Institutional Animal Care and Use Committee
SUNY Upstate Medical University

ANIMAL CARE AND USE PROTOCOL

Updated: NOVEMBER 2021

Federal and State Regulations require that the use of living vertebrate animals be reviewed for their appropriateness and approved by the Institutional Animal Care and Use Committee (IACUC) ***BEFORE*** commencement of a study.

All of the information requested in the following form is based on USDA Federal Regulations (Animal Welfare Act), PHS/NIH policy (Health Research Extension Act) and/or the New York State Department of Health Regulations.

Submission Deadline: **The 15th of each month. Protocol will be reviewed at the following month's meeting, scheduled for the 2nd working Monday of each month.**

Instructions:

1. Complete **SECTIONS A – O** of this protocol.
2. Complete the **APPENDICES** that apply to this protocol. Delete non-applicable appendices.
3. The IACUC **strongly recommends that you have another individual, who is familiar with the protocol review process, read and evaluate your protocol prior to submission**. This often identifies common errors that may delay approval of the protocol.
4. **Federal regulations require that you consult with the veterinarian in the Department of Laboratory Animal Resources (DLAR) regarding issues of pain and/or distress *before* submitting your protocol.** Dr. Quinn may be contacted via phone: 464-6563 or via email: quinnr@upstate.edu
5. The completed protocol should stand as an independent document, i.e. none of the answers should require the reviewer to refer to a grant application, scientific publication or any other external source for the requested information.
6. It is essential to use language understandable to all reviewers, particularly in the Lay Description (Section C). The remainder of the document must be understandable by a scientist OUTSIDE of your discipline.
7. Please answer all questions. Questions that are not relevant must be answered "N/A".
8. The Principal Investigator must electronically submit this protocol via his/her own email account. Document submission by other lab personnel **will not be accepted. DO NOT** submit a hard copy.
9. Approval of an animal use protocol is not required by PHS prior to grant review. "Just in time" policy allows for approval after the grant receives a "fundable" priority score, but prior to receipt of funds. (Note: To avoid delay in funding, protocols should be submitted at least 3 months prior to earliest possible funding date.)

Questions? Email the IACUC office or call 315-464-4292.

IACUC Office use ONLY

IACUC #: _____

Approved: _____

Expires: _____

Institutional Animal Care and Use Committee
SUNY Upstate Medical University

ANIMAL CARE and USE PROTOCOL

Principal Investigator: _____

Full Name | Degree | Department | Bldg./RM

Protocol Title: _____

Place an [X] in the appropriate column.

