

ADDENDUM TO ANIMAL CARE AND USE PROPOSAL INSTRUCTIONS

This document was designed to assist investigators in requesting significant changes to their approved animal care and use protocols. The document may be submitted as an e-mail attachment to IACUC@kumc.edu. If a new surgical procedure is being added, then a hard copy with original signature should be delivered to the Animal Research Protection Program located at 1040 Wescoe.

If new procedures that have the potential to cause more than slight or momentary pain or distress are proposed, please complete a new search for alternatives by completing the Literature Search Form and Veterinary Pain/Distress Consultation Form. Both are located at the end of this document.

3.0 **Conflict of Interest** – All new staff members should complete an annual conflict of interest disclosure form, if he/she has not already done so.

3.1 Do any of the investigators, study personnel, or members of their family (defined as spouse, children, siblings, parents, equivalents by marriage [in-laws], or other household members) have a financial relationship relevant to **the sponsor of this study** (e.g. patent rights, stock ownership, equity holdings, consultant fees, board membership)?

Yes No

3.2 Does this study involve research on a University and/or Research Institute-owned technology?

Yes No

4.0 **Intellectual Property** - Does this research have a possibility of generating intellectual property such as a novel model or compound? If yes, contact the Division of Technology Transfer, Intellectual Property & Commercialization at ext. 8-5721 or <http://www2.kumc.edu/researchinstitute/tech.index.html>

Yes No

If a change in personnel is the only modification requested, stop here.

5.0 **Difference between approved ACUP and this addendum** - Describe how the proposed changes are different from the existing protocol.

6.0 **Surgery**

6.1 Are new surgical procedures done as part of the experimental protocol? YES NO .

If “No”, skip to question Item 7.0.

Procedures are Survival (animals wake up after surgery)
 Non-survival (animals are euthanized before waking up)

6.2 Where is the surgery being done?

Building:
Room Number:

6.3 What **pre-operative** procedures or drugs will be employed **prior** to surgery (overnight fasting, pre-surgical medications, etc.)?

Answer:

6.4 What anesthetics/analgesics will be used **during** the surgery? Provide the **drug name, dose, and route of administration.**

Drug	Dose	Route of administration

6.5 YES NO . Do any of the procedures involve inhalation anesthetics that must be scavenged (fumes removed from the work environment)? If “Yes”, indicate how the agents will be scavenged from the environment (gas scavenging system, fume hoods, etc.).

Answer:

6.6 YES NO . Are paralytics used in conjunction with the surgical anesthesia and surgical manipulation? If YES, provide the name of the agent, dose, and route of administration and confirm that paralytics will only be used with appropriate anesthetics.

Drug	Dose	Route of administration
I affirm that paralytic drugs will only be used with appropriate anesthetics or analgesics.		Signature Required.

6.7 For each procedure, provide a short name (this should be the same name used in the experimental design), a detailed description, indicate if the procedure will be survival or non-survival, and include a description of monitoring and supportive care provided during procedure. If more than one species is covered by the protocol indicate which species is used per procedure.

Answer:

6.8 YES NO . Is more than one major survival surgery planned for any single animal? If yes, provide the name of the procedure, the species involved, the interval between major surgeries, and justification for multiple major procedures. Note that a major procedure is one that penetrates a body cavity or produces significant impairment of function. (Subcutaneous implants are not considered a major operative procedure. You may call the veterinary staff for guidance, if needed).

Procedure	Species	Interval between surgeries

Justification:

6.9 Read and sign.

As the responsible party for this protocol, I affirm that aseptic technique will be used for all survival surgical procedures, regardless of the species and I further affirm that all drugs and sutures will be used within the expiration date assigned by the manufacturer.	Signature required.
--	----------------------------

6.10 What post-operative care will be provided and for how long after the surgery? Current standard of veterinary medical care is that most major surgeries should be accompanied by the use of intra-operative and post-operative analgesics. .

Answer:

Drug name	Dose	Route of administration

6.11 Surgical records should be maintained on all species. Describe how operative/post-operative records will be maintained. We encourage all research staff to record all surgical procedures in the LAR Medical Records Database. The database is located at the following web-address <http://classes.kumc.edu/training/larmedrecords/login.asp>.

Answer:

7.0 **Change in USDA Classification** - Do the proposed procedures change the USDA classification?

Yes No

8.0 **Change in species or number of animals** - Are additional animals or is a new species requested for this ACUP?

Yes No

8.1 If a new species is being added, please provide rationale for including this species and address the appropriateness of the species or model(s) chosen.

