Form Version Date: March 12, 2015

**Annual Reviews, Modifications of Approved Protocols, and 3 year Renewals**

**Annual Reviews**

Even though you may be approved for a multiple year project, the IACUC must review each protocol on an annual basis as required by federal regulations. You will be sent a reminder two months before the anniversary of the original approval date. Updated information and any changes in the animal use protocol must be supplied on the [Continuing Review form](http://iacuc.usc.edu/hsc/dar/iacuc/forms). Approvals will be extended for another year or for a specified time period if there are no major changes in the protocol.

**Submitting a Modification (Amendment) to an Approved Protocol**

If there are any changes to the protocol during the course of the research project or upon annual renewal, an amendment should be submitted to the IACUC for approval using the Amendment form.

The following minor changes to an approved animal use and care protocol can be submitted to the IACUC in the form of an amendment:

*a) change of title
b) change of funding agency
c) addition or deletion of personnel
d) change of the animal strain
e) change or addition of minor procedures
f) increase in animal numbers with justification
g) addition of a new co-investigator
h) change of research facility
i) change in the method of euthanasia
j) change in anesthetic or drug dosage*

The following major changes generally require a submission of the entire protocol and must be reviewed by the full committee. Contact the IACUC Coordinator for instructions at 305-575-3444.

*a) change of species*

*b) change of drug classification which will be administered to animals
c) change from type A to type B or C procedures
d) addition of major procedure (i.e. survival surgical manipulation or other procedures requiring anesthesia with recovery, procedures involving hazardous or infectious agents provided the PI also shows evidence of approval from the appropriate safety committee)
e) transfer of the protocol to a new principal investigator*

*f) adding an ACORP to an existing study*

The IACUC reserves the right to request a full protocol if deemed necessary for any protocol.

**3-year Renewals**

The Public Health Service policy requires a complete review of activities every three years. To do this, a completed [ACORP](http://iacuc.usc.edu/hsc/dar/iacuc/forms) must be submitted and approved by the IACUC.

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| --- | --- | --- |
|  |  |  **For IACUC Use Only** |
| **IACUC#:**  | Date Initial IACUC approval |  | Date form received |  | Review Period |  |

 **Annual Animal Protocol Review (AAPR form)**

|  |  |
| --- | --- |
| **Principal Investigator Name:**  | **Phone No:**       |
| **Study title:**       | **Animal Procedure Location(s):**      **Contact Info**:       |

1. **RECORD OF ANIMAL USAGE *(Note: Information can be obtained from your approved ACORP(s) or amended animal information you’ve submitted to the IACUC)***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **Strain** | **Animal Use Classification- defined below*****(\*see section ‘I’ of Your Current ACORP)*** | **Total Number Requested Per Year *(\*see section ‘I’ of Your Current ACORP)*** | **Total Number Used in the Previous Year on this Protocol** |
|  |  | [ ] **A** [ ] **B** [ ] **C** [ ] **D** |  |  |
|  |  | **[ ] A [ ] B [ ] C [ ] D** |  |  |
|  |  | **[ ] A [ ] B [ ] C [ ] D** |  |  |

**[USDA] PROJECT (Pain) CATEGORIES**

|  |  |  |  |
| --- | --- | --- | --- |
| **Category B**  | **Category C**  | **Category D**  | **Category E**  |
| Animals being bred, acclimatized, or held for use in teaching, testing, experiments, research, or surgery **but not yet used** for such purposes. Non‐invasive observation only of animals in the wild.  | Animals that are subject to procedures that cause no pain or distress, or only momentary or slight pain or distress and do not require the use of pain‐relieving drugs.  | Animals subjected to potentially painful or stressful procedures for which they receive appropriate anesthetics, analgesics and/or tranquilizer drugs.  | Animals subjected to potentially painful or stressful procedures that are **not** relieved with anesthetics, analgesics and/or tranquilizer drugs. Withholding anesthesia/analgesia must be scientifically justified in writing and approved by the IACUC.  |

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1. **PROTOCOL STATUS.** Please indicate (**X**) the status of this project.

