***Puget Sound IACUC Protocol No.***

***(Office Use Only)***

# ANIMAL USE PROTOCOL

**University of Puget Sound**

**Institutional Animal Care and Use Committee**

**(Cover Sheet)**

**This protocol form is required for use of live vertebrate animals as specified in the *NIH Guide for the Care and Use of Laboratory Animals* (**[**http://www.nap.edu/catalog.php?record\_id=12910#toc**](http://www.nap.edu/catalog.php?record_id=12910#toc)**) “*The Guide*”). Beginning June 1, 2021, approval is also required for use of cephalopods in research.**

**Submission:**

* **Protocols must be word-processed, not hand-written, and include digital versions of all investigators’ signatures.**
* **A complete protocol includes this filled out form (with digital signatures), which includes a narrative, reference list, and CITI course completion certificate(s).**
* **Submit the complete protocol as a single PDF or Microsoft Word document by email to Erin Colbert-White, chair of the IACUC, at** **ecolbertwhite@pugetsound.edu****. Incomplete protocols or protocols in any other format will be returned without review.**
* **The review process can take between 10 business days and one month.**

**Protocol Description (*Please check one box in each row*):**

 **Initial Submission Renewal Amendment**

 **Course Use Research Use Both**

 **Laboratory Study Field Study Both**

#### Project Title:

**Date of Submission: (*Allow at least 2 weeks for protocol review.)***

## Principal Investigator: Department/Program:

##  Telephone Number: E-mail:

 Emergency contact number:

 Signature:

***Faculty Advisor’s Statement* (student projects only): I, , am the advisor of**

 **. My signature below indicates that I have read the attached protocol, have checked the contents with the *Guide*, and have provided appropriate training for the student.**

**Faculty Advisor Signature:**

**List the names of all individuals authorized to conduct procedures involving animals under this protocol:**

**All personnel affiliated with this protocol have completed a *Medical History and Risk Assessment Questionnaire for Persons Handling or Working with Live Vertebrate Animals.***

x

**All personnel affiliated with this protocol have completed the necessary CITI training modules. The completion certificates are included at the end of this protocol.**

x

**Funding Source:**

**Effective Period of Investigation:**

**PLEASE CHECK ONE OF THE FOLLOWING:**

 **Study involves no significant pain or distress to animals greater than that from routine injection or venipuncture.**

x

 **Study involves the use of appropriate anesthesia, analgesic, or tranquilizer to avoid significant pain or distress.**

x

 **Study involves significant pain or distress without administration of appropriate anesthetic, analgesic, or tranquilizer.**

#### Part I: NARRATIVE DESCRIPTION OF THE PROJECT

Provide a brief overview of the research, testing, or teaching project *written in language understandable to non-scientists*. State the overall objectives of the research and its relevance to human or animal health, advancement of knowledge, and/or the good of society. Briefly explain the experimental design and describe all animal procedures. This description should allow the IACUC to understand the experimental course of an animal from its entry into the experiment to the endpoint of the study. A flowchart may be an effective presentation of the planned procedure(s). State the anticipated risks associated with this study.

Include the following specific information, if applicable:

* **Animal identification methods** [e.g., ear tags, tattoos, collar, cage card, implant].
* **Methods of restraint**  Describe how animals are restrained, including for routine procedures like blood withdrawals. Prolonged restraint must be justified with appropriate oversight to ensure it is minimally distressing to the animal. Describe any sedation, acclimation or training to be used.
* **Experimental injections or inoculations** Describe substances to be injected, dose, sites of injection, volume, route, and schedule.
* **Blood withdrawals** Include volume withdrawn, frequency, withdrawal site, and methodology.
* **Radiation**  Include dosage and schedule as well as confirmation of approval from the Radiation Safety Officer (RSO).
* **Food or fluid restriction** If food, or fluid, or both food and fluid, will be restricted, describe method for assessing the health and wellbeing of the animals. The amount of food and/or fluid earned during testing and amount freely given must be recorded and assessed to assure proper nutrition. If you are seeking a departure from the recommendations of the *Guide*, provide a scientific justification.
* **Pharmaceutical-grade and Non-pharmaceutical-grade Compounds** Identify any drugs, biologics, or reagents that will be administered to animals. If these agents are not human or veterinary pharmaceutical-grade substances, provide a scientific justification for their use and describe methods that will be used to ensure appropriate preparation and administration.
* **Other procedures** Describe any procedures not covered by the above categories (e.g., survival rate procedures, tail biopsies).
* **Resultant effects**, if any, that the animals are expected to experience [e.g., pain or distress, ascites production, recovery from surgery].
* **Other potential stressors** [e.g., noxious stimuli, environmental stress] **and procedures to monitor and minimize distress**.
* **Experimental endpoint criteria** [e.g., tumor size, percentage body weight gain or loss, inability to eat or drink, behavioral abnormalities, clinical symptomatology, signs of toxicity] must be specified when the administration of tumor cells, biologics, infectious agents, radiation or toxic chemicals are expected to cause significant symptomatology or are potentially lethal. List the criteria that will be used to determine when euthanasia is to be performed. Death as an endpoint must be scientifically justified.
* **Veterinary care** Indicate the plan of action in case of animal illness[e.g., initiate treatment, call investigator prior to initiating treatment, euthanize].
* **Surgical procedures** [provide details of survival and non-survival surgical procedures in Part II, Section G.].