Yes	No	
		Does this protocol involve **surgery** (survival and/or nonsurvival surgery)? **If yes,** please complete **Appendix I**.
		Does this protocol involve **cardiac perfusion?** (The IACUC considers cardiac perfusion to be nonsurvival surgery) **If yes,** please complete **Appendix I.**
		Does this protocol involve the maintenance of a **breeding colony**? **If yes**, please complete **Appendix II**.
		Do you anticipate using any **expired materials** and or drugs on animals? (Non-survival procedures only.) **If yes,** please complete **Appendix III** and explain in **Section N**.
		Does this protocol involve the **Production of Polyclonal and Monoclonal Antibodies in Rodents and Rabbits**? **If yes,** please complete **Appendix IV**. [If noncompliant with this Guideline, you must provide justification in **Section N**]
		Does this protocol involve the **Utilization of Animals in Experimental Neoplasia and Ascites Production?** **If yes,** please complete **Appendix V**. [If noncompliant with this Guideline, you must provide justification in **Section N**]
		Does this protocol involve **Death as an Endpoint? If yes,** please complete **Appendix VI** and provide justification in **Section N**.
		Does this protocol involve the **Use of Paralytic Agents during Anesthesia?** **If yes,** please complete **Appendix VII** and provide justification in **Section N**.
		Does this protocol involve **Tail Biopsy of Rodents?** **If yes,** please complete **Appendix VIII.** [If noncompliant with this Guideline, you must provide justification in **Section N.**]
		Does this protocol use **animal tissues from a source other than the animals requested** on this protocol? **If yes**, please complete the **Use of Animal Products Form.** [Download from website http://www.upstate.edu/iacuc/forms.php]
		Does this protocol involve **restraint** of conscious animals for longer than 15 minutes? **If yes**, please provide justification in **Section N**.
		Does this protocol involve **food or water restriction beyond standard pre-surgical fasting?** **If yes**, please provide justification in **Section N**.
		Does this protocol involve **collaborative research** wherein any animal studies will be conducted at another institution? **If yes,** please attach the following information from the collaborating institution: (1) approval letter from the Institutional Animal Care and Use Committee (IACUC), (2) a copy of the protocol, and (3) the institution's PHS Assurance Number.
		Does this protocol involve the in **vivo use of biohazardous materials, human tissues/blood/body fluids, recombinant DNA and/or infectious agents**? **If yes,** approval from the ***Institutional Biosafety Committee*** must be obtained prior to receiving IACUC approval to conduct those specific experiments using these agents. A copy of the IBC approval letter must be supplied to the IACUC office. **IBC info:** phone 464-4317 or http://www.upstate.edu/researchadmin/ibc/basic_science.php **List Agent(s) to be used:**
		Does this protocol involve the **in vivo use of radioactive materials**? **If yes,** approval from the ***Radiation Safety Office)*** must be obtained prior to receiving approval to conduct those specific experiments using radioactive materials. A copy of the approval letter must be supplied to the IACUC office. **Radiation Safety Info:** phone 464-6510 or http://www.upstate.edu/researchadmin/rad.php **List Material(s) to be used:**
		Does this protocol involve the **in vivo use of carcinogens, toxins or mutagens?** **If yes,** approval from ***Environmental Health & Safety*** must be obtained prior to receiving approval to conduct those specific experiments using these agents. A copy of the approval letter must be supplied to the IACUC office. **EHS Info:** phone 464-5782 or http://www.upstate.edu/ehs/ **List Agent(s) to be used:**
		Does this protocol involve animals previously used on a different project? **If yes,** provide Investigator's name:_____ and IACUC Number:_____

What is the funding source for this project?
Note: Approval of IACUC application is not required by PHS prior to grant review. "Just in time" policy allows for approval after the grant receives a "fundable" priority score, but prior to receipt of funds. (To avoid delay in funding, applications should be submitted at least 3 months prior to earliest possible funding date.)

Funding Source Place an **[X]** in the box next to all anticipated funding sources.		**Status of Funding** Place an **[X]** in the appropriate column.		
		Funded	**Under Review**	**To be submitted**
	Public Health Service (NIH) **Please specify Agency/Institute:**	**Grant #:**		
	Other Federal/State Agency **Please specify:**			
	Foundation or Industry **Please specify:**			
	Departmental, Clinical or Personal Funds **Please specify:**			

A. PERSONNEL:

At least one person listed on the protocol must be available at all times to deal with complications. (If all of the personnel will be unavailable at the same time (meetings, vacations, etc.), prior arrangements should be made with DLAR (4-6563) to handle emergency situations involving the animals on this protocol.)

Who will serve as the **"Primary Contact?"**

Name: _____

Bldg. / RM#: _____

Work Phone: _____

Cell Phone: _____

Email: _____

* * * * * * * * * * * *

Please complete the following Personnel Information section for <u>each</u> person with animal contact (principal investigators, technicians, graduate students, medical students, residents, fellows & visiting faculty). It is the responsibility of the investigator to notify the IACUC Office at 464-4292 of any changes in personnel.

Personnel Information

(Complete a separate form for each individual working on this protocol - *Duplicate as needed)*

Name	Degree	Dept.	Work Phone	Alternate phone	Email

Has this individual completed the mandatory CITI Lab Animal Welfare Laws & Regulations online training or provided documentation of equivalent training? Training requirements are posted on the IACUC website.	**YES**	**NO**

Instructions & Certification of Training

In the checklist below, place an [X] in the appropriate column for each procedure that this individual will perform on this protocol.