8.2 How many additional animals are requested?

Specific Aim #	Study number	Species	Type, Strain or Cross	Sex	Housing Location	Pain Category	Number Animals
Category B	Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, surgery but not yet used for such purposes. (Animals held for research or breeding, but not used in studies)						
Category C	Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain relieving drugs. (Animals used of studies involving no pain or distress)						
Category 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. (Animals used for studies involving pain or distress alleviated by treatment)						
Category E	Number of animals upon which teaching, experiments, research, surgery tests were conducted involving 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, experiments, surgery or tests. (Animals used for studies involving untreated pain or distress)						

8.3 Please justify the number of animals requested for each USDA category. Please be specific to the category.

9.0 Studies involving untreated pain or distress (USDA category E studies), require the principal investigator to provide scientific justification in writing. This justification will be submitted in an annual report to the USDA.

10.0 **New Drugs** - Are any new drugs to be used? Yes No

If yes, complete the information below

Drug	Dose	Route	Toxicity (yes/no)?

If the drug(s) is (are) expected to induce toxicity, please indicate the anticipated effects below.

11.0 **Euthanasia** - If a new species was added in this addendum. Please describe the method of euthanasia. (Must be consistent with the AVMA Guidelines on Euthanasia).

12.0 **Hazards** - Are there any new hazards to personnel in this project? Yes No

Do any of the procedures involve hazardous materials or agents either administered to the animals or indigenous to the animals (zoonotic agents)?			<input type="checkbox"/> Yes	<input type="checkbox"/> No
Name of the Hazard	Animal Dose	Route of Administration	Duration	
If the hazard is indigenous to the animal but may be hazardous to lab personnel, in the space below, define safety precautions and personnel protective equipment required to minimize risk to personnel.				

- Yes No: **Does this project involve the new use of hazardous chemicals?**
- Yes No: **Does this project involve the new use of recombinant DNA technology?**
- Yes No: **Does this project involve the new production and/or acquisition of transgenic animal models?**
- Yes No: **Does this project involve the new use of human etiologic agents?**
- Yes No: **Does this project involve the new use of radiation producing devices?**
- Yes No: **Does this project involve the new use of radioisotopes?**
- Yes No: **Does this project involve new personal protective equipment?**

If you have answered yes to any of the questions above, please fill out and attach the safety form at the following link:

<http://www2.kumc.edu/researchcompliance/irscforms.htm>

Veterinary Pain-Distress Consultation Form

April 2009

Principal Investigator	
Project Title	
Protocol No.	

Instructions--Complete the non-grayed areas of the table in 1.0 and your plan for managing pain or distress in 2.0. Print the form and then set up an appointment with one of the veterinarians to establish consensus on the plan of action. Both you and the veterinarian will then sign and date the document. The original document must then be included with the Animal Care and Use Proposal as it is submitted to IACUC. **The Animal Care and Use Proposal will not be considered without this completed form.**

1.0 List all of the procedures that will be done to the animals in this protocol. Include everything that will be done to the animals including injections, measurements, etc. Add lines if necessary.

Species	Procedure Name	How many times per animal?	Pain Distress Score ¹

Pain Distress Score¹: This is a general score of 1-5 indicating the overall potential for and duration of pain or distress, based on veterinarian's understanding of the procedure. **The grayed column is to be completed by the veterinarian in ink.**

2.0 Provide an overview of how you plan to manage the pain or distress.

3.0 The following are the recommendations of the veterinarian for this project.

4.0 Signatures. The signatures below indicate that the principal investigator and the veterinarian have consulted and agreed on this pain-distress management proposal to be included in the above identified project.

Principal Investigator _____ Date _____

Veterinarian _____ Date _____

Literature Review

Instructions: The USDA stipulates that principal investigators must provide assurances that their research does not duplicate previous research and consideration must be given to alternatives to procedures that cause more than slight or momentary pain or distress in animals. The **USDA** requires that an animal welfare database be used in literature searches (something other than PubMed or Medline). See for a list of animal welfare databses:
<http://www.nal.usda.gov/awic/databases/database.htm>.

Databases searched				
Date Range	From		To	
Key Words (must include procedures that are painful or distressful to animals):				
Provide below how your study design implements:				
Reduction ¹				
Refinement ²				
Replacement ³				
Provide below a summary of findings from the literature review related to a search for alternatives to procedures that cause more than slight or momentary pain or distress. If an alternative to painful or distress procedures was discovered but will not be implemented in the study design, provide scientific justification for why the alternative cannot be implemented in the proposed research design.				

- 1 Reduction = using the fewest number of animals necessary to accomplish the aims.
- 2 Refinement = employing refining methods to reduce pain or distress.
- 3 Replacement = using a less sentient species as replacement for a higher more sentient species.