substances.

Please provide the certificate holder's name:_____

9. Housing Requirements:

	Species 1	**Species 2**
9A. Number to be housed at one time.		
9B. Period of time to be housed.		

9C. Location(s) for animal **<u>housing</u>** (Add additional sections if necessary for multiple species):

___ Sorensen Animal Facility ___ Hanson Hall of Science ___ Other (specify)

<u>IMPORTANT</u>

9D. Identify every laboratory, building, and room where live animals will be used in procedures outside of vivarium areas:

- **Will you be removing animals from the housing room?** Yes
  - *If yes, please specify where animals will be taken:*
- **Will you return animals back to the room after procedures?** Yes
  - *If the above question was answered yes, describe methods employed to prevent transmission of pathogens:*

9E. Will you house rodents for >24 hours, or other species for >12 hours in your lab?

___ Yes Please provide the room number(s):_____

___ No

If yes, please provide scientific justification:

9F. Requirements: animals with special needs

___ Wire bottom cages (rodents)

___ Metabolic caging

___ Sterile caging

___ Feed

___ Water

___ Other (specify) _____

10. Describe the 'SOURCES' and 'EXTENT' of searches for animal procedure/pain alternatives:

10A. List relevant citations to address the value of animals in examining this scientific question (as opposed to computer models, tissue culture, invertebrates or microbes). A printout of each reference is not necessary.

10B. Do you certify that you have done an adequate literature search to ensure that the proposed protocol will not simply reproduce known results?

___ Yes, adequate searches have been conducted to avoid unnecessary duplication of experiments.

10C. Alternative statement and rationale for animal use: The PI must certify, by supplying a written statement in his/her own words, that no alternatives to potentially painful or distressful animal procedures were found. **This includes methods that use non-animal systems or less sentient animal species to partially or fully *replace* animals (i.e., the use of an <u>in vitro</u> or insect model to replace a mammalian model), methods that *reduce* the number of animals to the minimum required to obtain scientifically valid data and methods that *refine* animal use by lessening or eliminating pain or distress and, thereby, enhancing animal well-being.** The narrative should be such that the IACUC can readily assess whether the search topics were appropriate and whether the search was sufficiently thorough. *(Cost savings is not adequate or appropriate justification for the use of a specific species in biomedical research.)*

10D. State rationale for the selected species.

10E. State rationale for the numbers of animals involved in this project. Describe the scientific endpoints or outcome variables that are being measured and the anticipated difference in these endpoints between the experimental and control groups. If available, a formal power analysis is desirable. For assistance

with a power analysis or statistical design, please visit the following website(s):
http://faculty.vassar.edu/lowry/VassarStats.html
www.graphpad.com

11. Assurances/Certifications:

A. I assure that the activities to be carried out under this protocol are not unnecessarily duplicative.

B. I certify that all statements made are true. Whenever there are significant changes in the protocol, I will submit these changes to the IACUC for review and approval **prior to** carrying out the procedures.

C. I assume responsibility for my work and those of my co-workers related to this project and assure that all will have read the approved protocol and are qualified, or will receive the appropriate training, to conduct the animal studies in a humane and scientific fashion.

D. I shall: operate to comply with the Animal Welfare Act (Public Law 89-544), as amended; follow the Public Health Service Policy of Humane Care and Use of Laboratory Animals; follow the Guide for the Care and Use of Laboratory Animals; comply with other related federal, state, and local laws and comply with Augustana institutional policies.

E. I am aware that failure to comply with any of the above stated assurances could result in suspension of my privileges to use live vertebrate animals.

12. Principal Investigator/Course Director
(Must be an Augustana faculty member)

_____
Signature **Date**

_____
Typed Name

Student Investigator/Course Director

_____
Signature **Date**

_____
Typed Name

I am aware of, and endorse the care and use of live vertebrate animals outlined in this application.

Department Chair or Dean:
Note: PI may not sign as Chair or Dean

_____
Signature **Date**

_____
Typed Name