By indicating that this individual is adequately trained in the procedure(s) below, the Principal Investigator is certifying that the individual is competent to independently perform these procedures. Furthermore, the Principal Investigator understands that procedures marked "Training Required" may not be performed unsupervised by this individual until adequate documentation of training is submitted to the IACUC office.

Person responsible for training*	

***"Trainer"** must contact the IACUC office (464-4292) at the completion of training to provide documentation. DLAR can provide training on handling and basic procedures (injections, etc.) Please contact DLAR (464-6563) to arrange a training session.

List all species that will be used on this protocol →	**Species 1:**		**Species 2:**		**Species 3:**		**Species 4:**	
PROCEDURES:	**Adequately Trained**	**Training Required**	**Adequately Trained**	**Training Required**	**Adequately Trained**	**Training Required**	**Adequately Trained**	**Training Required**
Handling & Restraint								
Euthanasia:								
Cervical Dislocation								
Decapitation								
CO2								
Injectable agents								
Other – describe:								
Anesthesia:								
Injectable								
Inhalational								
Regional (local)								
Aseptic Survival Surgery (rodents only)								
Sterile Survival Surgery (other mammals)								
Injections:								
Subcutaneous (SQ)								
Intramuscular (IM)								
Intraperitoneal (IP)								
Intravenous (IV)								
Submandibular								
Retro-orbital								
Gavage								
Other – describe:								
Other procedures – list below:								

B. ANIMAL INFORMATION (Please provide a separate table for **each** species)

Species:	**Sex**:
	Age or Weight:
Preferred Source (if any):	
Total Number Requested (must equal the total for all groups in Section D(IV):	
Please describe any special environmental requirements (cages, feed, etc.):	

C. LAY DESCRIPTION

Please provide a succinct description of the proposed experiments that could be understood by an **average high-school student**. Any technical or scientific terms and all abbreviations must be defined. This description must answer all of the following questions:

(1) What are the goals of the research?

(2) Why are these goals important?

(3) What are the proposed experiments?

(4) How will the proposed experiments help achieve these goals?

D. INFORMATION IN SUPPORT OF THE EXPERIMENTAL APPROACH

I. Please describe the scientific background and the rationale for the proposed experiments.
(Answer must include citations that reference specific statements in the narrative.)

II. What value or potential contributions to biology or medicine may come from this work?

III. Please give specific reasons why the chosen species should be used. (Answer must take into consideration the use of species lower on the phylogenetic scale. Animals higher on the phylogenetic scale should also be considered if they represent a more suitable model. Cost savings alone is not an adequate justification.)

IV. Table of Animals Required for Each Proposed Experiment
(Insert rows as needed to list all proposed experiments. The total of all groups listed here **must** match the total requested in **Section B**.)

Experiment	Species	Strain(s)	Group Size (n)	TOTAL # of animals required

V. Please provide a description of how the number of animals for each group (n) was determined. (It is preferable that this determination be based on a power analysis and/or previous experience as to the number required for statistical significance. Do not include animals used solely for breeding purposes unless integral to the scientific aims of the study.)

VI. Please describe the proposed experiments.

E. PROCEDURES

I. Flow Diagram. For each different type of experiment, provide a flow diagram or sequential list of procedures to help the Committee understand what happens experimentally to each animal from initiation of experiment to euthanasia.

II. Describe ALL experimental procedures involving animals. Every potential manipulation of an animal must be described in detail. Details on surgical procedures may be deferred to Appendix I – Surgical Intervention Form. Please duplicate the table below for each experimental procedure.

Procedure:	**Bldg/Room#**:
Description:	

F. USE OF PHARMACEUTICAL GRADE COMPOUNDS:

Principal investigators are required to use pharmaceutical grade compounds for all experiments involving the use of live animals. The administration of non-pharmaceutical grade compounds (NPG) to live animals will only be permitted following review and approval by the IACUC.

- NPG compounds are defined as any compound not specifically formulated and approved by the FDA for administration into humans or animals. Any chemical purchased from a chemical supply company (e.g.: Sigma-Aldrich) and mixed in the lab is considered NPG by definition.

