

USSOCOM VRO Review of Animal Use for Research, Development, Testing, and Evaluation (RDT&E) funded by the DoD

*****VRO ONLY reviews protocols approved by the IACUC.*****

****Animal research/testing work MAY NOT be initiated prior to receipt of VRO approval. ****

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

A DoD Component Oversight Office must approve DoD-funded projects that propose to use animals for research, development, testing, and evaluation (RDT&E). The research institution must provide electronic copies of the following documents to the US Special Operations Command (USSOCOM), Veterinary Review Office (VRO) for review and approval:

- A. A read-only copy of the **Institutional Animal Care and Use Committee (IACUC)-approved animal use protocol(s)** and documentation of initial IACUC approval. - Note: If the protocol expires within the next 60 days, please wait to submit until your protocol is renewed.
- B. A read-only copy of each IACUC-approved protocol major amendment with documentation of IACUC approval (**future approval of major amendments, including change of Principal Investigator (PI)**, must be reviewed and approved by VRO **PRIOR** to implementation)
- C. Completed VRO Animal Use Request (This Document) for each IACUC-approved protocol
- D. Proof of the institution's USDA registration as a research institution, or the exemption document
- E. A copy of the research site's **most recent facility inspection report** from the USDA, or exemption document
- F. A copy of the animal supplier's USDA vendor license, or exemption document
- G. Copy of current AAALAC, International Accreditation, or DoD on-site inspection

This requirement applies to all institutions subcontracted to use animals in support of DoD-funded projects or programs.

Specific information requested in the following VRO Animal Use Request is derived from requirements in the Animal Welfare Act and Regulations (AWA/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 RDT&E are described in DoD Instruction 3216.01, *Use of Animals in DoD Programs*, updated March 20, 2019. These requirements may differ from those of other funding agencies. Use of this document is intended to meet specific DoD and USSOCOM requirements.

The above represents the **minimum** information that is required to initiate a review by the USSOCOM VRO and additional information and/or on-site compliance visits and detailed program reviews may be required. Failure to comply with subsequent information requests may result in non-approval by the USSOCOM VRO.

Direct questions concerning animal use and review to the USSOCOM VRO:

Phone: 813-826-6548

Email: socom_vet@socom.mil

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Submit electronic documents only; please do not submit printed copies to VRO.

## 1. DOD Funding of Protocol

**Fully funded by DoD:** All of the experiments described in the accompanying animal use protocol are funded by this DoD award.

**Partially funded by DoD:** This animal use protocol contains some experiments that are NOT funded by this DoD award. **VRO's review covers only those aspects of the protocol related to work funded by DoD. The copy of the protocol submitted should include highlighting of all information relevant to the DoD-funded portion of the study.**

## 2. Administrative Data:

DOD Award PI Name:

DOD Award PI Email:

Phone:

DOD Funding Source:

DOD Grant/Award/Proposal Number:

Institution Where Animal Studies are Conducted (Including Facility Address):

IACUC Protocol PI Name:

IACUC Protocol PI Email:

Phone:

IACUC Protocol Title:

IACUC Protocol Number:

IACUC Approval Date:

Attending Veterinarian Name:

Attending Veterinarian Email:

Phone:

IACUC Administrator or Chair Name:

IACUC Admin or Chair Email:

Phone:

Institutional Grants Manager Name:

Grants Manager Email:

Phone:

Facility USDA Registration Number:

USDA Registration Expiration Date:

Date of Last USDA Facility Inspection:

Date of last AAALAC, International Site Visit:

OLAW Assurance Number:

**3. Total Number of Animals Used (by Species) and USDA Pain/Distress Category**

*Note: All animals proposed for use must be accounted for in this section, including species not currently regulated by the USDA. Animals can be consolidated by species and do not need to be broken down by strain/stock or breed.*

- **Category B:** Animals being bred and animals being held for use but not yet used for such purposes.
- **Category C:** Animals that will experience no more than momentary pain or distress
- **Category D:** Animals that will potentially experience accompanying pain or distress and for which appropriate anesthetic, analgesic, or tranquilizing drugs **WILL** be used.
- **Category E:** Animals that will potentially experience accompanying pain or distress and for which appropriate anesthetic, analgesic, or tranquilizing drugs **WILL NOT** be used.

*Attach additional sheets if needed*

| SPECIES | HIGHEST USDA<br>PAIN/DISTRESS CATEGORY<br>(B, C, D, E) | TOTAL NUMBER |
|---------|--------------------------------------------------------|--------------|
|         |                                                        |              |
|         |                                                        |              |
|         |                                                        |              |

**4. Unalleviated Pain/Distress Justification** (only for Category E studies):

- a. Provide in the box below a detailed justification for any unalleviated pain or distress.
- b. The justification should provide the rationale for withholding pain relieving medication, including, as applicable:
  - i. Procedures or conditions that will result in unalleviated pain or distress
  - ii. Outcomes or parameters to be measured that can be altered by use of pain-relieving medication
  - iii. Expected effect of pain-relieving medications on those outcomes
    - Note: When applicable, justification should address commonly used pain-relieving medications (e.g., NSAIDs, opioids, local anesthetics).
    - When possible, provide references from the scientific literature or data from previous studies that demonstrate the adverse effect on specific study variables to be measured.
  - iv. Why the effects on these outcomes will compromise the validity of study results
  - v. Why you believe the confounding effects of pain-relieving medications will be more severe than the confounding effects of unrelieved pain

If this is NOT a category E study, enter "N/A."

