

DO NOT SUBMIT THIS SET OF INSTRUCTIONS WITH THE COMPLETED FORM

**UNIVERSITY OF HAWAII -- INSTITUTIONAL ANIMAL CARE & USE COMMITTEE
2006 – PROTOCOL FORM INSTRUCTIONS**

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 blank. **Handwritten protocols will be returned to the applicant without IACUC review. Double-sided photocopies are encouraged.** 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. Ph: 808- 956-4552. FAX: 808-956-5785 or 808-956-4448**

I. Administrative Data. Self explanatory – complete all that apply.

II. Personnel Qualifications.

- List all personnel on your project by name and position title who will be involved with animal use. Indicate duties, qualifications (specific course work, training, degrees, etc), and any other training related received in animal handling care procedures.
- If physical methods of euthanasia such as cervical dislocation, decapitation, thoracic compression or gunshot are being used in your protocol, document the personnel qualifications of the personnel performing these procedures.
- If surgical procedures are being used in your protocol, document the personnel qualifications of the personnel performing the procedures.
- If the personnel are not trained in any of the procedures listed in your protocol, describe how you will provide appropriate training. When the new personnel are adequately trained for the procedures, **provide written documentation to the IACUC.**
- Mandatory: All personnel on this protocol are required to review and complete the training modules on the ***Regulations for the Care and Use of Vertebrate Animals*** by visiting the web address:

<http://www.hawaii.edu/LAS>

- The web administrator will acknowledge successful completion of the review of regulations. Completion must be documented prior to the start of the animal work on this protocol.

III. Project Objectives.

Indicate the type of project by checking the appropriate box. Provide a **non-technical** explanation for the purpose of animal use in layman's language. Layman's language is defined as language understood by an individual with at least a 12th grade education. Failure to use layman's language may result in rejection of the protocol.

- **Research** – the abstract from your grant application may be attached. Do not attach the entire grant application.
 - **Teaching/Training** – explain the scope and purpose of the class or laboratory, and why animals will be necessary. Provide a course manual or syllabus with the completed protocol.
 - **Herd/Flock/Breeding** – explain the intent for maintaining the animal colony. List the protocol identification numbers of the research and/or teaching/training projects that this application provides animals for.
- Full renewals (every 3 year intervals) only. Provide a brief progress report with regard to achieving specifications and project objectives as stated in the original submission.

IV. **Animal Requirements and Number of Animals Required.**

- List species (**include common name if scientific names are used**), strain, age, weight, sex, source of animals, animal holding and procedure location (if different from holding location), and proposed numbers of animals to be used. Be sure to check the appropriate pain or distress category(ies) and indicate the number of animals in each. Sum(s) should equal total number of animals requested. **[NOTE: USDA Category C = minimal, transient, or no pain or distress; USDA Category D = pain or distress relieved by appropriate measures such as anesthetics, analgesics, and/or tranquilizers (complete Section VII.); USDA Category E = Unrelieved pain or distress. If animals are indicated in category E, a scientific justification is required to explain why the use of anesthetics, analgesics, sedatives or tranquilizers during and/or following painful or distressful procedures is contraindicated].** If your project uses more than two species of animals please photocopy this page and provide the information on the other species.

V. **Electronic Database Searches (Federal Assurances – Policies 11 and 12)**

A. **Federal assurance for the Project is not Unnecessarily Duplicated.**

- All animal use categories (C,D,E), except for herd/flock/breeding protocols are required to address this section. Federal law (9 CFR 2.31d) requires that you provide written assurance that the animal activities do not unnecessarily duplicate previous experiments, and that you have considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals. If you indicate yes, this project duplicates previous activities, provide an adequate justification to explain the necessity for duplication.

B. **Assurance that Alternatives to Painful and Distressful Procedures have been considered.**

- Complete this section for animals categorized in D and E. Federal Law, USDA Policy #12 requires, *“The minimal written narrative should include: the databases searched or other sources consulted, the date of the search and the years covered by the search, and the key words and/or search strategy used by the PI when considering alternatives or descriptions of other methods and sources used to determine that no alternatives were available to painful or distressful procedures. The narrative should be such that the IACUC can readily assess whether the search topics were appropriate and whether the search was sufficiently thorough.*

Reduction, replacement, refinement (the three R's) must be addressed, not just replacement."

- Reference: AWIC, <http://www.aphis.usda.gov/ac/policy12.html>

VI. Rationale for Use of Animals.

- Information requirements of the Animal Welfare Act (9 CFR 2.31 d) requires that the PI documents that the three R's have been considered in the design of the project – Reduction, Refinement, and Replacement.
 - **Replacement** – defined to mean, the substitution of live animals with non-animals. Consideration of replacement can be demonstrated by searching for isolated cell and nerve preparations; use of tissues from the grocer or animal processing plant; use of mannequins; computer simulations based on in vivo data; use of endoparasites; use of invertebrate animals, microorganisms, or plants; computer automated structure evaluation systems; and human tissue cultures.
 - **Refinement** – defined to mean, the use of techniques to reduce pain and distress. Consideration of refinement can be demonstrated by: having knowledge of species physiology and normal and abnormal behavior; proper use of anesthetics and analgesics; modifications in restraint, handling, blood collection; increased sensitivity of monitoring devices and chemical assays; and proper personnel training.
 - **Reduction** – defined to mean, minimize the number of animals used. Consideration of reduction can be demonstrated by; performing a quality literature search; use of appropriate statistical design, use of pilot studies, sharing animals, tissues or organs, use of new methods in testing.