- Justifications for using NPG compounds can include the following:

  a. No pharmaceutical grade veterinary or human drug is available or consistently available.
  b. Although a pharmaceutical grade drug is available, a greater concentration, different formulation, or route of administration is required.
  c. Although a pharmaceutical grade drug is available, it contains preservatives or inactive ingredients that confound the research goals of the study.
  d. Although a pharmaceutical grade drug is available, the NPG drug is required to replicate methods from previous studies.
  e. Although a pharmaceutical grade drug is available, the exorbitant cost has made it logistically unavailable (generally, cost savings alone is not adequate justification).
  f. Other (provide justification in table below).

Will this protocol only use pharmaceutical grade substances? Mark (X) appropriate response:

	YES. All chemicals and substances used in animals will be pharmaceutical grade. *(**Skip** to **Section G**.)*
	NO. Some or all chemicals and substances used in animals will be non-pharmaceutical grade. ***Complete** the table below for <u>each</u> NPG compound to be administered to live animals.*

NPG Compound Name:	
• What is the justification for the use of the NPG compound? (*See a. – f. above for guidance*)	
• How is the compound prepared?	
• How will the sterility be assured? (N/A for gavage or topical)	
• How will the compound be stored?	
• How long will the compound remain safe and effective?	

G. EXPOSURE TO HAZARDOUS MATERIALS: Describe specific methods to protect employees from exposure to hazardous materials (biological, chemical, radiation) used in animals. This should include methods to be used:

1) during transport of the agent or exposed animals to and from the animal facility,
2) during the actual inoculation or exposure,
3) during animal housing post-exposure, and
4) during terminal procedures.

H. EUTHANASIA: Describe the euthanasia method(s) to be used, including the dose and route of administration of any drugs. All methods must comply with the ***AVMA Guidelines for the Euthanasia of Animals: 2020 Edition***. If the method of euthanasia does not include a physical disruption incompatible with life (opening the thorax, decapitation, etc.), please describe how death will be assured prior to disposal of the animal.

I. RESULTS: What are the outcome measures and how do they relate to the hypothesis being tested? Please describe so that an outside reviewer could understand the type of data that will be collected and how that information addresses the question(s) being investigated.

J. PAIN and/or DISTRESS INFORMATION:

One of the major responsibilities of the IACUC is to determine the degree of pain and/or distress that will be imposed on the animals and what method(s) will be used to prevent, relieve or minimize that pain and/or distress. The Animal Welfare Act (as amended July 22, 1993) defines a ***Painful procedure*** as:

"any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure was applied, that is, pain in excess of that caused by injections or other minor procedures"

Significantly Painful and/or Distressful Procedures: The following are some examples. (incomplete list)

- Surgery
- Fracturing bones
- Neurophysiological preparations
- Drug or radiation toxicity
- Intracardiac or periorbital blood collection
- Moderate to severe malnutrition
- Diseases that result in tissue destruction or death
- Agents causing excessive inflammation or necrosis, e.g. Freund's complete adjuvant, Bradykinin
- Chair or stock restraint of unadapted animals or restraint of any animal for more than 12 hours
- Burning or freezing
- Electrical shocks, including shock reinforcement
- LD 50 determinations
- Intracerebral or intracardiac inoculations
- Application of noxious stimuli without escape
- Imposition of abnormal environmental conditions

Behavioral Indicators of Pain: *Note*: There is <u>considerable</u> interspecies and individual variability in response to pain.

- Biting or resistance to handling (in adapted animals)
- Guarding the painful area
- Vocalization
- Self-mutilation
- Looking at, licking, chewing, or smelling painful area
- Reluctance to bear weight, limping
- Reluctance to move or rise
- Lethargic behavior
- Abnormal breathing pattern
- Excess salivation
- Inappetence
- Shivering
- Assuming unusual positions
- Acting “anxious”

Nutritional Distress: Nutritional distress is defined as a level of malnutrition that **significantly** interferes with the normal physiology of the animal. Fasting for up to 24 hours in most animals (48 hours for ruminants) is not considered to be significant nutritional stress, except in the case of neonates or animals with high metabolic rates (e.g. mice). Nutritional distress can be imposed by either fasting or feeding a diet with one or more nutrients below recommended levels. Any planned nutritional distress must be described in **Section E and** a justification for its use provided in **Section N.**

* * * * * * * * * * *

K. USDA CATEGORY THAT APPLIES TO THIS PROTOCOL: (indicate more than one **only** if there are different uses of animals that would distinctly fall into different categories, i.e., some animals are only euthanized for tissue collection (“C”) while others undergo surgery (“D”) prior to euthanasia.)

