

Presentation at the Third Plenary
Meeting of the Advisory Committee on
Acoustic Impacts on Marine Mammals
27-29 July 2004
San Francisco, California

***This presentation is the sole product of
the author(s) and does not reflect the
view of the Marine Mammal Commission
or the Advisory Committee on Acoustic
Impacts on Marine Mammals.***

Steps to complete before beginning research

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Marine Mammal Research Requirements

- Submit Marine Mammal Permit Application (usually 50 pages)
Reviewed by Marine Mammal Commission and other agencies plus public comment following announcement in federal register
- Wait – normally at least 6 months, at least 8 months for endangered or threatened species
- Write protocol for Institutional Animal Care and Utilization Committee (IACUC) (example: www.hawaii.edu/ansc/IACUC/ for process details at University of Hawaii)

Both Laboratory and Field Studies. IACUCs are required by APHIS and NIH/PHS. All Universities receiving federal funds **MUST HAVE** PHS/Office of Laboratory Animal Welfare Assurance Statement. Assurance withdrawal stops federal funding to University.

- Obtain IACUC Approval
- Annually renew IACUC Approval including progress report
- Be Inspected by IACUC twice a year
- Be Inspected by APHIS at least once per year (random, unannounced)
- Write an annual report on the activities of the Marine Mammal Permit

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Project Protocol Number

**UNIVERSITY OF HAWAII – INSTITUTIONAL ANIMAL CARE & USE COMMITTEE
2004 – VERTEBRATE ANIMAL USE PROTOCOL FORM**

PLEASE READ CAREFULLY: The applicant is responsible for providing complete and accurate information. The completion of this form is required by Federal Law through the Animal Welfare Act (USDA) and by the Public Health Service Policy (NIH). All sections must be addressed. Use a different font type for your answers. Some blanks may accept a limited amount of text, use additional pages if necessary. Check the appropriate boxes. If a section does not apply to your study, indicate, “does not apply” to avoid leaving a blank. **Handwritten protocols will be returned to the applicant without IACUC review.** Submit the **TYPED** original and 19 photocopies of the completed protocol form to this address: **Animal Care and Use Committee, c/o Compliance Office, 2538 The Mall, Snyder Hall Room 410, Honolulu, HI 96822. Phone: 808-956-4552 Fax: 808-956-5785 Alternate Fax: 808-956-4448**

The University of Hawaii Institutional Animal Care and Use Committee fully abides and is compliant with institutional and committee policies regarding matters of Confidentiality and Conflicts of Interest.

I. ADMINISTRATIVE DATA:

Principal Investigator/Instructor: _____ Position Title: _____

Contact Person (and phone no.) if not PI: _____

Institutional Affiliation: _____ Department: _____

Building: _____ Room Number: _____

Phone Number: _____ E-mail: _____ FAX Number: _____

Project Title: _____

Project Type: Please check the appropriate category for your work.

<input type="checkbox"/> New	<input type="checkbox"/> Pilot Study	<input type="checkbox"/> Revision (Major)	<input type="checkbox"/> Renewal (Full Project Review at 3 Year Intervals)
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Animal Project Category: Research Teaching/Training Herd/Flock/Breeding Management

Application Contains: Confidential Information Proprietary Information

Project Starting Date: _____ Total Project Period: from _____ to _____

Project Funding Information:

Project funded:	<input type="checkbox"/> No	<input type="checkbox"/> Private Sector	<input type="checkbox"/> Dept/College	<input type="checkbox"/> UH Research Council	<input type="checkbox"/> Extramural
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Name of source or funding agency: _____

Peer Reviewed: No Yes

Proposal submitted to Office of Research Services (ORS): No Yes, date submitted?: _____

The applicant may be required to submit a copy of the grant application to the compliance office when the protocol is submitted to the IACUC for review.

II. PERSONNEL QUALIFICATIONS: List each person and answer the questions for each individual.
The PI should be listed as one of the project personnel.