VII. Description of Experimental Design and Animal Procedures.

A. Research, Training/Teaching, and Management Activities

- Explain the project design (pre-, experimental, and post – procedures). Specify all animal procedures performed. Provide a complete and accurate description which will allow the committee to understand the course of an animal from its entry into the project to the endpoint of the activity. For complex activities, flow charts are highly recommended.
- **Paralytic Agents.** If you use a paralytic agent in your experiments or surgical procedures you are required to provide scientific justification for its use.

B. Herd/Flock/Breeding Activities

- Provide a description of the procedures performed on the animals. Are the animals subjected to any procedures that are likely to cause more than slight, momentary pain or distress: (special agricultural practices like castration, dehorning, tail docking, break or toe trimming, forced molting, electro-ejaculation, branding, toe-clipping, or ear notching). Attach copies of the relevant portions of your Standard Operating Procedures (SOPs) for the committee to review.

VIII. Survival Surgery. Self explanatory – complete all that apply.

- **Review of Regulations for Rodent Surgery and Anesthesia** – Refer to the reference in the webCT if using rodents for surgical procedures.

IX. Anesthesia, Analgesia, Tranquilization, and Sedatives.

- For animals indicated in Section IV, USDA Category D, specify the anesthetics, analgesics, tranquilizers, or sedatives that are to be used. Complete the table for use of these agents by providing the name of the agent(s), the dosage, route, frequency of administration, monitoring methods and information on person(s) responsible. Note, you must keep adequate records of anesthesia monitoring while the animal is under anesthesia or tranquilized. Anesthetized and tranquilized animals should be monitored until they are able to right themselves and able to sustain themselves in their environment.

X. Methods of Euthanasia or Disposition of Animals at End of Activity.

- Euthanasia is the primary means for the disposition of animals at the end of a study; however, in some special cases, animals may be put up for adoption. To determine if adoption is applicable for this protocol, refer to the criteria for adoption as described in IACUC Policy 2.0. The IACUC in consultation with the University veterinarian(s) reserves the right to make the final decision if adoption is applicable.

- **Requirement**

- An acceptable method of euthanasia must be provided by the applicant even if the animals are not planned to be sacrificed after the research, teaching/training, or herd/flock/breeding activities. Note that even if you do not intend to euthanize the animals, you should provide a method that you would use in the event of unanticipated injury or illness. For acceptable euthanasia methods refer to the **2000 American Veterinary Medical Association – Report of the AVMA Panel on Euthanasia (internet address below)**. If the method of euthanasia is not referenced in this Report, provide a reference or journal article along with scientific justification that supports the use of the proposed method. <http://www.avma.org>

- **Chemical Euthanasia**

- If a chemical agent is used, specify the dosage and route of administration.

- **Personnel Performing Euthanasia**

- All personnel that euthanize animals must be properly trained to administer the method of euthanasia proposed in this application. If they are not trained, explain how you will accomplish euthanasia by the method proposed. **Provide written documentation to the IACUC when personnel are adequately trained.**

- **Method of Carcass Disposal**

- You must list the means of carcass disposal.

XI. Hazardous Agents.

- The use of hazardous agents requires the review and approval of the UH Environmental Health & Safety Office. Contact: <http://www.hawaii.edu/ehso/>. Hazardous agents include materials which are used directly on animals and/or expose the animal care and research personnel to the agents.

XII. Veterinary Care.

- In case of injury to the animal or problems that occur where the animal(s) may unexpectedly not respond normally, it is the investigator's responsibility to contact the attending veterinarian for emergency care or euthanasia. List the names and contact numbers for the attending veterinarians providing animal care.
- **Supporting documentation is required for local or contract veterinarians** – Provide (attach to protocol) written documentation from the local or contract veterinarian of the terms of acceptance of responsibilities for this project.

XIII. Other IACUCs.

- If this application is being reviewed by other IACUCs, the UH committee may require that you provide documentation of approval from the other committee or review board.

XIV. Endangered, Threatened, and Protected Species and Special Permits.

- If this application involves the handling of endangered, threatened, or protected species, the committee will require that you provide documentation of government collection and importation permits.
- Special permits may include but are not limited to: 1) the use and proficiency of firearms and 2) training and declaration of proficiency for a specific procedure or methodology.

XV. Assurance Statements.

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

- The PI is responsible for reading the pertinent sections that apply to his/her field, understanding, and abiding by all applicable federal, state, and local rules and regulations, and ethical conduct with professional society guidelines, and UH institutional policies pertaining to the use of vertebrate animals for research, training or testing, including, but not limited to, the *US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*, *Public Health Service Policy*, and *USDA Animal Welfare Act*.

B. UH Vertebrate Facility Occupational Health and Safety Program Manual

- The PI is responsible for reading, understanding, and enforcing the principles found in the *UH Vertebrate Animal Facility Occupational Health and Safety Program* manual for his/her faculty, staff, and students. The manual can be reviewed and downloaded by visiting

<http://www.hawaii.edu/LAS>

Alternatively, the PI may develop a similar document for his/her specific activities.

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

- The signature of PI is required to acknowledge compliance with accuracy and responsibility of the proposed animal use activity.