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

**Abbreviated 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

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**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.

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| --- | --- | --- | --- | --- |
|  | Yes |  | No | All animal studies described in the attached IACUC-approved protocol are funded by this DOD award/contract. If no, **MCj03710820000[1]**! You must use the **full version** of the Animal Use Appendix. |

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

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| --- | --- | --- | --- |
| **DoD/Contract PI Name:** |  | | |
| **Grant/Contract PI Email:** |  | **Phone:** |  |
| **Protocol PI Name:** |  | | |
| **Protocol PI Email:** |  | **Phone:** |  |
| **Animal Research Site (RS):** |  | | |
| **RS Attending Veterinarian:** |  | | |
| **Attending Vet Email:** |  | **Phone:** |  |
| **RS IACUC Point of Contact (POC):** |  | | |
| **IACUC POC Email:** |  | **Phone:** |  |
| **RS Grants Office Point of Contact (POC):** |  | | |
| **Grants Office POC Email:** |  | **Phone:** |  |
| **Animal Protocol Title:** |  | | |
|  | | | |

**2. 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.***:**

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

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

**a. 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*

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Federal Research in Progress (FEDRIP) <http://www.ntis.gov/products/fedrip.aspx>

or

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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:**

*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.*

**\*\*\*\*Questions 4-10 refer to the Research Site and Protocol Principal Investigator.\*\*\*\***

Information and/or documents required in questions 4-8 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.

**4. 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.*

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

**5. Veterinary Care:** 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.

**6. 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)**:**

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

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

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

**c. Non-accredited, Unassured Facilities**: If neither 6.a. nor 6.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.

**7. Animal Procurement:**

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| --- | --- | --- | --- | --- | --- | --- |
| |  | | --- | |  | | 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, federal and/or international capture and use permits. |

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

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

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| 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. |

**9. Site Visits**

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| --- | --- | --- | --- | --- |
|  | 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. |

**10. 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.

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(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.