**Part II: PROTOCOL STATEMENT**

***NOTE:* Your protocol is being approved for the procedures and techniques described in this protocol statement. Any changes in protocol (e.g., increase in animal number, increase in pain and/or distress) must be approved by the IACUC before they are implemented.**

**A. List the species, number and source of animals to be used. *Include animals needed for personnel training.* Give both scientific and common names.**

**Animal Number Source**

**1.**

**2.**

**3.**

**(add lines as needed)**

1. **Rationale for Animal Use**
2. Explain your rationale for animal use. The rationale should include reasons why it is necessary to use animal models.
3. Justify the appropriateness of the species selected.
4. Justify the number of animals to be used. The number of animals should be the minimum number required to obtain statistically valid results. Include justification for group size through a power analysis when possible, considering the expected variance, mean difference, and degree of reliability.

##### Animal Housing/Study Location(s)

**1. Laboratory Study**

 **(a) Primary housing location(s):**

 **(b) Will animals be individually\_\_\_\_\_\_\_ or group\_\_\_\_\_\_\_\_ housed?**

 **(c) Describe the caging used for housing, etc.**

**(d) Describe any special requirements for housing (i.e., diet, handling above routine care). Attach additional pages if necessary.**

**(e) Where will the experiments be conducted?** List all rooms where animal experimentation will be conducted and describe what will be done in each room. Attach additional pages if necessary.

**2. Field Study:** Where will the study be conducted? Attach additional pages if necessary.

1. **Transportation**

Transportation of animals must conform to all institutional guidelines/policies and federal regulations. If animals will be transported on public roads or out of state, describe methods you will use to comply with federal regulations. If animals will be transported between facilities, describe the methods and containers that will be used. If animals will be transported within a facility, include the route and elevator(s) that will be used.

**E. Present evidence that this work does not duplicate work already done in this field.** Please list all applicable databases searched to determine that the proposed experiments are not unnecessarily duplicative. The IACUC requires that at least two databases be searched. If the project *does* involve duplication, please justify the duplication.

##### Will this study cause significant pain or distress to animals?

 **Yes \*\_\_\_\_\_\_\_ No \_\_\_\_\_\_ (If *no*, proceed to Section G.)**

##### \*If *yes*, will anesthetic, analgesic, or tranquilizing drugs used on animals to relieve pain and distress?

 **Yes \_\_\_\_\_\_\_ (If yes, proceed to F.1) No \_\_\_\_\_\_ (If no, proceed to F.2)**

1. **If *yes*:**
2. List the drugs and dosages used.

(B) How did you evaluate the appropriateness of these drugs and dosages (i.e., current literature, consultation with veterinarian, etc.)?

**2. If *no*:**

**(A)** Describe the justification for *not* using drugs to relieve pain and distress.

(B) Describe your consideration of alternatives and your determination that alternatives are not available.