____ **Category C** Pain and/or distress no greater than an injection.

_____

_____ **Category D**[1] Pain and/or distress fully alleviated with analgesics and/or anesthetics.

_____ **Category E**[1,2] Pain and/or distress not fully alleviated with analgesics and/or anesthetics.

[1]For protocols in *either* **Categories D or E**, Section L **must** be completed.
[2]The Principal Investigator **must also include a written justification in Section N** as to the necessity of withholding anesthetics and/or analgesics. You may also be requested to attend a meeting to discuss the proposed research with the IACUC.

L. SEARCH FOR ALTERNATIVES: The Principal Investigator must provide a search for alternatives to painful and distressful procedures When performing the search for alternatives, please refer to: ***AWIC Tips for Searching for Alternatives to Animal Research and Testing*.** At the very minimum, this description must include a database search with all of the following components identified.

I. The database(s) searched:

II. The date on which the search was conducted:

III. The time period covered by the search (*e.g,1970 – present*):

IV. The key words and/or search strategy used:

V. Other methods utilized:

M. POTENTIAL ALTERNATIVES: Please give specific reasons why the anticipated data could not be obtained using a non-animal alternative or an alternative procedure. ALL methods or techniques that could result in the **Reduction** of animals used, **Replacement** of animals with non-animal models, and/or result in **Refinement** of experimental techniques to reduce pain and distress must be considered and an explanation provided as to why they are unsuitable.

N. JUSTIFICATIONS: If this protocol involves any of the following procedures that require specific justification, please provide below **OR** check (X) box for N/A.

I. Non-compliance with "Guidelines for Production of Polyclonal and Monoclonal Antibodies in Rodents and Rabbits"

☐ N/A

II. Non-compliance with "Guidelines for the Utilization of Animals in Experimental Neoplasia and Ascites Production"

☐ N/A

III. Non-compliance with "Guidelines for Tail Biopsy of Rodents"

☐ N/A

IV. Death as an Endpoint – Justification for why earlier euthanasia would invalidate study.

☐ N/A

V. Use of Paralytic Agents – Justification for why paralytic agents must be used.

☐ N/A

VI. Use of Expired Medical Materials – Description of expired materials to be used and justification for why this is necessary.

☐ N/A

VII. Restraint of Conscious Animals for Longer than 15 minutes – Explain the necessity.

☐ N/A

VIII. Food or Water Restrictions Beyond Standard Pre-Surgical Fasting – Explain the necessity.

☐ N/A

IX. USDA Category E – Justification for why anesthetics/analgesics must be withheld.

☐ N/A

X. Multiple Survival Surgery – Justification for why multiple, separate surgical procedures must be conducted on the same animal.

☐ N/A

O. PRINCIPAL INVESTIGATOR CERTIFICATION FOR ELECTRONIC SUBMISSIONS*

The Principal Investigator certifies that:

- all the information provided is accurate to the best of his/her knowledge and s/he will adhere to the procedures described;
- the animals in this study will be used in accordance with the laws and regulations of:
  - the Animal Welfare Act
  - the Public Health Service
  - the New York State Health Department
  - the SUNY Upstate Medical University Department of Laboratory Animal Resources
- the species, number of animals, and procedures to be used are the most appropriate for the proposed study;
- consideration has been given to any and all alternatives to painful and/or distressful procedures;
- pain and/or distress to animals will be limited to that which is unavoidable in the conduct of scientifically-valuable research;
- analgesic, anesthetic and tranquilizing drugs will be used where indicated to minimize pain and/or distress;
- the activities described in this study do not unnecessarily duplicate previous experiments. If activities will duplicate previous experiments, I have included a written explanation and justification for the duplicative procedures;
- all individuals listed on this protocol are trained and qualified for their specific duties involving animals under this proposal;

