VIRGINIA STATE UNIVERSITY
Petersburg, Virginia 23806

FOR IACUC USE
Review Month:
Protocol Number:

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE
ANIMAL PROTOCOL REVIEW QUESTIONNAIRE

Submission Procedures: Submit the completed signed questionnaire to the IACUC Office, P O Box 9407. The IACUC has established a review cutoff date of 5 business days to complete the review of a protocol. Please call the IACUC Office for additional information.

ADMINISTRATIVE INFORMATION:

(1) TITLE OF PROJECT:

(2) PERSONNEL: Principal Investigator and Co-Investigators:

Name	Role on Protocol	Department	P. O. Box	Phone	Email
a)					
b)					
c)					
d)					

(3) FUNDING AGENCY: **SUBMISSION DATE:**

(4) REVIEW STATUS:
Initial Review Revised Submission
(If this is an annual renewal, please use the IACUC Annual Renewal Form.)

(5) PURPOSE OF THE STUDY:
Provide a brief summary in commonly understood terms describing the purpose, hypothesis, and importance of the study. Remember that a layman or USDA inspector may review your proposal and that not all members of the IACUC are familiar with your area of research.

(6) RATIONALE FOR USING ANIMALS:

Describe the potential benefits to be gained in either improved medical care of humans or animals or the contribution of new scientific information.

(7) SPECIES JUSTIFICATION:

State why the animal species selected represents the best model to test the hypothesis of the study.

(8) ALTERNATIVES TO ANIMAL USE:

A search in at least two databases is required to determine that alternatives are not available and/or are scientifically unacceptable. Database names, key words, dates searched and date search was performed are required plus at least one additional database. For USDA covered species (gerbils, hamsters, rabbits, cats, dogs, ruminants, pigs and primates), an Agricola (http://agricola.nal.usda.gov/) search is required. For non-USDA covered species (rats, mice, birds), appropriate databases may include PubMed (http://www.pubmedcentral.nih.gov/), Norina (http://oslovet.veths.no/NORINA/), Ovid (http://www.ovid.com/site/index.jsp?top=1), Google (http://www.google.com/), Biosis Previews (http://www.biosis.org/), CAB Abstracts (http://www.cabi-publishing.org/AbstractDatabases.asp?SubjectArea=&PID=125), SCISEARCH (http://library.dialog.com/bluesheets/html/bl0034.html), CRIS (http://cris.csrees.usda.gov/) or others as applicable.

Key words that must be used in the search include: "alternative(s)," species proposed (dog, cat etc.) and experimental procedure. Other terms may be searched as applicable.

(9) UNNECESSARY DUPLICATION:

Provide written assurance that the animal experimentation does not unnecessarily duplicate previous experiments. If there is duplication, state why duplication is necessary.

Provide a description of how the P.I. accessed the pertinent literature (sources, key words, dates).

(10) PROCEDURES INVOLVING ANIMALS:

A. Describe all experimental procedures to be done to live animals, including anesthesia, surgeries, blood volume to be drawn, etc. Use as much space as necessary.

B. **Do you intend to breed animals?**

If Yes, list the species. You are responsible for submitting the number of animals bred to the IACUC on the first day of each month.

C. **List All Drugs to be Used:**

Species	Agent	Purpose	Dose	Route
a)				
b)				
c)				
d)				
e)				

D. Will any non-pharmaceutical grade compounds be used?

If "Yes," include a scientific justification of why use of this compound is necessary:

E. Will this study involve prolonged restraint of unanesthetized animals?

If "Yes," provide a description of the restraint method/procedure and scientific justification for its use:

F. Will the animals be deprived of water? Withholding water for the immediate pre-surgical period (rodents up to 8 hours and non-rodents up to 12 hours) need not be described.

If "Yes," provide a description of the method of deprivation and monitoring of animal welfare along with a scientific justification for water restriction.

G. Will the animals be deprived of food? Withholding food for the immediate pre-surgical period (rodents up to 12 hours and non-rodents up to 24 hours) need not be described.

If "Yes," provide a description of the method of deprivation and monitoring of animal welfare along with a scientific justification for food restriction.

H. Will the animals undergo multiple major survival surgeries?

If "Yes," provide scientific justification for multiple survival surgeries.

I. Endpoints: What clinical criteria or specific observations might be anticipated that would result in premature euthanasia? Example: 20% loss in body weight; severe, unrelievable pain; animal expected to die within 24 hours, moribund. (Death as an endpoint is strongly discouraged and must be justified.)

J. Euthanasia: Will euthanasia be carried out? ☐

If "Yes," provide information below. Please use the most recent AVMA panel on euthanasia for guidance (www.AVMA.org/resources/euthanasia.pdf) Note: cervical dislocation and decapitation without anesthesia requires scientific justification.

