

Form Notes: Before completing this form, please read the following:

Adobe Reader must be used to complete this form.

If you have saved this form to your computer, please confirm revision date with current webform before proceeding.



**PROTOCOL FORM FOR USE OF VERTEBRATE ANIMALS
IN RESEARCH AND EDUCATION
UNIVERSITY OF MARYLAND CENTER FOR ENVIRONMENTAL SCIENCE**

UMCES has on file with the Public Health Service (PHS) a written Assurance which commits the Center to following the standards and regulations established by the Animal Welfare Act. UMCES has established an Institutional Animal Care and Use Committee (IACUC) to ensure that all activities are in compliance with the Act, other applicable federal and state law, and PHS and institutional policy. The IACUC is responsible for review and approval of all animal research and education protocols. The IACUC is responsible for the welfare of "any live vertebrate animal used or intended for use in research, experimentation, teaching, training, or related purposes" if these animals are maintained at an UMCES facility or are used under funds administered by UMCES.

Note: A separate form must be filed for each different project or protocol.

Date of Submission: _____

Applicant: _____

Telephone: _____

Fax: _____

Email: _____

Check one box per line: Initial Submission De Novo Submission Modification

Faculty Research Thesis Research Other: _____

If Faculty Research: Principal Investigator: _____

UMCES Laboratory: _____

Research Sponsor: _____

If Thesis Research: Faculty Advisor: _____

UMCES Laboratory: _____

Program or Dept.: _____

Degree-Granting Institution: _____

Degree Sought: _____

NOTE: Appendix B may be used to provide any additional or overflow information, where field space is limited.

Project Title:

Grant Title (if different from Project Title):

Anticipated Starting Date: _____ Anticipated Ending Date: _____

Location Where Animals Will be Housed: _____

A. JUSTIFICATIONS

The U.S. Government's *Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training* includes: "Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society."

1. Research Goals:

a. What are the scientific issues addressed by the research? Specifically, how will this research improve human or animal health or advance knowledge?

b. What are the specific goals of the animal studies described in this protocol?

U.S. Government *Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training* states, "The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results."

1. Research Species: _____

Strain: _____

Why is this the most appropriate species/strain to use in these studies?

2. How many animals do you plan to use for this protocol? Complete the following table below to define the number(s) of animal(s) to be used in each category. Use the following animal welfare categories:

- CATEGORY: 0: No pain.
 1: Little or momentary pain or discomfort.
 2: Potential discomfort or pain which is relieved by the appropriate anesthetic or analgesic.
 3: Discomfort or pain which is not relieved.

	Experimental Groups or Animal Species			
Category				
0				
1				
2				
3				

You *must* provide a breakdown of the animals into experimental groups if substantially different procedures will be used between groups or if different species will be used (identify each experimental group and the numbers of animals in each group) *and* you must provide a justification for the numbers of animals. It would be beneficial if you include in your justification statistical analysis which was used to determine that the animal numbers are the minimum required for valid results. You can provide this information in your description of the Experimental Procedures, Section B.

The Animal Welfare Act states: "The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources (e.g., the Animal Welfare Information Center) used to determine that alternatives were not available . . ."

3. If you have placed any animal numbers in categories 2 or 3, you *must* complete the following (use Appendix B, if additional space is necessary):

a. Explain why the pain or discomfort cannot be relieved and what procedures will be used to minimize discomfort.

b. What informational methods and resources did you use to determine that (non-animal or non-painful) alternatives were not appropriate for this research?

Data bases searched (include keywords used)¹

Literature citations

Meetings with knowledgeable individuals (name, date)

Other methods/resources

¹See C.P. Smith, *AWIC Tips for Searching for Alternatives to Animal Research and Testing*. Animal Welfare Information Center, USDA, National Agricultural Library, Beltsville, MD.

B. EXPERIMENTAL PROCEDURES

1. General Procedures:

Describe (on Appendix A of this form) the animal procedures that are to be performed and the necessity of conducting these experimental procedures in fulfilling the goals of the project. Be sure to be specific about any procedures which may impact on the health and comfort of the study animals (examples: frequency of performance of any procedures, methods of restraint, blood sample volumes, etc.). As mentioned earlier, you may wish to include the experimental groups in this section. When defining your experimental groups include the numbers of animals within each group. Please provide a justification for the animal numbers used.