- all individuals listed on this protocol who lack sufficient training must be supervised while performing such tasks until adequate documentation of training is submitted to the IACUC office;
- all individuals listed on this protocol have read the protocol or will be provided access to the complete protocol approved by the committee before engaging in any animal use related to this project;

and s/he agree to:

- obtain approval from the IACUC in advance of any changes in the project;
- notify the Attending Veterinarian and/or the IACUC of any unexpected study results that impact\ animal welfare;
- be familiar with and comply with all pertinent institutional, state, and federal rules and policies;
- be responsible for the supervision and work of my staff; and
- retain copies of this protocol and all correspondence associated with it for three years beyond the completion of the animal use.

Please certify (X) the following*:

☐ I certify adherence to the criteria listed above **and** that I have read and understand the information on potentially painful / distressful procedures and behavioral indicators pain provided in **Section J** of this animal use protocol.

*Electronic submission of this document by the Principal Investigator via his/her own email serves as his/her electronic signature. Document submission by other lab personnel **will not be accepted.** **DO NOT** submit a hard copy.

Appendix I

SURGICAL INTERVENTION FORM

If more than one type of surgery is planned, please complete a separate Appendix I for each type of surgery.

Type of surgery:

☐	**Major –** Major Surgery is defined as any surgical intervention that exposes a body cavity or has the potential for producing permanent physical or physiological change.
☐	**Minor**
☐	Multiple Survival – Justification for multiple survival surgeries must be provided in **Section N**.
☐	**Nonsurvival**

Name of Surgical Procedure: _____

Species: _____

1. **Detailed Description of Surgical Procedure:**

2. **Approximate length of surgical procedure:** _____

3. **Location of Surgical Procedure (DLAR or other) -** Survival surgical procedures on all mammals (except rodents) *must* be conducted in dedicated surgical facilities. The DLAR surgical facilities must be used unless justification is provided for another location (see Survival Surgery section). Survival surgery on rodents does not require a dedicated facility, but rodent surgeries may also be performed in DLAR facilities. Contact Jennifer Kieffer @ Ext. 4-4289 to schedule surgery within the DLAR facilities.

   Building: _____ Room Number _____

4. **Personnel Performing Surgery: Please list all personnel who may be performing this surgery*.**
   *Training for this procedure must be documented on each individual's Training Summary in the IACUC office.

5. **Will animals be attended at all times during the surgical procedure?** ___ **YES** ___ **NO***
   *If no, please explain:

Method of Anesthesia During Surgical Procedure

6. **Pre-anesthetic**:

Agent(s)	**Dose** (mg/kg)	**Route** (IM, IP, etc.)

7. **Anesthetic**:

Agent(s)	**Dose** (mg/kg)	**Route** (IM, IP, etc.)

Survival Surgery - Complete the following sections of Appendix I ONLY if animals will recover from anesthesia.

Survival surgery on **non-rodents** must be performed using standard sterile operating room procedures. Survival surgery on rodents must be performed using aseptic procedures, which include (as a minimum) sterile surgical gloves, mask, and sterile instruments.

8. **Will survival surgery on non-rodent species be performed in facilities other than DLAR?**

_____ Yes*
_____ No
_____ Not applicable, using rodent species

***If yes, please provide justification for the location chosen (specialized equipment, etc.):**

9. **Describe the pre-operative procedures to be performed (i.e., fasting, pre-medication, preparation of surgical site, etc.):**

10. **Describe the sterile or aseptic procedures to be followed by all personnel (gowns, gloves, masks, instruments preparation, etc.):**

11. **Immediate Post-Operative Care:**

Location of recovery: _____
Person(s) monitoring: _____
Minimum frequency of monitoring: _____
When will animal be returned to DLAR? _____

12. **Describe all potential post-operative complications and what procedures are planned to monitor and address these complications:**

