

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

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?

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/i/index.html>. Estimate # of trials and give justification for multiple trials.

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.

4. DETAILS OF ANIMAL USE PROCEDURES - Con't

D. Describe method for euthanasia used at study termination and, if CO₂, method to assure animals are dead. (For CO₂ narcosis, see [http://rxweb.ulm.edu/pharmacy/admin/CO₂%20Euthanasia%20Guide.pdf](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?

5. SURGICAL PROCEDURES

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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

tumor model(s) cardiovascular shock

In the space below, provide criteria for morbidity 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 Human Endpoints for Experimental Animals Used in Safety Evaluation (2000).

[http://search.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO\(2000\)7&docLanguage=En](http://search.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2000)7&docLanguage=En)

Another is Table 4 of the NIH document

If prolonged pain and distress associated with experimental endpoints cannot 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	_____	_____