**BUMED Animal Use Appendix for Research Involving Animals**

**FULL VERSION**

**\*\*\*NOTE: BUMED will ONLY review protocols that have been approved by your IACUC.\*\*\***

**\*\*Animal work MAY NOT be initiated until the awardee receives BUMED approval.\*\***

**\*Animal work initiated without BUMED approval is noncompliant and may not be funded.\***

Institutions using DoD funds to support the use of animals in research, product development, testing and education projects must provide electronic copies of the following documents to the Department of the Navy (DON) Bureau of Medicine and Surgery (BUMED) Veterinary Affairs Office for review and approval prior to initiation:

1. A copy of their **IACUC-approved institutional protocol(s)** (BUMED will ONLY review **approved** protocols) and documentation of IACUC approval
2. A copy of all existing IACUC-approved protocol amendments or modifications and documentation of IACUC approval (**future modifications or amendments** must be reviewed and approved by BUMED **PRIOR** to implementation)
3. A completed Appendix for each IACUC-approved protocol.

This requirement also applies to all subcontractors using animals in support of DoD-funded projects or programs.

Specific information requested in the following animal use Appendix is derived from requirements in the Animal Welfare Regulations (AWRs), the *Guide for the Care and Use of Laboratory Animals*, and other applicable Federal and DoD regulations. The DoD policies and requirements for the use of animals in DoD-supported research, development, testing and evaluation are described in DoD Instruction 3216.01, dated September 13, 2010 and SECNAVINST 3900.38C, *The Care and Use of Laboratory Animals in DOD Programs*, dated February 16, 2005. These requirements differ from those of other funding agencies. Use of the Appendix is intended to meet the requirements of these documents.

Questions concerning animal use and review should be directed to BUMED Veterinary Affairs:

Phone: 301-619-9241 or 301-619-9224

Email: DON – VRPP, [usn.ncr.bumedfchva.mbx.don---vrpp@mail.mil](mailto:usn.ncr.bumedfchva.mbx.don---vrpp@mail.mil)

Mail: Department of the Navy Bureau of Medicine and Surgery

ATTN: Director for Veterinary Affairs

Bldg 1564 Room 122

1564 Freedman Drive

Fort Detrick, MD 21702

**~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~**

**Each section of this Appendix must be completed**. To assist you in completing this appendix, instructions and explanations are provided as *hidden,* *red and italicized text*. To view the instructions and/or examples for each section, select the “**Show/Hide ¶**” button on your tool bar (the button itself appears as the **¶** symbol). To print the hidden text, select “Print Hidden Text” in the print options section. It is important that you carefully **read the instructions** for each paragraph to ensure you provide a comprehensive response. Begin typing responses after the colon (“:”) for each section to ensure your typing is not within the hidden text. Submit electronic copies of the appendix only; please do not submit printed copies to BUMED. Any section of the Appendix that is not applicable to your proposal, e.g., no surgery or no prolonged restraint, should be marked “**No**” or “**N/A**”. There are no space limitations for the responses.

It is essential that only animal studies or procedures documented in an IACUC–approved protocol or amendment be performed at your facility. BUMED will collect animal usage information for end-of-year DoD animal use reports separate from the grant annual progress reporting requirement throughout the life of your award. For this reason, Principal Investigators or other delegated research personnel should keep accurate records and be able to provide an audit trail of all animal use that correlates to their approved protocol.