13. Postoperative Analgesia:

Agent(s)	**Dose** (mg/kg)	**Route** (IV, etc.)	**Frequency**	**Duration** (days)

14. Postoperative Treatments:

Agent(s)	**Dose** (mg/kg)	**Route** (IV, etc.)	**Frequency**	**Duration** (days)

15. Other postoperative procedures: (suture removal, etc.):

Appendix II

BREEDING COLONY INFORMATION*

***The experimental use of embryos or offspring does not necessarily constitute a breeding colony (i.e., ordering pregnant dams). It is only when you intend to breed multiple generations of offspring that it becomes a breeding colony.**

Species: _____
Specific strain of male: _____
Specific strain of female: _____
Original source of animals: _____
Purpose for establishing and/or maintaining breeding colony (special strain, etc.)**:**

Phenotypic considerations (clinical signs; special care):

Approximate number of animals to be produced (This should be the total number of animals that you expect to produce over the entire approval period which should include experimental animals, replacement breeders and all unusable animals. Any animals determined to be unusable for your experimental purposes (e.g. wrong genotype) should be transferred to DLAR for disposal, and should not appear as animals that were "used" on your "Record of Animal Usage" during annual protocol review.):

Please explain how the number to be produced was determined:

Breeding system: ____ Inbred ____ Outbred ____ Other (please explain):

Breeding method: ____ Monogamous ____ Harem Other (please explain):

Method of identification: _____

Method of genetic monitoring: _____

Personnel responsible for pedigree records: _____

Additional Information: _____

Appendix III

GUIDELINES FOR THE USE OF EXPIRED MEDICAL MATERIALS

The Animal Care division of the United States Department of Agriculture (USDA) has developed a policy (Policy #3: Veterinary Care) concerning the use of expired medical materials for non-survival experimental procedures. In consideration of this policy, the IACUC has developed the following guidelines, which should be followed when utilizing outdated pharmaceuticals or medical devices in experimental animals:

1. Outdated materials may only be used if the item is irreplaceable or replacement would be prohibitively expensive and its use does not adversely affect the animal's well-being or compromise the validity of the study.

2. Drugs administered to relieve pain or distress and emergency drugs must not be used beyond their expiration dates.

3. The outdated items must be physically separated from other similar items and clearly labeled **"Outdated Materials – For Terminal Procedures Only"** (or similarly).

4. Expired materials should be maintained in as sterile or clean condition as possible.

5. A description of the expired materials to be used and justification for why this is necessary must be provided in **Section N** of the animal use protocol.

Please certify (x) the following:

☐ I have read and agree to comply with the above guidelines.

and

☐ I have provided written justification in **Section N.**

Appendix IV

GUIDELINES FOR THE PRODUCTION OF POLYCLONAL AND MONOCLONAL ANTIBODIES IN RODENTS AND RABBITS

I have read the Guidelines for the Production of Polyclonal and Monoclonal Antibodies in Rodents and Rabbits, revised 10/17/01. I understand that the use of Freund's Complete Adjuvant (FCA) is discouraged and alternatives should be considered. I also understand that intradermal or foot pad injections require specific justification.

I understand that any deviation from these guidelines requires justification in **Section N** of animal use protocol.

Please certify (x) the following:

☐ I have read and agree to comply with the above guidelines.

OR

☐ I have provided written justification for noncompliance with these guidelines.

Appendix V

GUIDELINES FOR THE UTILIZATION OF ANIMALS IN EXPERIMENTAL NEOPLASIA AND ASCITES PRODUCTION

I have read the Guidelines for the Utilization of Animals in Experimental Neoplasia and Ascites Production**,** revised 10/17/01.

I understand that any deviation from these guidelines requires justification in **Section N** of animal use protocol.

Please certify (x) the following:

☐ I have read and agree to comply with the above guidelines.

OR

☐ I have provided written justification for noncompliance with these guidelines.