- (1) Personnel Name: _____ Position Title: _____
- Describe the animals handling skills required for this study:
- Will surgery be performed by the person? No Yes
- Will physical methods of euthanasia be performed by this person? No Yes
- List the qualifications and experience of the person for the preceding procedures listed. If the person is not yet qualified, describe how you will provide training. The applicant is responsible for providing written documentation to the IACUC when personnel are qualified to perform the procedures listed.
- Has this person completed the *Review of the Regulations for Care and Use of Vertebrate Animals in Research, Training, and Testing*? No Yes If yes, when:

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- (2) Personnel Name: _____ Position Title: _____
 - Describe the animals handling skills required for this study:
 - Will surgery be performed by the person? No Yes
 - Will physical methods of euthanasia be performed by this person? No Yes
 - List the qualifications and experience of the person for the preceding procedures listed. If the person is not yet qualified, describe how you will provide training. The applicant is responsible for providing written documentation to the IACUC when personnel are qualified to perform the procedures listed.
 - Has this person completed the *Review of the Regulations for Care and Use of Vertebrate Animals in Research, Training, and Testing*? No Yes If yes, when:

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- (3) Personnel Name: _____ Position Title: _____
 - Describe the animals handling skills required for this study:
 - Will surgery be performed by the person? No Yes
 - Will physical methods of euthanasia be performed by this person? No Yes
 - List the qualifications and experience of the person for the preceding procedures listed. If the person is not yet qualified, describe how you will provide training. The applicant is responsible for providing written documentation to the IACUC when personnel are qualified to perform the procedures listed.
 - Has this person completed the *Review of the Regulations for Care and Use of Vertebrate Animals in Research, Training, and Testing*? No Yes If yes, when:

III. PROJECT OBJECTIVES:

- Provide a **non-technical explanation** of the purpose of animal use in layman language.

- Full renewals (every 3 year intervals) only. Progress report. Include the number of animal subjects used and whether the previous years of work have met the project objectives as stated in the original submission.

IV. ANIMAL REQUIREMENTS AND NUMBER OF ANIMALS REQUIRED:

- Complete the table.

Animal Information	Year 1	Year 2	Year 3
Species:			
Stock/Strain:			
Sex/Age/Weight:			
Source(s):			
Animal Holding Location:			
Transgenic – Yes or No:			
Special Husbandry Needs – Yes or No:			
Animal Procedure Site:			
Pain or Distress Category: # of Animals			
#Herd/Flock/Breeding			
#USDA Category C			
#USDA Category D			
#USDA Category E			
Total Number of Animals:			
Species:			
Stock/Strain:			
Sex/Age/Weight:			
Source(s):			
Animal Holding Location:			
Transgenic – Yes or No:			
Special Husbandry Needs – Yes or No:			
Animal Procedure Site:			
Pain or Distress Category: # of Animals			
#Herd/Flock/Breeding			
#USDA Category C			
#USDA Category D			
#USDA Category E			
Total Number of Animals:			

VII. DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES:

A. Research and Teaching/Training Projects No Yes If yes, complete the following:

- Describe the experiment design, the methods and procedures used on the animals.

• Injections or inoculations: No Yes If yes, complete table below:

Injections or Inoculations	Dosage/Volume	Injection Site	Route of Administration	Administration Schedule

• Blood withdrawals: No Yes If yes, complete table below:

Sampling Methodology	Volume	Withdrawal Sites	Frequency

• Radiation administration: No Yes If yes, complete the table below:

Isotope	Dosage/Volume	Anatomical Site	Route of Administration	Administration Schedule

• Use of Restraint: No Yes If yes, describe the following.

- Method:
- Restraint Device:
- Duration of restraint

• Describe Animal Identification Methods:

• Non-survival Surgery Procedures: No Yes If yes, describe the procedures.

• Other Procedures: No Yes If yes, describe the procedures.