**Before completing this Appendix, please ensure you can view the red, *italicized* hidden text that provides specific instructions for sections of this document.**

**Refer to the cover page for directions on viewing the hidden text in this document.**

**When completing this Appendix, INCLUDE ONLY animals, experiments and procedures that are funded by this Grant/Contract**

**1. Administrative Data:** (Provide Attending Vet, IACUC, and Research Office info for the research site.)

|  |  |  |  |
| --- | --- | --- | --- |
| **DoD Grant/Contract PI Name:** |  | | |
| **Grant/Contract PI Email:** |  | **Phone:** |  |
| **Animal Research Site (RS):** |  | | |
| **Protocol PI Name:** |  | | |
| **Protocol PI Email:** |  | **Phone:** |  |
| **RS Attending Veterinarian:** |  | | |
| **RS Attending Vet Email:** |  | **Phone:** |  |
| **RS IACUC Office Point of Contact (POC):** |  | | |
| **RS IACUC POC Email:** |  | **Phone:** |  |
| **RS Grants Office POC:** |  | | |
| **RS Grants Office POC Email:** |  | **Phone:** |  |
| **Animal Protocol Title:** |  | | |
| **Brief Objective Summary:**  *Provide a few sentences, written in lay language, that briefly describes the objective of your proposal.* | | | |

**2. Rationale for Using Animals:**

***DOD policy requires that alternatives to the use of animals be thoroughly investigated prior to submission of any proposal involving animals.*** *Provide scientific justification for the proposed use of animals in this study. List all non-animal alternatives that were considered (e.g., computer modeling, cell cultures or other in vitro methods, etc.), and explain why these alternatives cannot be used to meet the research objectives (i.e., why animals are needed).*

**3. Species Identification and Rationale:**

**a. Species:**

**b. Stock/Strain/Breed/Etc.:**

**c. Animal Model Rationale**:

*Provide scientific justification for selecting this particular animal model -- what unique physiologic, morphologic or genetic characteristics does this specific animal strain or breed possess that makes it the best possible model? Discuss species, sex, strain or stock, previous use in this type of research, etc. If less sentient animal models were considered (e.g., invertebrate vs. vertebrate, mice vs. rabbits, pigs vs. nonhuman primates, etc.) but not chosen, explain why. Include similar justification for all species used.*

**4. Experimental Design:**

*Provide an explanation of experimental design that will allow reviewers of this document to be able to understand and follow the progress of animals through the proposed procedures. Succinctly describe the formal scientific plan and direction of experimentation. If several experiments or sequential studies are included in the protocol, describe the experimental design of each separate experiment in sub-parts to this section. Technical methodology need not be described in this section; describe it under the appropriate subparagraph for section 5. Specific Procedures/Technical Methods.*

*Provide a complete description of the proposed use of animals. A flow chart illustrating the experimental design and a summary table of the experimental groups may help to describe this study.* ***A clearly understandable description of the numbers of animals and their distribution into experimental groups is essential.*** *Reviewers must be able to clearly understand your animal calculations. The total numbers described in this section must match the total animal numbers described in paragraph 6. Basis for Animal Numbers/Total Numbers/USDA Pain Category.*

**5. Specific Procedures / Technical Methods:** In the subparagraphs listed below, provide a complete description of all procedures the animals will experience. Procedures not specifically addressed in subparagraphs a. through m. below should be described under Other Procedures (subparagraph n).

**a. Animal Observations and Health Status Assessment Criteria:**

*Describe frequency of animal observations once experimental procedures start and describe health status assessment criteria used.*

**b. Anesthesia/Analgesia/Tranquilization and /or Non-pharmaceutical Methods of Relieving Pain or Distress:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes |  | No | Anesthetics/Analgesics/Tranquilizers will be used to relieve pain or distress. |
|  | Yes |  | No | Non-pharmaceutical methods will be used to relieve pain or distress. |
|  | | | | |
| If “Yes” to either of the above, | | | | |

**i. Describe methods or strategies planned to effectively relieve pain and/or distress:**

*Describe the methods or strategies planned to effectively relieve pain and distress (e.g., acclimation to novel restraint device, net rescue during forced swim test, routine handling to calm animals before beginning procedures, use of anesthetics and analgesics during surgeries, etc.). If drugs are used for anesthesia, analgesia or tranquilization, list the drug name, dosage, frequency, duration, and route of injection.*

**ii. Intra-procedural Observations: list the observational or monitoring criteria used to assess depth of anesthesia while the procedure is being performed and/or to determine if animals are experiencing pain or distress and require additional anesthetics, analgesics, tranquilizers or non-pharmaceutical pain relief:**

Signs used to monitor for evidence of pain or distress should be specific to the species of animal and painful or distressful procedure(s) being performed.