**Request Protocol Continuance**

[ ]  A. Active - project ongoing.
[ ]  B. Currently inactive - project was initiated but is presently inactive.
**[ ]** C. Inactive - project never initiated but anticipated start date is      .

**[ ]**  D. Project is Active but animal subjects are not currently being used and

 none will be used in the future. Delete animal use for the project.

**Request Protocol Termination**

[ ]  E. Inactive - project never initiated.
[ ]  F. Currently inactive - project initiated but project has not/will not be

 completed.
[ ]  G. Completed - no further activities with animals will be done.

1. **PROGRESS REPORT.** If the status of this project is 4.A. (active; project ongoing) or 4.B. (project was initiated, but is presently inactive), provide a brief update on the progress made in achieving the specific aims of the protocol. *Also, please provide an adequate justification for the use of non-pharmaceutical-grade or compounded drugs in the animal(s).*

**4. Were there any unexpected or unforeseen complications in your experimental protocol or animal usage? (For example: wrong dosage or experimental agent, or loss of funding to continue experiments).**

[ ]  Yes

[ ]  No If yes, describe:

1. **FUTURE PLANS.**

**[ ]** No changes are planned at this time and the project will continue as previously approved by the IACUC.

**[ ]** Changes are planned. Provide a full description and justification for the proposed changes. (Note: You must provide an IACUC Protocol Amendment Form if you request approval to make changes for this purpose.)

**[Please note that if the modifications are significant, you may be required to complete a new application. If you have questions or require assistance in making this determination, please contact the IACUC Office at x3444.]**

**[ ]  Other. Provide a brief explanation.**

**6. Were there significant changes made to the protocol submitted during the past year?**

 ***\*If not sure, check with Research Office Staff to print out a protocol history report.***

**[ ]  Yes, If yes, describe:**

**[ ]  No**

**7. If applicable, list staff who are transporting of animal specimens or animal pathogens to or from an off-site location.**

*Note: Staff are required the PI and staff as applicable to submit with the amendment, proof of IATA training on CITI.program.org or at the VA’s Intranet training portal “TMS”*

 [ ]  N/A

|  |  |
| --- | --- |
| **Name** | **Date of TMS Training**  |
|       |       |
|       |       |

**7. If applicable, list staff who are transporting of animal specimens or animal pathogens to or from an off-site location.**

*Note: Staff are required the PI and staff as applicable to submit with the amendment, proof of IATA training on CITI.program.org or at the VA’s Intranet training portal “TMS”*

 [ ]  N/A

|  |  |
| --- | --- |
| **Name** | **Date of TMS Training**  |
|       |       |
|       |       |

**7a. Have you added new staff members since the last approval period?:**

**[ ]** Yes If yes, please complete table.

[ ]  No

|  |  |
| --- | --- |
| **Name** | **Effective Date**  |
|       |       |
|       |       |

*Note: Any new or added personnel must be approved by the IACUC via an amendment. Please submit an amendment Go to* [*www.sfvafre.org*](http://www.sfvafre.org) *to obtain forms and instructions*.

**7b. Have you removed or plan to remove staff member(s) from this study?:**

**[ ]** Yes If yes, please complete table.

[ ]  No

|  |  |
| --- | --- |
| **Name** | **Effective Date**  |
|       |       |
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**8. List of Study Personnel** *Note: (The IACUC coordinator will verify that all personnel listed on the ACORP have met the IACUC’s local requirements). A notice will be sent to the PI and/staff if failure to meet renewed annual training was foun and individual may not work on animals until requirements are met.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of personnel listed on the study and****ACORP working on animals** | **Role in Study (PI, Co-inv. staff, etc.)** | **Did you attend the annual required workshop this year?** | **IACUC verification that yearly requirement has been met** |
|       |       |       |       |
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**9. VA Sensitive Information (VASI) Plan Acknowledgement**

