Print Form

# THE UNIVERSITY OF LOUISIANA AT MONROE
# OFFICE OF SPONSORED PROGRAMS AND RESEARCH
# ANIMAL WELFARE ASSURANCE FORM

**1. ADMINISTRATIVE**

Project Title: _____

Project Director (PD): _____ Application Date: _____

PD email _____ Funding Source Target(s) _____ Termination Date: _____

☐ New Protocol

Protocol # (to be completed by IACUC)

☐ Previous Protocol IACUC # _____ _____

List names of individuals conducting procedures under this protocol [must have CITI completion certificates on file with IACUC]

**2. RATIONALE FOR ANIMAL USE: SPECIES AND NUMBER**

Will mice or rats be used? [Separate protocols are required for different species]

Genetically modified? Which gene/locus? Special handling?

Immune-deficient mice? Which strain?

☐ Check box if these animals irreplaceable, i.e, this is the only breeding colony available with these traits.

Give estimate of animal # to detect desirable effect size for most variable endpoint and method used for estimate. Methods could include experience from previous trials or trials of others with same endpoint. Preferably determine sample size with a statistical power analysis to give power of at least 0.8. (Free java-based program piface.jar can be downloaded at http://homepage.statuiowa.edu/~rlenth/Power/index.html. Estimate # of trials and give justification for multiple trials.

Briefly justify your choice of species (e.g., previously used model, literature citation)

**3. STUDY OBJECTIVES AND VALUE**

Briefly explain, in layperson's language, the study's aim and its important to human or animal health, advancement of know-ledge, or the good of society. Comment on how the study adds new knowledge, i.e. that it is not a duplication of other studies.

**4. DETAILS OF ANIMAL USE PROCEDURES**

Describe the experimental design and specify all animal procedures. Description should allow IACUC to understand the experimental course of an animal from entry into the experiment to the endpoint of the study. Also, give answers to specific questions A - F below. If not applicable, indicate N/A.

A. Methods of restraint (other than when anesthesized for surgery), such as plastic holders for drawing blood. If restraint is prolonged for hours, **justify** based upon scientific need. If prolonged, describe sedation or acclimation, if applicable.

B. Experimental injections, gavages, other exposures to agents. Give substance, eg. adjuvants; dose; site; volume route and schedule.

C. Blood withdrawals. Give volume, frequency, withdrawal site and methodology, including sedation or anesthesia, if applicable. Guidance is available at http://oacu.od.nih.gov/ARAC/documents/Rodent_Bleeding.pdf

**4. DETAILS OF ANIMAL USE PROCEDURES - Con't**

D. Describe method for euthanasia used at study termination and, if $CO_2$, method to assure animals are dead. (For $CO_2$ narcosis, see http://rxweb.ulm.edu/pharmacy/admin/CO2%20Euthanasia%20Guide.pdf). For others, Appendix 1 of AVMA guidelines (https://www.avma.org/KB/Policies/Documents/euthanasia.pdf)

E. If procedures are to be conducted outside of the Vivarium, how long will live animals be kept outside the Vivarium?

F. Check if study does NOT include animal surgery. If not, proceed to section 6.

**5. SURGICAL PROCEDURES**

Will animals be recovered after surgery or euthanized?

If nonsurvival, how euthanized?

Describe pre-operative procedures (eg. fasting, how long?)

Name and dose of anesthetic

Criteria for adequate depth of anesthesia

Estimated time of anesthesia

Describe support care during surgery

Analgesia for post-operative pain? Name

Endpoints monitored post-operatively to indicate recovery.

How frequently observed?

Will study include multiple survival surgeries? If so, justify their need.

**6. UNIQUENESS OF STUDY, UNAVAILABILITY OF SUITABLE ALTERNATIVES**

Give results of a search of at least two databases (eg PUBMED) and specify search terms. Give the # of hits and give citations of closely related studies. Indicate how study of this protocol differs or advances on results of studies recovered in the database searches. This should include a very brief description of most recent studies of PD providing precedent for protocol studies.

Briefly defend why the study of this protocol can not be done with alternative models, eg., cell culture, lower phylogenetic species

**7. OCCUPATIONAL HEALTH & SAFETY/HAZARDOUS CHEMICALS/RADIOACTIVITY**

LIST THE FOLLOWING IF ADMINISTERED TO ANIMLALS AND ESTIMATE AMOUNT

All study chemicals except anesthetics

Chemical carcinogens

Reproductive/Developmental Toxicants

☐ Check if isotopes will be administered to animals of this study. Attach approval from ULM Radiation Safety Office

Which isotope(s) and how much radioactivity?

List controlled substances and give CDS license #

**8. SPECIAL CONSIDERATION**

Some types of studies require special consideration during IACUC review because experimental endpoints incur risk of imposition of prolonged pain and distress, including death. Examples of study types that may require special consideration include those addressing: 1) assessment of toxicological effects, 2) organ or system failure, 3) tumor models, 4) cardiovascular shock, and others (p. 27, Guide). Check the boxes below if this protocol applies to a study addressing:

☐ toxicological effects ☐ organ or system failure ☐ tumor model(s) ☐ cardiovascular shock

**If your study does NOT address these areas, skip this section and proceed to the signature page.**

Such endpoints can be considered humane with intervention to alleviate prolonged pain and distress, including euthanasia for moribund animals. If intervention does not compromise the scientific goals of the study, then humane endpoints must be employed. Specific criteria must be listed below that are to be used to trigger initiation of palliative measures by the PD or ULM animal program veterinarian. If palliative measures for pain and distress associated with the experimental endpoint can not be alleviated without compromising the scientific outcome of a study and if the PD presents strong scientific justification for use of experimental endpoints, then IACUC is obliged to weigh the objectives of the study against potential animal welfare concerns. Scientific justification for compelling, beneficial impact on human and/or animal health would be a strong argument justifying imposition of prolonged pain and distress to experimental animals. A discussion that no alternative methods exist to obtain comparable information should be presented.

In the space below, provide criteria for morbundity upon which study animals will be euthanized.
For toxicological studies, organ/system failure, and cardiovascular shock, specify clinical criteria for euthanasia of moribund animals. For tumor studies, specify maximal tumor size (diameter = 20 mm or 40 mm for mice or rats, resp. or 10% of body weight is commonly used criteria for euthanasia of host animal.)
One guidance document is: OECD Guidance Document on the Recognition, Assessment, and Use of Clinical Signs as Humane Endpoints for Experimental Animals Used in Safety Evaluation (2000).
http://search.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2000)7&docLanguage=En
Another is Table 4 of the NIH document Guidelines for Pain and Distress in Laboratory Animals:
http://oacu.od.nih.gov/ARAC/documents/Pain_and_Distress.pdf
Others are cited in the Guide (http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf)

If prolonged pain and distress associated with experimental endpoints can not be alleviated without compromising the scientific outcome of a study, provide a strong scientific justification for the value of the study results.

We the undersigned give our assurance that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals.

| Review and Approval | Signature | Date |
|---|---|---|
| Project Director | _____ | _____ |
| Department Head | _____ | _____ |
| Dean of College | _____ | _____ |

Final Review and Approval

| | | |
|---|---|---|
| Animal Welfare Assurance Officer | _____ | _____ |