**c. Anesthesia/Analgesia/Tranquilization for Chemical Restraint:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes |  | No | Anesthetics/Analgesics/Tranquilizers will be used for chemical restraint. |
|  | | | | |
| If “Yes,” | | | | |

**i. Describe methods or strategies planned for chemical restraint (i.e., if a procedure would not otherwise cause more than slight or momentary pain or distress, but the anesthetic is used to facilitate administration by holding the animal still):**

*Describe the methods or strategies planned for chemical restraint. List the drug name, dosage, frequency, and route of administration for drugs used in chemical restraint.*

**ii. Intra-procedural Observations: list the observational or monitoring criteria used to assess depth of anesthesia while the procedure is being performed:**

Signs used to monitor should be specific to the species of animal and procedure(s) performed.

**d. Paralytic Agents (Note: the use of paralytic agents without anesthesia is prohibited)**:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes |  | No | Paralytic agents will be used during this protocol. |
|  | | | | |
| If “Yes,” describe the following: | | | | |

**i. Rationale for using paralytic agents:**

**ii. Paralytic Agent Protocol (e.g., drug, dose, frequency of injection, etc.):**

*Describe the paralytic agent protocol. List the drug name, dosage, frequency, and route of administration.*

**iii. Monitoring methods to ensure adequate depth of anesthesia while animal is under influence of paralytic agents:**

*Describe in detail any instrumentation and monitoring methods used to ensure animals are adequately anesthetized while under the influence of paralytics. Include monitoring frequency.*

**e. Surgery**:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes |  | No | Surgical procedures are performed on live animals during this protocol. |
|  | | | | |
| If “Yes,” describe the following: | | | | |

**i. Pre-operative Considerations and Animal Preparation:**

*Describe animal preparation and the aseptic or sterile technique used for survival surgeries.*

**ii. Surgical Procedures:**

*Describe in detail any surgical procedures planned. Each procedure must be described separately and in sufficient detail that someone with appropriate surgical training could repeat it with minimal variation.*

**iii. Immediate and Long-Term Post-operative Monitoring/Observations/Treatment:**

*Describe immediate (during anesthetic recovery), intermediate (1-3 days post-operative) and long-term post-operative monitoring and observations performed to ensure that any post-op complications or animal pain/distress are identified and treated. Monitoring frequency should be consistent with the expected duration of analgesic activity. Signs of pain/distress should be specific to the animal species and procedures performed. Include any early removal criteria for post-op animals.*

**f. Multiple Major Survival Surgeries (performed on the same animal)**:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes |  | No | Multiple major survival surgeries will be performed on the same animal. |
|  | | | | |
| If “Yes,” provide a scientifically valid justification: | | | | |

**g. Biosamples**:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes |  | No | Biosamples are collected from animals during this protocol. |
|  | | | | |
| If “Yes,” state the frequency, volume, harvest site, and collection method for each sample type (samples collected after euthanasia need not be described here but should be mentioned in section 4. Experimental Design above): | | | | |

**h. Adjuvants**:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes |  | No | Adjuvants are used in animals during this protocol. |
|  | | | | |
| If “Yes,” list any adjuvants used and the plan for their use: | | | | |

*List any adjuvants used and the plan for their use. Specify frequency and method of injection site monitoring and describe your response plan (for example, alternative endpoint and veterinary medical treatment) in the event of an adverse reaction.*

**i. Genotyping/DNA Analysis**:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes |  | No | Genotyping/DNA analysis will be performed on animals during this protocol. |
|  | | | | |
| If “Yes,” describe any methods used for genotyping or other DNA analysis: | | | | |