## 5. Animal Procurement

- |     |    |                                                                                                                                                                                                                                       |
|-----|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Yes | No | Does the protocol involve Animal Welfare Act USDA-regulated species?                                                                                                                                                                  |
| Yes | No | N/A If so, 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. |
| Yes | No | Are <b>wildlife species</b> are used? If so, provide IACUC assurance that animals have been obtained legally and provide copies of all applicable capture and use permits.                                                            |
| Yes | No | Will <b>privately-owned animals</b> be used for RDT&E? If "yes" provide a copy of the <b>owner consent form</b> that will be used. The form must inform the owner that the animal will be used in DoD-funded research.                |

## 6. Institutional Accreditation/Assurances

### a. AAALAC International Accreditation

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

### b. Office of Laboratory Animal Welfare (OLAW) Animal Welfare Assurance

- |     |    |                                                             |
|-----|----|-------------------------------------------------------------|
| Yes | No | Animal work is being performed at an OLAW-assured facility. |
|-----|----|-------------------------------------------------------------|

### c. Non-accredited, Unassured Facilities.

If neither 8.a. nor 8.b. above apply to the facility where animal work is being performed, submit a statement signed by the Institutional Official stating that the care and use of animals will be conducted in accordance with the National Research Council's 2011 *Guide for the Care and Use of Laboratory Animals* and applicable Federal and DoD regulations.

## 7. IACUC Review and Approval of Animal Activities

- |     |    |                                                                                                                                                                                                                                                                                                                                       |
|-----|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Yes | No | Does the facility's IACUC have a written policy that governs procedures for animal use protocol review and approval that describe methods and circumstances for different types of review (i.e. Full Committee Review (FCR) vs. Designated Member Review (DMR))? If "yes" provide a copy of the IACUC policy governing this practice. |
|-----|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## 8. Exemptions to "The Guide" or Animal Welfare Act/Regulations Standards

- |     |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Yes | No | Do the proposed animal activities include any IACUC reviewed and approved exemptions to the standards defined in the <i>Guide for the Care and Use of Laboratory Animals</i> and/or the <i>Animal Welfare Act &amp; Regulations</i> (e.g. single housing of social animals, food & water restriction, multiple major survival surgeries, restricted enrichment, non-standard housing or husbandry practices, etc.). If not detailed in protocol, |
|-----|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

provide a summary of exemptions in the box below including scientific justification for not adhering to standards.

### 9. Continuing Review

|     |    |                                                                                                                                                                                                           |
|-----|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Yes | No | For USDA regulated species, does the IACUC conducted continuing review of animal use protocols, no less than once per year, in accordance with the Animal Welfare Act & Regulations and DoD requirements? |
|-----|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### 10. Significant Changes to Animal Activities

|     |    |                                                                                                                                                                                                                                                                                                                            |
|-----|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Yes | No | Does the IACUC have a written policy that allows for significant changes to protocols (i.e. amendments) following consultation with a veterinarian (i.e. veterinary verification and consultation (VVC)) in accordance with PHS Notice NOT-OD-14-126? If "yes" provide a copy of the IACUC policy governing this practice. |
|-----|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### 10. Program Review & Facility Inspections

|     |    |                                                                                                                                                                                                                                                                                                                                                            |
|-----|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Yes | No | Does the facility's IACUC conduct animal care & use program reviews and facility inspections at least once every 6 months; identifying and classifying deficiencies as either significant or minor, and providing a report of these inspections to the Institutional Official along with recommended corrective actions and expected dates for resolution? |
|-----|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### 11. Animal Disposition

|     |    |                                                                                                                                                                                                                                                                                    |
|-----|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Yes | No | Are animals used in the covered activities euthanized at the end of the RDT&E activity? NOTE – Humane euthanasia at the direction of a veterinarian for medical conditions or circumstances not related to covered activities should not be included when answering this question. |
|-----|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|     |    |     |                                                                                                                                                                      |
|-----|----|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Yes | No | N/A | If "yes", are euthanasia methods consistent with the current version of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals? |
|-----|----|-----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|     |    |                                                                                                                                                                                                                                              |
|-----|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Yes | No | Were non-terminal animal dispositions (e.g. adoption, retirement, inter-agency transfer) considered and will they be applied whenever possible? If not detailed in protocol, provide a summary of final animal disposition in the box below. |
|-----|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### **Animal Use Protocol Principal Investigator Assurances:**

Several written assurances from the P.I. are required, please read and sign below (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 pain and distress to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research. A veterinarian was consulted and analgesic, anesthetic, and/or tranquilizing drugs will be used where indicated and appropriate to minimize pain and/or distress to animals. Specific exceptions to this practice will be scientifically justified and approved by the IACUC.

B. Animal Use: I assure that 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. Special Operations Command Veterinary Review Office (VRO), 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, and 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 and/or 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: I assure that this proposed animal use protocol has received appropriate peer scientific review and is consistent with good scientific research practice.

H. Alternatives: I assure that alternative methods to the proposed animals use were considered and were used whenever possible to attain the objectives of this proposal if such methods produced scientifically valid and/or equivalent results.

I. Disposition: I assure that animals used in DoD funded Research, Development, Testing, and Evaluation will have non-terminal disposition (e.g. adoption, retirement, inter-agency transfer) whenever possible.

\_\_\_\_\_  
(Principal Investigator Name)

\_\_\_\_\_  
(Principal Investigator Signature)

\_\_\_\_\_  
(Date)