The Animal Welfare Act states that, "Procedures that may cause more than momentary or slight pain or distress to the animals will: a) Be performed with appropriate sedatives, analgesics, or anesthetics unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time; b) Involve in their planning, consultation with the attending veterinarian . . . , c) Not include the use of paralytics without anesthesia"

2. Anesthetics and Analgesics:

If anesthetics or analgesics are to be used, please provide the following information (this section need not be completed if the requested information is provided in the animal use procedures described above):

PROCEDURE	ANESTHETIC	DOSE & METHOD OF ADMINISTRATION

The Animal Welfare Act states: "Activities that involve surgery include appropriate provision for pre-operative and post-operative care of the animals in accordance with established veterinary medical and nursing practices. All survival surgery will be performed using aseptic procedures, including surgical gloves, masks, sterile instruments, and aseptic techniques."

3. Surgical Procedures:

If surgery is to be performed:

a. Surgery location/room: _____

Is it a terminal procedure? YES NO

Is it a survival procedure? YES NO

b. On Appendix A, describe the surgical procedures to be performed. Be sure to include the procedures to be followed to ensure asepsis. (If aseptic procedures are not to be performed, use this space to justify why not and describe the procedure of choice.)

c. Describe the post-operative care (both immediate and long-term). (If described in Appendix A, do not repeat here.)

4. Euthanasia

Please consult UMCES *Research Protocol Guidelines* for acceptable euthanasia practices.

Will the animals be terminated at the end of the experiment?

YES NO

IF YES, the method of euthanasia is:

The Animal Welfare Act states, "Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures."

5. Please describe below the training and qualifications of yourself and other individuals who are included in this protocol. In particular, please be very specific about the hands-on training of those individuals performing procedures which may produce animal discomfort, i.e., restraint, injections, blood collection, surgery, euthanasia, etc. (Use Appendix B, if necessary.)

C. HUSBANDRY PRACTICES

1. Describe the husbandry practices that will be used. [If fish are raised as hatchery or laboratory aquarium stocks, you may refer to established standard operating procedures for the appropriate facility. If you are raising fish yourself, you must complete this section.]

2. Describe procedure for disposition of dead animals, including whether or not necropsy will be performed.

D. WILL THE ANIMALS BE REMOVED FROM THE FACILITY IDENTIFIED ON PAGE 1 OF THIS PROTOCOL FORM?

YES NO

If YES: For how long? _____

NOTE: If removal will be greater than 24 hours a variance request may be required.

To where? _____

Will they be returned to the facility? YES NO

If NO, why not?

E. ENVIRONMENTAL SAFETY

1. Are infectious agents to be used? YES NO

IF YES, the agent is _____

IF YES, is the agent infectious to humans? YES NO

2. Are chemical hazards to be used? YES NO

IF YES, the chemical hazard is _____

3. Are radioisotopes to be used? YES NO

IF YES, the radioisotope is _____

4. Are other biohazards to be used? YES NO

IF YES, the biohazard is _____

If any of the above questions are answered YES, all procedures must comply with Environmental Safety requirements of the appropriate UMCES Laboratory.

F. HAVE YOU COMPLETED THE UMCES VERTEBRATE ANIMAL CARE AND USE TRAINING PROGRAM?

YES NO

If YES, give date of program session: _____

If NO, you must complete this Program within 1 calendar year of the date of approval of this protocol and submit certification thereof to the Chair of the IACUC. This program covers the composition and function of the IACUC, historical background, federal laws, PHS Assurance, protocol submission and reviews, occupational health and safety issues and much more. **Failure to complete this program within 1 calendar year could result in suspension of the project by the IACUC.**

In the interim, it is the responsibility of the employee to make themselves aware of any health and safety issues related to the performance of their duties. They should seek assistance and training from their immediate supervisor, Laboratory Manager or Principle Investigator, to insure that they fully understand the health and safety issues of working with their specific vertebrate species. New employees who plan to work with vertebrates must provide documentation that they have had a tetanus/diphtheria vaccination/booster within the past 10 years. A tuberculin skin test is required for employees working with finfish. They should be tested every 2 years, as positive tuberculin reactions may be due to infection with *Mycobacterium marinum*. Those working with bats or vertebrates known to harbor rabies are required to have the pre-exposure rabies vaccination. Their serum should be tested for rabies antibody every 2 years and, if the titer is inadequate, have a booster dose. It is impossible to cover every zoonoses or health risk here, as many are species specific. It is the employee's and immediate supervisor's responsibility to make sure that they are informed of any health and safety risks before beginning work with a specific vertebrate species. If there are any concerns, the IACUC Chair should be contacted.