*Describe any methods used for genotyping or other DNA analysis (age of animals at sampling, amount and type of tissue obtained for sampling, and anesthetic use as described in paragraph #5.b. above).*

**j. Injections**:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes |  | No | Substances will be administered to animals by injection during this protocol. |
|  | | | | |
| If “Yes,” at a minimum, describe the agent, dose, and route of administration for each type of injection and each compound/substance injected (injectable anesthetic or analgesic use should be described in 5.b. above and need not be repeated here): | | | | |

**k. Other Test Article or Therapeutic Agent Administration**:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes |  | No | Test articles, therapeutic agents, special diets or other compounds will be administered to animals by a route other than injection. |
|  | | | | |
| If “Yes,” at a minimum, describe the agent or drug, dose, route and/or method of administration, frequency of administration, and duration of administration for each test article, therapeutic agent or other compound administered: | | | | |

**l. Prolonged Restraint**:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes |  | No | Animals will undergo prolonged restraint (as defined by institutional IACUC policies or the Animal Welfare Act regulations) during this protocol. |
|  | | | | |
| If “Yes,” justify and describe restraint and duration in detail: | | | | |

*Justify and describe in detail any prolonged restraint (as defined by institutional IACUC policy or the AWA regulations) intended for use during the study, e.g., primate chairs, restraint boards, metabolism cages, etc. The description must specify the method of restraint, the period of restraint, and the timing of animal observations. Also describe the planned procedures for habituation or training of animals to the device prior to the prolonged restraint. This section is not intended for short-term actions such as rodent restraint for bleeding, etc.*

**m. Behavioral Studies or Behavioral Modification Techniques:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes |  | No | Animals will be involved in behavioral studies or undergo behavioral modification during this protocol. |
|  | | | | |
| If “Yes,” describe any behavioral studies or modification planned for this protocol. Include details on the use of aversive stimuli and food and/or water regulation and/or restriction; describe other behavioral studies or methods of behavioral modification; describe the outcome or behavioral measures assessed and criteria used to evaluate the animal’s performance; describe methods used to monitor physiological or behavioral indices, including criteria (e.g., % weight loss, hydration status, etc.) for temporary or permanent removal from the study: | | | | |

**n. Other Procedures (e.g., electrocardiograms, radiology or other imaging procedures, tissue perfusions, stress induction, etc.):**

*Describe all other procedures that will be performed while conducting this research but have not been explained in other subparagraphs of this section.*

**6. Rationale for Number of Animals Required/Animal Numbers/USDA Pain or Distress Category:**

**a. Statistical/Other Basis for Number of Animals Used:**

*Describe the methodology used to determine group size and total number of animals. If a power-based assessment of the sample size is used, state the minimum animal numbers that are likely to yield significant results with given alpha and beta errors, estimated effect size and expected variability. If applicable, state the appropriate CFR or federally-mandated testing reference which requires specific group sizes and total number of animals to be used in an experiment or test.*

**b. Total Number of Animals Used (by Species) and USDA Pain/Distress Category** *List the total number of animals, by species, used in this proposal. Include animals necessary for controls, technique development, expected losses, etc. This number must correlate to the number of animals, number of groups, etc., described in the Experimental Design section above. Identify the highest USDA Pain/Distress Category for animals using the definitions below the table.***:**

|  |  |  |
| --- | --- | --- |
| **SPECIES** | **HIGHEST USDA**  **PAIN/DISTRESS CATEGORY (B, C, D, E\*) See table below for definitions** | **TOTAL NUMBER** |
|  |  |  |
|  |  |  |
|  |  |  |

