

AF/SGE-C Animal Use Appendix for Research Involving Animals
ABBREVIATED VERSION

*****NOTE: SGE-C will ONLY review protocols that have been approved by your IACUC.*****
******Animal work MAY NOT be initiated until the awardee receives SGE-C approval.******
******Animal work initiated before receipt of SGE-C approval will not be funded.******

DoD-funded institutions using animals in U.S. Air Force sponsored research, product development, testing and education projects must provide electronic copies of the following documents to their DoD program manager for Air Force Surgeon General, Office of Research Oversight and Compliance (AF/SGE-C) review and approval:

- a. a copy of their **IACUC-approved protocol(s)** (SGE-C will ONLY review **approved** protocols)
- b. a copy of all IACUC-approved protocol amendments or modifications
(**major** changes must be reviewed and approved by SGE-C **PRIOR** to implementation)
- c. a copy of this completed Appendix and associated documents for each IACUC-approved protocol.

This requirement also applies to all subcontractors using animals in support of U.S. Air Force sponsored DoD-funded projects or programs.

The DoD policies and requirements for the use of animals in DoD-funded research, development, testing and evaluation are described in DoD Instruction 3216.01, dated 13 Sept 2010 and Air Force Manual 40-401, *The Care and Use of Laboratory Animals in DOD Programs*, dated February 16, 2005. These requirements may differ from those of other funding agencies. 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 regulations and DoD directives. Use of the Appendix is intended to meet the requirements of these documents.

Questions concerning animal use and review should be directed to AF/SGE-C:

Phone: 703-681-8160
Fax: 703-681-8050
Email: Robin.L.Burke8.mil@mail.mil
Mail: Office of Research Oversight and Compliance
Office of the Air Force Surgeon General
ATTN: LTC Robin L. Burke
7700 Arlington Blvd Ste 5151
Rm# 3NW408A
Falls Church, VA 22042-5151

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**Each section of this Appendix must be completed.** Begin typing responses after the colon (":") for each section to ensure your typing is not within the hidden text. It is important that you carefully **read the instructions** for each paragraph to ensure you provide a comprehensive response. The additional instructions and written explanations provided for individual paragraphs are **red, italicized**, and coded as hidden 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" on the drop down file menu. Under the "Options" button, select "Hidden text" under the "Include with document" section. Please do not submit copies with the hidden text printed out to SGE-C.

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 to the protocol be performed at your facility. Additionally, 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. SGE-C will collect this information for end-of-year DoD animal use reports.

Yes

No

All animal studies described in the attached IACUC-approved protocol are funded by this DOD award/contract. If no,  ! 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.)

**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 :**

| 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.*
- **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.*
- **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.*

- **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: . .**

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

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

<http://brd.dtic.mil><http://www.ntis.gov/products/fedrip.aspx><http://projectreporter.nih.gov/reporter.cfm>

Biomedical Research Database (REQUIRED) <http://brd.dtic.mil/>

AND one of the following

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

or

Research Portfolio Online Reporting Tool Expenditures and Results (RePORTER)  
<http://projectreporter.nih.gov/reporter.cfm>

**b. Date of Search:**

**c. Years Covered By Search:**

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

**e. Results of Search:**

**\*\*\*\*Questions 4-9 refer to the Research Site and Protocol Principal Investigator.\*\*\*\***

Information and/or documents required in questions 5-8 should be obtained from the research site's IACUC or veterinary staff. Documents may be provided directly to SGE-C by the Protocol Principal Investigator or institution staffs. If the Protocol PI prefers that SGE-C staff contact the institution to obtain this information and/or documents, the PI must specifically request this action in writing. The Protocol PI should send this written request via email to [krinon.d.moccia.mil@mail.mil](mailto:krinon.d.moccia.mil@mail.mil).

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

Institutional Animal Use Protocol Number: \_\_\_\_\_

IACUC approval date: \_\_\_\_\_ Protocol expiration 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:**

**a. Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) Accreditation:**

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 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 2010 *Guide for the Care and Use of Laboratory Animals* and applicable Federal and DoD regulations.

**7. 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.

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

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

If "Yes," answer the following questions.

- a. 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.
- b. 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?
- c. If the research site is in Canada, does the institution hold a Canadian Council on Animal Care (CCAC) certificate?
- d. 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.
- e. 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**

|  |     |  |    |                                                                                                                                                                                                                                                                                                                                                                    |
|--|-----|--|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | 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 U.S. Air Force Surgeon General’s Office of Research Oversight & Compliance (SGE-C) 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 AFMAN 40-401\_IP, the SGE-C (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.