Appendix VI

GUIDELINES ON DEATH AS AN ENDPOINT

Death as an endpoint is defined as the experimental necessity to allow animals to die spontaneously (not euthanasia). Regulatory agency guidelines highly discourage the use of death as an endpoint for **any** experiment. Investigators **must** euthanize moribund experimental animals unless there is significant scientific support that euthanasia would invalidate experimental data collection. For the definition of moribund, please refer to the IACUC Policy on Euthanasia for Humane Purposes.

If death as an endpoint is a necessity, scientific justification must be provided in **Section N** of the animal use protocol**.** Investigators who receive approval to use death as an endpoint **must** agree to the following:

1. To use the minimum number of animals necessary to achieve statistical significance.
2. To use alternative endpoints (other than death) whenever possible.
3. To monitor animals at least twice daily (including weekends and holidays) and separate out debilitated animals to allow easy access to food and water.
4. To keep written records of all monitoring sessions which indicate the time observed, person observing, and any noteworthy observations such as clinical signs, number dead, etc. These records must be current and available to the Department of Laboratory Animal Resources and the IACUC at all times (within the housing area unless other arrangements are made with DLAR).

Investigators should note that any approved use of death as an endpoint will normally be categorized in the highest USDA pain and distress **category E.**

Please certify (x) the following:

☐ I have read and agree to comply with the above guidelines.

and

☐ I have provided written justification in **Section N.**

Appendix VII

GUIDELINES FOR THE USE OF PARALYTIC AGENTS DURING ANESTHESIA

Although the use of paralytic agents is recognized as a necessary component of some experimental protocols, the use of these agents renders assessment of the level of general anesthesia much more difficult. The IACUC policy on the Use of Paralytic Agents During Anesthesia provides the following guidance for the use of paralytic agents during anesthesia:

1. Paralysis should not be induced until the animal has reached a surgical plane of anesthesia (no response to toe pinch).

2. To an extent consistent with the experimental protocol, potentially painful procedures should be minimized in paralyzed animals.

3. The planned anesthetic regimen should be sufficient to prevent the animal from experiencing significant pain or distress. This shall be determined based upon previous experience, consultation with a veterinarian, documentation, and/or trial use in non-paralyzed animals exposed to the same planned experimental procedures.

4. To the extent consistent with the experimental protocol, paralytics should be temporarily withheld periodically to reassess anesthetic depth (best accomplished by utilizing short-acting paralytics).

5. During paralysis, adequacy of anesthesia should be assessed continuously by monitoring heart rate and/or blood pressure. Temperature should also be monitored and maintained within normal parameters. If necessary, provisions for voiding urine should be provided.

6. I understand that the use of paralytic agents requires justification in **Section N** of the animal use protocol.

Please certify (x) the following:

☐ I have read and agree to comply with the above guidelines.

and

☐ I have provided written justification in **Section N.**

Appendix VIII

GUIDELINES ON TAIL BIOPSY OF RODENTS

Tail biopsy of rodents is often used to obtain tissue samples for genetic analysis.

For a single sample collection in an UNANESTHETIZED animal, the following criteria must be met:

a. Sample length must not exceed 0.5 cm
b. Animal must be 4 weeks of age or less
c. Excisional tool (scalpel or scissors) must be sharp
d. Bleeding must be controlled (if it exceeds 1-2 drops)

This sample collection will be considered a USDA pain or distress category "C".

ANESTHESIA is required for any repeat biopsies, sample size > 0.5 cm, and/or animals older than 4 weeks. Bleeding must be controlled. Post-procedural analgesics may also be required. This must be determined in consultation with DLAR veterinary staff **PRIOR to collecting samples.** (4-6563).

If anesthesia is required, this procedure will be considered a USDA pain or distress category "D".

The IACUC encourages investigators to consider alternatives to tail biopsy such as utilizing ear punch tissue obtained during identification or using oral swabs to obtain cells from mucous membranes (contact DLAR for specific references). These techniques have been used successfully for genetic monitoring, especially when PCR techniques are utilized that require very little tissue.

I understand that any deviation from these guidelines requires justification in **Section N** of animal use protocol.

Please certify (x) the following:

☐ I have read and agree to comply with the above guidelines.

OR

☐ I have provided written justification for noncompliance with these guidelines.