**USDA Pain/Distress Category Definitions:**

* ***Column B:*** *Animals being bred, and animals being held for use in research, testing, teaching, experiments or surgery but not yet used for those purposes. This would include breeders (unless surgery, genotyping, or some other manipulation was involved) and ALL offspring produced on this protocol that were NOT subjected to any manipulations such as genotyping and NOT used for experimental purposes.*
* ***Column C:*** *List the number of animals that will experience no more than slight or momentary pain or distress as a result of experimental manipulations or procedures on this protocol. Examples of procedures or manipulations that would require an animal to be placed in Column C are those involving not more than slight or momentary pain or distress in a human being to which that procedure is applied, such as injections or other minor procedures.*
* ***Column D:*** *List the number of animals that will potentially experience more than momentary or slight pain or distress that* ***WILL*** *be alleviated through the use of anesthetics and/or analgesics. General anesthetics given for surgical procedures or the use of analgesics or anti-inflammatory agents to relieve pain or distress are examples of this category.*
* ***Column E:*** *List the number of animals that will experience more than momentary or slight pain or distress that* ***WILL******NOT*** *be alleviated or relieved with anesthetics or analgesics.*  **If any animals are listed in USDA Column E (Unalleviated Pain or Distress), the PI must provide a scientifically valid justification for withholding pain relieving medication:***. Examples include research procedures or manipulations in which alleviation of pain or distress are contraindicated for a scientifically justifiable reason such as the experimental results are likely to be confounded if drugs relieving pain or distress were administered.*

**c. Column E only- If any animals are listed in USDA Column E (Unalleviated Pain or Distress), the PI must provide a scientifically valid justification for withholding pain relieving medication:**

**7. Columns D or E only- Consideration of Alternatives to Painful Procedures.** *The USDA defines a painful procedure as “any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure was applied..."* If there are no animals listed in USDA Column D or E, mark this section “N/A.” If **any animals are listed in USDA Column D or E**, the PI must perform this literature search. **You MUST provide a narrative summary of the results of the literature search for alternatives to painful procedures.** The Animal Welfare Act regulations specifically state that the P.I. must provide a narrative description of the methods and sources that he/she used to determine that alternatives to the painful or distressful procedure(s), including those in which pain or distress is alleviated, were not available: **DOD regulations require this for all animals undergoing painful procedures including those not covered by the Animal Welfare Act.**

**8. Study Endpoint:**

*State the projected study endpoint for each animal, animal group, or experiment (e.g., survival until the specified time point and then euthanasia, recovery, death without early euthanasia). Define specific, and when possible, objective criteria that will be used to determine early study endpoints or early removal criteria (for example, percentage of weight loss, tumor size, number of abdominal taps, abdominal distension, loss of locomotion, significant lowering of body temperature, decreased food or water consumption, decreased activity, etc.).*

*Specifically address and scientifically justify any proposal in which critically ill or moribund animals are allowed to die as a result of the experimental procedures without the benefits of veterinary medical treatment or early euthanasia.*

**9. Euthanasia:**

*Describe the method(s) of euthanasia for all animals on this study. Provide scientific justification in all cases if cervical dislocation or decapitation will be performed* ***WITHOUT*** *accompanying anesthesia.*

**10. Literature Search for Unnecessary Duplication:** This search is required for all animal use proposals. Note the DoD-specific database requirements in subparagraph a.

**a. Indicate Literature Source(s) Searched:**

*List the databases searched for unnecessary duplication. A search of EITHER the Federal Research in Progress (FEDRIP) database (*<http://www.ntis.gov/products/fedrip.aspx>*) OR the Research Portfolio Online Reporting Tool Expenditures and Results (RePORTER) (*<http://projectreporter.nih.gov/reporter.cfm>*) database is required*

|  |  |  |  |
| --- | --- | --- | --- |
|  | | | |
| **AT LEAST 1 OF THE FOLLOWING REQUIRED:** | | | |
|  | Federal Research in Progress (FEDRIP) -OR-  <http://www.ntis.gov/products/fedrip.aspx> |  | Research Portfolio Online Reporting Tool Expenditures and Results (RePORTER) <http://projectreporter.nih.gov/reporter.cfm> |
|  | | | |