G. LIST ALL NAMES AND TELEPHONE NUMBERS OF PERSONNEL, INCLUDING YOURSELF, ASSOCIATED WITH THE PROJECT IDENTIFIED IN THIS PROTOCOL WHO WILL WORK WITH ANIMALS OR ANIMAL TISSUE. CHECK THE APPROPRIATE BOX TO INDICATE WHETHER OR NOT EACH INDIVIDUAL HAS COMPLETED THE UMCES ANIMAL CARE AND USE TRAINING PROGRAM. ALSO, CHECK THE APPROPRIATE BOX TO INDICATE IF EACH INDIVIDUAL HAS FULFILLED REQUIREMENTS FOR VACCINATION/TESTING.

UMCES Animal Care and Use Training		Vaccination/ Testing		Name	Phone	Email
<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> YES	<input type="checkbox"/> NO			
<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> YES	<input type="checkbox"/> NO			
<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> YES	<input type="checkbox"/> NO			
<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> YES	<input type="checkbox"/> NO			
<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> YES	<input type="checkbox"/> NO			
<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> YES	<input type="checkbox"/> NO			
<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> YES	<input type="checkbox"/> NO			
<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> YES	<input type="checkbox"/> NO			

H. ASSURANCE

I attest to the accuracy and completeness of the information provided. I promise to conduct this work with animals in accordance with the protocol as approved by the UMCES IACUC under UMCES animal care and use policy. I will not make any substantive changes in the above protocol without first obtaining the approval of the UMCES IACUC, and I will not use any procedures which are not included in this form.

Applicant: _____ date: _____

I acknowledge responsibility for the conduct of these procedures with animals which will be performed by the individual identified above under my direction.

Principal Investigator: _____ date: _____

OR

Student's Thesis Advisor: _____ date: _____

I have reviewed the research protocol outlined on this form and hereby transmit it to the UMCES Institutional Animal Care and Use Committee for review.

Laboratory Director: _____ date: _____

ACTION BY UMCES IACUC: Protocol No. Assigned: _____

- _____ **Approved as submitted**
- _____ **Yes if modification []**
- _____ **Hold for discussion by Committee**
- _____ **Disapproved as presented; must resubmit**

COMMENTS OR INSTRUCTIONS:

FINAL ACTION: _____

IACUC Chair: _____ date: _____

STATEMENT ON CONFIDENTIAL INFORMATION

The Animal Welfare Act, Section 27, states that it is unlawful for any member of an Institutional Animal Care and Use Committee to release any confidential information including the following: processes, operations, style of work, apparatus, buildings used, confidential statistical data, etc. UMCES considers ALL information on Protocol Forms confidential, and will not forward these forms to any institution that does not honor this confidentiality.

Appendix A

B. Experimental Procedures Description(s), from page 6:

Describe the animal procedures that are to be performed and the necessity of conducting these experimental procedures in fulfilling the goals of the project. Be sure to be specific about any procedures which may impact on the health and comfort of the study animals (examples: frequency of performance of any procedures, methods of restraint, blood sample volumes, etc.). As mentioned earlier, you may wish to include the experimental groups in this section. When defining your experimental groups include the numbers of animals within each group. Please provide a justification for the animal numbers used.

The Animal Welfare Act states that, "Procedures that may cause more than momentary or slight pain or distress to the animals will: a) Be performed with appropriate sedatives, analgesics, or anesthetics unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time; b) Involve in their planning, consultation with the attending veterinarian . . . , c) Not include the use of paralytics without anesthesia"

Appendix B

Additional Information: This page may be used to include additional or overflow information from sections where the form fields space is limited.