B. Herd/Flock/Breeding Projects No Yes If yes, provide the following.

- Describe the procedures performed on the animals. Attach copies of the relevant portions of your Standard Operating Procedures (SOPs) for the committee to review.

- Will there be procedures that involve more than slight or momentary pain.
No Yes If yes, describe.

VIII. SURVIVAL SURGERY:

Survival surgery procedures. No Yes If yes, complete this section.

- Describe the surgical procedures:
 - Pre-

 - Intra-operative

 - Post-

- How will asepsis be maintained?

- Where will the surgery be performed? Building: Room:

- Is this a dedicated surgical facility? No Yes

- Will anesthesia monitoring and other surgical records be kept? No Yes

- Who is responsible for monitoring anesthesia?

- Who is responsible for the care of the animal post-operative?

- Will analgesics be administered? Yes No If no, justify:

- Has major survival surgery been performed on any animal prior to being placed on this protocol?
No Yes If yes, explain:

- Will more than one major survival surgery be performed on an animal?
No Yes If yes, justify:

- If you are planning on performing surgery on animals, have you provided written documentation that all personnel involved with the surgical procedures are qualified to perform their responsibilities?
Yes No If no, explain:

IX. ANESTHESIA, ANALGESIA, TRANQUILIZATION AND SEDATIVES:

- Anesthesia, Analgesia, Tranquilizers, Sedatives No Yes If yes, complete table:

Name of Agent	Dosage	Route of Administration	Administration Schedule

- Monitoring methods(s):

- Person(s) Responsible for monitoring:

X. METHOD OF EUTHANASIA OR DISPOSITION OF ANIMALS AT END OF STUDY:

- Euthanasia – Describe method. You are required to provide a method even though you do not intend to euthanize any animals after the study or activity.

- Chemical Agent No Yes If yes, complete the table below:

Name of Agent or Drug	Dosage/Volume	Route of Administration

- Physical Method No Yes If yes, what is the method and justify the use:

- Carbon Dioxide No Yes If yes, you must work with LAS personnel unless justified and approved by the IACUC to work independently.

- Adoption:
- Return to natural habitat:
- Other Describe:

- What is the method of carcass disposal if animals are euthanized?:

XI. HAZARDOUS MATERIALS:

- Be advised that if any of the categories are checked yes, a copy of this protocol will be forwarded to the UH Environmental Health and Safety Office for an independent review.

Hazardous Materials Used? No Yes If yes, complete the following:

Categories:

Radioisotopes or Radiation Producing Devices	No	Yes
Biological Commodities	No	Yes
Recombinant Materials	No	Yes
Chemicals (Provide copies of Material Safety Data Sheets(s))	No	Yes
Drugs (Including Controlled Substances) (If yes, provide package insert or equivalent)	No	Yes
Zoonotic Disease Exposure (Potential or Real)	No	Yes

Describe other Materials or Devices which may cause safety, health, or environmental concerns:
(e.g. high pressure, lasers, high electromagnetic fields, air or water pollution)

XII. VETERINARY CARE:

- Who have you made arrangements with to provide veterinary care?

UH Veterinarian(s) Provide date contacted and response:

Local or Contract Veterinarian(s) Provide (attach written documentation from the contract veterinarian(s) of the terms of acceptance of responsibilities for this project)

Veterinary care is not required/inaccessible. Provide written justification:

XIII. OTHER IACUCs:

- Other IACUCs reviewing this application? No Yes If yes, provide the following:
 - Institution or agency:
 - Name of contact person:
 - Address:
 - Telephone/Fax Number/e-mail address(es)

XIV. ENDANGERED SPECIES AND SPECIAL PERMITS:

- Are the animals being used in this activity endangered species? Yes No
- Special domestic or foreign government permits required? Yes No
- If yes, to any of the above, provide a copy of the permits for this activity.