**b. Date of Search:**

*List the date(s) you or your institution performed the literature search.*

**c. Years Covered by Search:**

*List the time period(s) covered by the searches (e.g, 1962-present, all yrs searchable, etc).*

**d. Key Words and/or Search Strategy Used:**

*List key words used to perform searches. Keywords used should describe the research proposed)*

**e. Results of Search:**

*Provide a narrative description of the results of the literature search(es). Include a brief summary of the articles identified during your literature search, and briefly describe how these projects are or are not related to your proposed animal work, how your work is different, unique, not unnecessarily duplicative, etc.*

**11. Qualifications:**

*List by name all personnel working with animals under this proposal and all procedures, manipulations and observations each individual will perform. Provide each individual’s* ***specific*** *training, experience, and qualifications to perform these particular duties (e.g., surgery, euthanasia, pre- and post-operative care, injections, phlebotomy, restraint). Training citations should include all institutional courses, PI instruction, hands-on training, etc., provided to comply with the Animal Welfare Act Regulations, CFR 9, paragraph 2.32.*

**STUDY PERSONNEL QUALIFICATIONS/TRAINING**

|  |  |  |  |
| --- | --- | --- | --- |
| Protocol activity or procedure (e.g., tail vein injections, euthanasia) | Name of person performing activity | Qualifications or experience of person performing activity in the proposed species (e.g., research technician; 2 yrs experience with intracranial surgical procedure; performed IP injections on 100s of mice ) | **Specific** training in this activity or procedure (e.g., rodent handling class; trained to do surgical procedure by PI; aseptic surgical techniques training; rabbit intubation) |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**\*\*\*\*Questions 12-18 refer to the Research Site and Protocol PI.\*\*\*\***

Information and/or documents required in questions 12-16 should be obtained from the research site’s IACUC or veterinary staff. Documents may be provided directly to BUMED by the Protocol Principal Investigator (PI) or institution staffs. If the Protocol PI prefers that BUMED staff contact the institution to obtain this information and/or documents, the PI must specifically request this action in writing. The Protocol PI should contact BUMED (see contact information on cover page) to arrange for submission of this written request.

**12. Institutional Animal Care and Use Committee(s) (IACUC) Approval(s):**

***Submit official documentation of current IACUC protocol review and approval*** *from the facility where the animal research will be performed--****to include any subcontracted facilities*** *if applicable. Documentation of IACUC review and approval* ***MUST accompany*** *proposal submission; BUMED* ***WILL NOT*** *review any protocols that do not already have local IACUC approval.*

|  |  |  |  |
| --- | --- | --- | --- |
| Institutional Animal Use Protocol Number: | |  | |
|  | | | |
| IACUC (initial) approval date: |  | Protocol expiration (rewrite) date: |  |

**13. Veterinary Care Plan:** Provide a brief description of the veterinary care plan at the research site. Describe routine care; weekend, holiday, and emergency care; and identify whether the attending veterinarian is on staff full-time or by contract.

**14. Institutional Accreditation / Assurances:**

*If applicable, provide the following information for* ***each*** *facility where the animal research will be conducted. Place an “X” in the appropriate box. The animal facility’s IACUC office or attending veterinarian can assist with this information.*

**a. Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) Accreditation** (do **NOT** provide AAALAC correspondence)**:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| |  | | --- | |  | | Yes | |  | | --- | |  | | No | Animal work is being performed at an AAALAC International-accredited facility. |

**b. Public Health Service Animal Welfare Assurance Statement**:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| |  | | --- | |  | | Yes | |  | | --- | |  | | No | Animal work is being performed at a PHS-assured facility. |

**c. Non-accredited, Unassured Facilities**: If neither 14.a. nor 14.b. above apply to the facility where animal work is being performed, submit a statement signed by the Institutional Official that states the care and use of animals will be conducted in accordance with the National Research Council’s *Guide for the Care and Use of Laboratory Animals* and applicable Federal and DoD regulations.