Species	Agent/Method	Dose	Route
a)			
b)			
c)			
d)			
e)			

If "No," describe disposition of animal(s) at conclusion of the study.

(11) ALTERNATIVES TO PAINFUL PROCEDURES:

A search in at least two databases is required to determine that alternatives to painful procedures are not available and/or are scientifically unacceptable. Database names, key words, dates searched and date search was performed are required plus at least one additional database. For USDA covered species (gerbils, hamsters, rabbits, cats, dogs, ruminants, pigs and primates), an Agricola (http://agricola.nal.usda.gov/) search is required. For non-USDA covered species (rats, mice, birds), appropriate databases may include PubMed (http://www.pubmedcentral.nih.gov/), Norina (http://oslovet.veths.no/NORINA/), Ovid (http://www.ovid.com/site/index.jsp?top=1), Google (http://www.google.com/), Biosis Previews (http://www.biosis.org/), CAB Abstracts (http://www.cabi-publishing.org/AbstractDatabases.asp?SubjectArea=&PID=125), SCISEARCH (http://library.dialog.com/bluesheets/html/bl0034.html), CRIS (http://cris.csrees.usda.gov/) or others as applicable.

Key words that must be used in the search include: "alternative(s)," "pain," species proposed (dog, cat etc.) and experimental procedure. Other terms may be searched as applicable.

(12) TOTAL NUMBER OF ANIMALS REQUESTED FOR THE ENTIRE PROJECT PERIOD:

By law, the number of animals requested can be approved for a maximum of 3 years only, but reviews are mandated annually.

CLASSIFICATION OF ANIMAL USAGE: The USDA requires all animal usage to be classified according to one of the following types:

Type C: Procedures involve no pain or distress (e.g., routine blood sampling without surgery from a superficial vein or routine injections IV, IM, subcutaneous or IP or euthanasia following AVMA panel on euthanasia guidelines.)

Type D: Procedures involve pain or distress, but the pain is relieved by appropriate drugs (e.g., surgery under anesthesia with pain relieving drugs postoperatively.)

Type E: Procedures involve pain or distress and they are not relieved by drug administration. If you classify your procedures as Type E, you must write a statement giving careful scientific justification for withholding such drugs.

Species	Number	Classification Type	Age or Weight	Sex
a)				
b)				
c)				
d)				
e)				

(13) CONSULTATION WITH VETERINARY STAFF. It is mandated that investigators consult with the facility veterinarian **during** preparation of this application **before** IACUC review for Type D and Type E protocols.

Name the veterinarian consulted _____ Date _____

(14) PLEASE PROVIDE THE FOLLOWING INFORMATION REGARDING HOUSING AND ANIMAL USE:

(a) Housing Location: _____

If OTHER, fill in text box. Describe the housing if animals will remain longer than 12 hours. Please list the location where the animals will be held. Indicate what provisions you will make for animal care (regulated light, heat, humidity, room air changes, and cage cleaning) if you plan to exceed the above time limit:
(Note: The IACUC requires the area to pass inspections prior to animals being housed and must be allowed access to inspect the housing location after it is approved.)

(b) Will animals be used outside of the vivarium?

If YES, describe location of animal use (building, floor and room number) and procedure(s) performed on animal. Please describe the housing conditions for the animals if they will remain longer than 12 hours:

_____

(c) Housing duration?

_____

(d) Do animals need exemption from cage space requirements per NIH Guide for the Care and Use of Laboratory Animals?

If YES, provide scientific justification: _____

(e) Do animals need exemption from enrichment per NIH Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act?

If YES, provide scientific justification:

(f) Do animals need exemption from exercise (dogs) per NIH Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act?

If YES, provide scientific justification:

(15) JUSTIFY THE NUMBERS OF ANIMALS TO BE USED:

The IACUC needs assurance that the minimum number of animals that will ensure a statistically sound investigation is being requested. "Past experience" and "previously published" literature are not, in themselves, an adequate justification.

(a) Has a biostatistician been consulted?

If "Yes," include memo from the biostatistician detailing the statistical analysis to be used and sample size calculations and skip item (b).

(b) Specify the experimental design and indicate how you arrived at the number of animals you propose to use:

(c) Provide a table summarizing animal use for each proposed experiment:

(16) QUALIFICATIONS OF INVESTIGATORS:

List only the personnel performing animal procedures and indicate for each individual their duties and their previous experience in the procedure or how they will acquire the necessary training. Experience should be described with the specific species and procedures described in this application.