XV. ASSURANCE STATEMENTS:**A. Acknowledgment of Compliance with Federal, State, Local Rules and Regulations; Ethical Conduct with Professional Society Guidelines; and UH Institutional Policies**

- I have read the pertinent sections, understand, and will conduct research or teaching activities in accordance to the rules, regulations, and guidelines of the following that apply to my work.
 Yes No
- Check all the boxes that apply to your field.

US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training
Public Health Service Policy

USDA APHIS Animal Welfare Act

Marine Mammal Protection Act

Endangered Species Act

Guide for the Care and Use of Laboratory Animals

Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching

Guidelines for the Use of Wild Birds in Research

Guidelines for the Use of Fishes in Field Research

Guidelines for the Use of Amphibians and Reptiles

Acceptable Field Methods of Mammalogy

2000 American Veterinary Medical Association – Report of the AVMA Panel on Euthanasia

Other federal, state, local rules and regulations and guidelines that apply to the species and funding

Provide listing:

B. UH Vertebrate Animal Facility Occupational Health and Safety Program Manual

- I have read and understand, and will abide by the *UH Vertebrate Animal Facility Occupational Health and Safety Program Manual* or have developed a similar document specific for my activities.
 Yes No

C. Statements for Accuracy and Responsibility for Implementation of the Animal Use Protocol.

(1) RESEARCH and/or HERD/FLOCK BREEDING activities that support research:

I certify that there is demonstrable evidence that this research will contribute to the future well being of humans and animals, that any discomfort or injury will be limited to that which is unavoidable, and that anesthetics, analgesics and tranquilizing drugs will be used whenever indicated and appropriate to minimize discomfort to the animals. I am aware of current research in my field. The proposed experiments do not unnecessarily duplicate earlier efforts. Painless alternatives to this work either do not exist or would not accomplish my research goals. I further certify that these statements are true and the protocol stands as the original OR is essentially the same as found in the grant application or program/project. The IACUC will be notified in writing immediately of any changes in the proposed project, or personnel, relative to this application prior to proceeding with any animal experimentation. I will not proceed with animal experimentation until approval by the IACUC is granted.

(2) TEACHING/TRAINING and/or HERD/FLOCK/BREEDING activities that support teaching/training:

I certify that the animal demonstrations and labs are an essential part of a well balanced curriculum. The use of animals has been carefully considered. I have considered the use of alternatives to the proposed procedures which cause more than momentary pain or distress to the animals. The minimum number of animals required to provide the quality of instruction necessary will be used in this course. I certify that the information in this application is essentially the same as contained in the course outline and a copy of the laboratory exercises using animals is on file at the Compliance Office.

Signature: Principal Investigator/Instructor

Date

As a reminder, have you...

- checked that all sections that pertain to your work have been completed, checked-off appropriate boxes, justified and provided detailed answers, and
- signed and dated the form.

Don't forget...

- to renew your protocol on a yearly basis, if your work takes longer than 1 year to complete.
- to inform the IACUC in writing and get approval when you make changes or revisions to the application.

Thank you for your time and cooperation in completing this form.

**INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE
FUNDING AGENCY INFORMATION**

PLEASE COMPLETE THIS PAGE ONLY IF YOUR PROJECT IS BEING FUNDED.

PRINCIPAL INVESTIGATOR:

SPONSOR OR FUNDING AGENCY:

AGENCY CONTACT PERSON:

AGENCY MAILING ADDRESS:

AGENCY TELEPHONE NUMBER:

AGENCY FAX NUMBER:

IS THE TITLE OF THE GRANT APPLICATION PROPOSAL THE SAME AS YOUR UH IACUC PROTOCOL
TITLE?: YES NO

IF NO, WHAT IS THE TITLE OF YOUR GRANT APPLICATION?:

GRANT PROPOSAL # IDENTIFIER:

YOUR SIGNATURE

DATE

Compliance Office Use Only
Project Protocol Number