**15. Animal Procurement:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| |  | | --- | |  | | Yes | |  | | --- | |  | | No | If the protocol involves Animal Welfare Act-regulated species, are the animals obtained legally from suppliers licensed by the USDA? If the supplier claims exemption from USDA licensing, provide confirmation from the research site’s IACUC that the exemption criteria have been met. If work is conducted outside the US, have animals been obtained legally in accordance with national policy? If wildlife are used, provide IACUC assurance that animals have been obtained legally and provide copies of applicable state and federal capture and use permits. |

**16. Overseas / Foreign Country Animal Work**:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| |  | | --- | |  | | Yes | |  | | --- | |  | | No | Animal work will be performed outside the United States. |

|  |
| --- |
| If “Yes,” answer the following questions.   1. What is the law or regulation governing the use of animals in research in the research site’s host country? Please provide a copy or link to this law or regulation in English. 2. Does the research site’s host country adhere to European Union (EU) Directive 86/609 or EU Directive 2010/63 standards of animal housing and care? 3. If the research site is in Canada, does the institution hold a Canadian Council on Animal Care (CCAC) certificate? 4. Does the research site adhere to any national or international standards of animal housing and care that are more stringent than the host country’s laws or regulations (such as AAALAC or CCAC)? If so, please describe below or provide a document, in English, that describes these standards. 5. Does the research site’s host country or local institute require a local ethical committee review or Animal Care and Use Committee review? If so, please describe below or provide a document, in English, describing the committee’s membership, purpose, authority and function. |

**17. Site Visits**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Yes |  | No | Does animal work involve at least one of the following species: dogs, cats, nonhuman primates, marine mammals? If yes, provide a planned start date for work in these species and point of contact for site visit coordination. Based on accreditation status, species used, and type of research conducted, a site visit to the performance site may be required. |

**18. Protocol Principal Investigator Assurances:**

The law specifically requires several written assurances from the P.I. Please read and sign the assurances as indicated (this page may be photocopied and signed).

As the Principal Investigator on this protocol, I acknowledge my responsibilities and provide assurances for the following:

A. Painful Procedures: I assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research and that analgesic, anesthetic, and/or tranquilizing drugs will be used where indicated and appropriate to minimize pain and/or distress to animals.

B. Animal Use: The animals authorized for use in this protocol will be used only in the activities and in the manner described herein, unless a modification is specifically approved by the IACUC and the DoD Department of the Navy **Bureau of Medicine and Surgery** (BUMED) Veterinary Affairs Office prior to its implementation.

C. Duplication of Effort: I have made a reasonable, good faith effort to ensure that this protocol is not an unnecessary duplication of previous experiments.

D. Statistical Assurance: I assure that I have consulted with a qualified individual who evaluated the experimental design with respect to the statistical analysis, and that the minimum number of animals needed for scientific validity will be used.

E. Training: I verify that the personnel performing the animal procedures/manipulations/ observations described in this protocol are technically competent and have been properly trained to ensure that no unnecessary pain or distress will be caused to the animals as a result of the procedures/manipulations.

F. Responsibility: I acknowledge the inherent moral, ethical and administrative obligations associated with the performance of this animal use protocol, and I assure that all individuals associated with this project will demonstrate a concern for the health, comfort, welfare, and well-being of the research animals. Additionally, I pledge to implement animal use alternatives where feasible, and conduct humane and lawful research.

G. Scientific Review: This proposed animal use protocol has received appropriate peer scientific review, and is consistent with good scientific research practice.

|  |  |  |
| --- | --- | --- |
|  |  |  |

(Protocol Principal Investigator Printed Name) (Protocol Principal Investigator Signature and Date)

**NOTE:** In accordance with SECNAVINST 3900.38C, the DON BUMED Veterinary Affairs Officer (or designee thereof) will conduct a site visit to all sites using nonhuman primates, dogs, cats or marine mammals in the proposal, or where a site visit is deemed warranted.