Procedure to be Done	Name of Individual	Individual's previous experience with this procedure in this species
a)		
b)		
c)		
d)		
e)		

(17) Infectious, Toxic Agents or Biohazards: Identify any agent(s) to be used that is harmful to humans or other vertebrates.

A. Radioactive Materials: It is strongly encouraged to discuss possible hazards with Animal Facility Management BEFORE starting the experiment.

1. Are radioactive materials given to animals?

2. If "Yes," identify the isotope(s) to be administered:
   Half-life:

3. Is the isotope a gamma emitter?

4. If "Yes," describe how animals in adjacent cages will be protected.

5. Describe any precautions which must be taken because of isotope excretion and respiration.

6. Who will be responsible for insuring that these precautions are taken properly?

7. How will the radioactive carcasses be disposed?

8. Approved by Radiation Safety Officer

(Name) (Date)

B. INFECTIOUS AGENTS: It is strongly encouraged to discuss possible hazards with Animal Facility Management BEFORE starting the experiment.

1. Are infectious agents given to animals?

2. Identify the Infectious Agents and describe safety precautions needed:

3. If "Yes," describe how the condition of the animal will be monitored throughout the experiment and safety precautions needed.

4. Has the Institutional Biosafety Committee approved the use of these materials?

C. CARCINOGENS: It is strongly encouraged to discuss possible hazards with Animal Facility Management BEFORE starting the experiment.

1. Are known carcinogens/mutagens/reproductive hazards to be given to the animals?

2. If "Yes," Identify and describe the carcinogens/mutagens/reproductive hazards being used.

3. If "Yes," describe how the condition of the animal will be monitored throughout the experiment.

4. Has Environmental Health and Safety approved the use of these agents?

D. TOXIC AGENTS: It is strongly encouraged to discuss possible hazards with Animal Facility Management BEFORE starting the experiment.

1. Are toxic agents to be given to the animals?

2. If "Yes," identify toxins and describe safety precautions needed.

3. If "Yes," describe how the condition of the animal will be monitored throughout the experiment.

E. BIOHAZARDOUS MATERIALS: It is strongly encouraged to discuss possible hazards with Animal Facility Management BEFORE starting the experiment.

1. Are biohazardous materials to be given to the animals?

2. If "Yes," identify the biohazard. Describe how the condition of the animal will be monitored throughout the experiment and safety precautions needed.

3. If the biohazard is greater than risk group 2, has the Institutional Biohazard Committee approved the use of these materials?

(18) Good Laboratory Practice:

GLP relates to compliance with special reporting requirements established by the Food and Drug Administration (FDA) for the testing of new drugs and devices.

1. Is this project subject to compliance with FDA standards?

(19) THIS PROTOCOL NEEDS TO BE REVIEWED IN USE EVERY 6 MONTHS. **Has this protocol been reviewed in the last 6 months for new and improved methods?** Attach search.

(20) SIGNATURES

The use of animals for research, education or other purposes requires prior approval of a specific protocol by the IACUC in accordance with Public Health Service (PHS) policy, the Health Research Extension Act (PL99-158) and New World Laboratories, Inc. policy. Please complete all items in the animal protocol review questionnaire and attach this assurance page.

Principal Investigator Assurance: The Principal Investigator is responsible for the humane use of research animals, and is accountable for the completeness and accuracy of the information offered on the attached protocol review questionnaire. While the care and use of animals may be delegated to other persons, this responsibility cannot be delegated. Only one PI may be identified for each project. The Principal Investigator must sign the following statement of assurance:

The proposed investigation involves the use of animals. I am submitting this form with a description of my protocol prepared in accordance with New World Laboratories, Inc. policy for the humane care and use of laboratory animals. I am responsible for:

1. Conducting activities involving animals in accordance with all provisions of the Animal Welfare Act, the U.S. Government Principles Regarding the Care and Use of Animals, the Guide (Guide for the Care and Use of Laboratory Animals, U.S. Dept. of Health and Human Services, Public Health Service, NIH), the PHS Policy on Humane Care and Use of Laboratory Animals and the CCF PHS Assurance Statement:

2. Insuring that protocols involving animals are submitted to the Institutional Animal Care and Use Committee for review and approval before the activity begins;

3. Submitting an annual protocol form to the IACUC;

4. Reporting, promptly to the IACUC proposed significant changes in my research activity involving animals. Such changes shall include differences in species and number of animals used in the project, changes in surgical and anesthetic methods, change of PI, and changes in the method of euthanasia;

5. Reporting promptly to the IACUC any serious or continuing deviation from the provisions of the Guide, PHS Policy or Animal Welfare Regulations.

Principal Investigator Signature

(Name) (Date)