##### G. Surgical Procedures

**Will this study involve surgical procedures?**

 **Yes \_\_\_\_\_\_\_\_ No \_\_\_\_\_\_\_\_ (If *no*, proceed to Section H.)**

 **If *yes*, complete the following:**

1. Identify and describe the surgical procedure(s) to be performed. Include preoperative procedures *[e.g., fasting, analgesic loading]*, and monitoring and supportive care during surgery. Include the aseptic methods to be used.
2. Identify the individual(s) that will perform surgery and their qualifications, training, and/or experience.
3. Identify the location where surgery will be performed *[building(s) and room(s)],*
4. If survival surgery, describe postoperative care that will be provided and frequency of observation. Identify the responsible individual(s) and location(s) where care will be provided *[building(s) and room(s)].* Include detection and management of postoperative complications during work hours, after hours, weekends and holidays.
5. If non-survival surgery, describe how euthanasia will be provided and how death will be determined.
6. Are paralytic agents used during surgery? If yes, please describe how ventilation will be maintained and how pain will be assessed.
	1. Will more than one survival surgery be performed on an animal while on this study?

 If yes, please justify.

H. Field Studies

If animals in the wild will be used, describe how they will be observed and/or captured, any interactions with the animals, whether the animals will be disturbed or affected, and any special procedures anticipated. Indicate if federal, state, and/or local permits are required and whether they have been obtained.

##### I. Disposition of Animals at the End of the Study

**Animals used in this study will be (check all that apply):**

 Euthanized           Returned to animal holding       Adopted\_\_\_\_\_ Other

Please describe your plan for the disposition of all animals in your study. If more than one method of disposition applies, please check all applicable boxes and include in your description which method will be used for which animals and why. The IACUC encourages PIs to consider whether adoption is a viable option for disposition.

* If “Euthanized” is checked, include in your description: a) the proposed method of euthanasia, and b) the method of carcass disposal. If a chemical agent is used, specify the dosage range and route of administration. If the method of euthanasia is **not** consistent with the AVMA 2013 Guidelines for the Euthanasia of Animals, provide scientific justification as to why such a method must be used.
* If “Returned to animal holding” is checked, include in your description a) the location of animal holding, b) the duration of holding, and c) who will be responsible for care of the animals.
* If “Adoption” is checked, include in your description a) an acknowledgement of your agreement to abide by the IACUC Animal Adoption Policy, including the requirement to schedule a consultation with the IACUC consulting veterinarian prior to initiating adoptions, and b) your disposition plan for animals that are not successfully adopted. Any animals that are eligible for adoption but are not adopted must have an approved disposition, whether euthanasia, return to animal holding, or other.

##### If “Other” is checked, briefly describe the planned fate of all animals used for the project. If an alternative disposition of the animals is planned, you must attach any necessary approval documentation from the appropriate agencies.

**J. Training**

Present evidence of experience and/or training of personnel conducting the procedures on the proposed animal model. *Include both investigators and students.*

**K. Risk Assessment**

Identify any risks or concerns for investigator safety that may result from the proposed animal use and discuss measures that will be taken to minimize risk to the investigator (and/or students).

Investigators conducting field studies should describe any relevant zoonotic diseases and/or safety issues applicable in the study area.

#### Special Concerns or Requirements of the Study

List any special housing, equipment, animal care or any departures from the *Guide* *[e.g., special caging, water, feed, waste disposal, environmental enrichment]*.

1. **Literature Cited within this Protocol**

Include a complete reference list

#### Principal Investigator Certifications

By signing this protocol, the Principle Investigator accepts the following certifications.

1. I certify that I have had appropriate training to undertake this study.
2. I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research.
3. I certify that all individuals working on this project understand the institution's Occupational Health and Safety Plan for Animal Care and Use.
4. I certify that all individuals working on this study are authorized to conduct procedures involving animals under this protocol, have received training in: the biology, handling, and care of the species used; aseptic surgical methods and techniques (if necessary); the concept, availability, and use of research or testing methods that limit the use of animals or minimize distress; the proper use of anesthetics, analgesics, and tranquilizers (if necessary); and procedures for reporting animal welfare concerns.
5. I certify that I have found no valid alternative to any procedures described herein which may cause more than momentary pain or distress, whether it is relieved or not.
6. I certify that I will obtain approval from the IACUC before initiating any significant changes in this study.
7. I certify that I will notify the IACUC regarding any unexpected study results that impact the animals. Any unanticipated pain or distress, morbidity or mortality will be reported to the IACUC.
8. I certify that I am familiar with and will comply with all pertinent institutional, state, and federal rules and policies.
9. I certify that all individuals working on this study have completed a *Medical History and Risk Assessment Questionnaire for Persons Handling or Working with Live Vertebrate Animals.*

**O. CITI course(s) Completion Certificate(s)**

Include at the end of the protocol the necessary CITI course Completion Certificates for all persons involved with this protocol.