**Have you submitted a VASI Plan for this study for signature by the Privacy Officer and Information Security Officer?**

**[ ]  Yes Submitted to and maintained by the Research office**

**[ ]  No If no, I have am submitting now with this** [document](file:///%5C%5CVhamiastorage%5Cresearch%5CResearch-Office%5CScience-Info%5CAnimals%5CFORMS-%20Animals%5CMVAHCS_Privacy%20and%20Data%20Security%20Plan.pdf) **to the IACUC Office. Form**

 **also may be obtained at** [www.sfvafre.org](http://www.sfvafre.org)**.**

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**10. Additional Information Section**

**Approved Species/Strain**:

**1. Total number of Animals used within the past years’ Approval period.**

 **(i.e., per species/strain per year):**

**2. How many animals were used in the following USDA categories: (per species/strain)?**

 **Category B** (Animals bred or purchased for breeding):

 **Category C** (Animals who underwent research procedures involving only

 brief or no pain/distress):

 **Category D** (Animals who underwent research procedures involving potential pain or

 distress but were relieved by appropriate anesthetics, sedatives or analgesics):

**Category E** (Animals who underwent research procedures involving pain or distress but were **Not** relieved with the use of anesthetics, analgesics, tranquilizers or by euthanasia):

**Approved Species/Strain**:

 **2b. Total number of other animals used within the past years’ Approval period.**

 **(i.e., per species/strain per year):** \_\_\_\_\_

**2. How many animals were used in the following USDA categories: (per species/strain)?**

 **Category B** (Animals bred or purchased for breeding):

 **Category C** (Animals who underwent research procedures involving only

 brief or no pain/distress):

 **Category D** (Animals who underwent research procedures involving potential pain or

distress but were relieved by appropriate anesthetics, sedatives or analgesics):

**Category E** (Animals who underwent research procedures involving pain or distress but were **Not** relieved with the use of anesthetics, analgesics, tranquilizers or by euthanasia):

1. **List all approved major and minor surgical procedures performed, number of animals per surgical procedure, and mortality. No mortality information is need for non-survival surgery.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Major/minor Surgical Procedures** | **#=s of animal used** | **\*Mortality from the procedures itself** | **Reasons for the mortality** |
|  |  |  |  |
|       |       |       |       |
|       |       |       |       |

Note: Mortality = # of animals that died due to procedure and/or procedural complications

**4. Were there any unexpected or unforeseen complications in your experimental protocol or animal usage? (For example: wrong dosage or experimental agent, or loss of funding to continue experiments).**

[ ]  Yes If yes, describe:

[ ]  No

**5. Were there significant changes made to the protocol submitted and approved by the IACUC in the past approval period?**

**[ ]** Yes, If yes, describe:

[ ]  No

[ ]  An amendment is in process.

**6. CERTIFICATION OF THE PRINCIPAL INVESTIGATOR.** Signature certifies that the Principal Investigator understands the requirements of the PHS Policy on Humane Care and Use of Laboratory Animals, applicable USDA regulations and the Institution's policies governing the use of vertebrate animals for research, testing, teaching or demonstration purposes. Signature further certifies that the investigator will continue to conduct the project in full compliance with the aforementioned requirements.

*I am aware that all research projects using animals must receive prior approval by the Animal Studies Subcommittee, that any change in animal use requires prior approval by the Subcommittee, that continuation of approval requires annual review, that animal use in projects not reviewed and approved must be discontinued, and that a copy of all animal related matters must be retained by the Principal Investigator for three (3) years after the study has terminated. This form, together with any requested additional information, is submitted in compliance with these regulations.*

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Signature (Principal Investigator) Date

Approved/Disapproved:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

      Date

Chair\ or Co-chair, Animal Studies Subcommittee

**[ ]**