

**REQUEST FOR EXPEDITED REVIEW
STANDARD OPERATING PROCEDURES**

**Animal Studies Subcommittee
Miami VA Healthcare System
1201 Northwest 16th St. Miami, FL 33125-1693**

1. Principal Investigator (PI) completes “Request for Approval of Amendment” and attaches the currently approved ACORP. PI must submit the original plus five copies of the amendment with revised ACORP(s) and/or appendices, if applicable, to the Research Office. A blank copy of the “Request for Approval of Amendment” form can be downloaded from www.varesearchfoundation.org or www.sfvare.org or from the Research Office.
2. Copies of the amendment are forwarded for initial review to the:
 - a. Supervisor of the Veterinarian Medical Unit
 - b. Attending Veterinarian
 - c. Chairman of the Animal Subcommittee
3. Reviewers send comments/corrections regarding the amendment to the Research Office.
4. PI will receive a memorandum, generated by Research Office staff, indicating any required changes to the amendment.
5. Amendment revisions (if any) are submitted by PI to the Research Office.
6. Revised amendment document and copies of all reviewer comments are sent to the Chair of the Animal Studies Subcommittee for confirmation that required changes have been made.
7. If the amendment is determined expeditable, and all changes made are deemed appropriate, then an initial approval letter (with attachments) will be given to the Investigator and the Supervisor of the Veterinary Medical Unit. Work described in the amendment request may now begin.
8. Amendment is scheduled for review by the Animal Studies Subcommittee at next convened meeting.

Notification of further revisions (if any) as required by the Animal Subcommittee will be given to the PI.
Required revisions are submitted by PI to Research Office.
Return to step 7 and then to step 10 if approved by Chair.
9. Amendment is reviewed by the Research and Development Committee.
If changes are required by the R&D Committee this information will be conveyed to the PI in a memorandum.

Date:

From:

Subj: Request for Expedited Review and Approval of Amendment to Approved
Animal Component of Research Protocol No. _____

To: Chairperson, Animal Studies Subcommittee

As Principal Investigator for the Research Protocol cited above, I wish to request approval by the Subcommittee, via the expedited review process available for amendments of a restricted nature, for the following changes:

1. I wish to add a **different strain/breed** from that previously approved, _____, (specify species and strain/breed previously approved), with the understanding that **all procedures to be used are unchanged** from those previously approved.
 - a. New strain/breed:

 - b. Total number of animals requested per year:
 - (1) Describe the characteristics of the selected strain that justify its use in the proposed study
 - (2) Describe how the estimated number of animals needed for the experiments was determined:

2. _____ I wish to continue to use the **same strain** previously approved (specify: _____), but to make **one or more of the following procedural changes**:
 - a. **Survival Surgery:** _____Yes _____No
If your answer is affirmative, **complete Appendix 5** from the ACORP and attach it to this memorandum. **Proceed to item 3.**

 - b. **Non-Survival Surgery:** _____Yes _____No
If your answer is affirmative, **complete Appendix 5** from the ACORP and attach it to this memorandum. **Proceed to item 3.**

 - c. **Non-Surgical Procedures. Complete all that apply and then proceed to item 3.**
_____ Perform new procedure(s) or previously approved procedures in a “**Non-VA Animal Facility**”. **Complete Appendix 1** from the ACORP and attach it to this memorandum. **Proceed to item 3.**

_____ Perform “**Antibody Production**”. Complete **Appendix 2** from the ACORP and attach to this memorandum. **Proceed to item 3.**

_____ Changes in “**Test Substances,**” including changes in dose, route or frequency. Complete **Appendix 3** from the ACORP, and attach it to this memorandum. **Proceed to item 3.**(If radioactive agent is involved obtain additional required forms from Research Office staff.)

_____ Perform “**Antemortem Specimen Collection**”. Complete **Appendix 4** from the ACORP, and attach it to this memorandum. **Proceed to item 3.**

_____ Perform “**Special Husbandry.**” Complete **Appendix 6** from the ACORP, and attach it to this memorandum. **Proceed to item 3.**

_____ **Other. Complete the following information and then proceed to item 3.**

Description of Procedure(s) to be performed on the animal (give details):

Provide the name(s) of the personnel who will perform the procedures and describe the experience and education of each person who will perform the procedure described above:

If personnel do not have experience on the described procedure, how will they be trained and by whom?:

Are any of the changes added in the amended procedures hazardous or toxic to humans or animals?

_____Yes _____No.

If you answer is affirmative, explain the nature of hazard or toxicity and attach appropriate biosafety plan:

3. _____ **The following information must be completed if any of the changes described in item 2. are requested:**

- a. Total number of animals per year to be used on new procedure(s): _____
- b. Does this require a change in number of animals from original ACORP?
 ____ Yes ____ No If yes, **complete item 6** of this form
 (“changes in number of animals”).
- c. Justification for the(se) requested change(s):

4. ____ **I wish to add the following funding source to the protocol as listed on the cover page of the Animal Protocol document.** *Note: A revised project data sheet must be submitted, which can be obtained from the Research Office.*

a. Name(s) of funding source(s):

1. _____

2. _____

3. _____

5. ____ I wish to make the following **changes in personnel** related to the handling and care of animals:

a. Name(s) of personnel to be removed from ACORP

b. Name(s) of personnel to be added to ACORP:

(1) Describe the experience(s) handling the specie(s) approved for the(se) protocol(s) and the education or experience(s) performing the procedures described in the protocol(s) for each personnel:

(2) If personnel do not have experience on the described procedure, how will they be trained and by whom?:

6. ____ I wish to add **tissue only** to the previously approved protocol. **Complete the following information:**

a. Describe the tissue(s):(give details)

b. Give name of the Source where you will obtain the tissue(s):

c. Describe the procedure to be performed on the tissue(s):

d. Describe the reasons for adding tissue(s) to the existing protocol:

Are any of the(se) tissue(s) hazardous to humans? _____Yes _____No

If you answer is affirmative, explain the nature of hazardous and attach appropriate biosafety plan:

7. ____ I wish to continue to use the **same strain** (specify: _____), **and procedures** previously approved, but to **change the age, size or number of animals** used:

- a. Change requested:
- b. Reason (if more animals will be added to the protocol, describe how you estimated the number of animals needed):

8. ____ I wish to **modify the title of the protocol** as follows:

I certify that I have discussed the change(s) described above with the Animal Research Facility Veterinary Medical Officer or Veterinary Medical Unit Supervisor and he or she concurs with the changes requested.

Signature of Principal Investigator

Name (typed)

Expedited Approval

For the Subcommittee: _____

Signature of IACUC Chair

Date

Disapproved/ Requires Full Committee Review

Action by Animal Studies Subcommittee:

Full Committee Review ____Approved ____Disapproved