ANIMAL COMPONENT OF RESEARCH PROTOCOL (ACORP) Main Body Version 4

See Instructions for Completion of the Animal Component of Research Protocol (ACORP Instructions), for help in completing specific items.

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- Full Name of Principal Investigator(s)▶
- 2. VA Station Name (City) and 3-Digit Station Number▶
- 3. Protocol Title▶
- 4. Animal Species covered by this ACORP▶
- 5. Funding Source(s). Check each source that applies:
 - ►() Department of Veterans Affairs.
 - ►() US Public Health Service (e.g. NIH).
 - ▶() Private or Charitable Foundation -- Identify the Foundation:
 - ▶() University Intramural Funds Identify the University and Funding Component:
 - ►() Private Company Identify the Company:
 - ►() Other Identify Other Source(s):
- 6. Related Documentation for IACUC reference.
 - a. If this protocol applies to a project that has already been submitted to the R&D Committee for review, identify the project:
 - (1) Title of project▶
 - (2) If approved by the R&D Committee, give the date of approval▶
 - b. Triennial review. If this protocol is being submitted for triennial *de novo* review, complete the following:
 - (1) Identify the studies described in the previously approved ACORP that have already been completed

▶

- (2) Indicate the numbers of animals of each breed/strain/genotype that have already been used, and adjust the numbers shown in Item I accordingly
 - ▶
- (3) Describe any study results that have prompted changes to the protocol, and <u>briefly summarize</u> those changes, to guide the reviewers to the details documented in other Items below.

▶

- c. List any other relevant previously approved animal use protocols (copy the lines below as needed for each protocol listed).
 - (1) Title of other protocol ▶
 - (2) IACUC approval number of other protocol ►
 Give the name of the VA station or other institution that approved it, if it was not approved by the IACUC that will review this ACORP ►
- 7. Indicate the type(s) of animal use covered by this protocol (check all that apply):
 - ►() Research
 - ►() Teaching or Training
 - ►() Testing
 - ▶() Breeding and colony management only; not for any specific research project
 - ►() Holding protocol (as specified by local requirements; not required by VA, PHS, or USDA)
 - ►() Other. Please specify ►

Proposal Overview

B. **Description of Relevance and Harm/Benefit Analysis.** Using non-technical (lay) language that a <u>senior high school student</u> would understand, briefly describe <u>how this research project is intended to</u> improve the health of people and/or other animals, or otherwise to <u>serve the good of society</u>, and <u>explain how these benefits outweigh the pain or distress</u> that may be caused in the animals that are to be used for this protocol.

- C. Experimental Design.
 - Lay Summary. Using non-technical (lay) language that a <u>senior high school student</u> would understand, summarize the <u>conceptual design</u> of the experiment in no more than one or two paragraphs.

▶

- 2. **Complete description of the proposed use of animals.** Use the following outline to detail the proposed use of animals.
 - a. **Summarize** the design of the experiment in terms of the specific groups of animals to be studied.

•

b. **Justify the group sizes and the total numbers of animals requested.** A power analysis is strongly encouraged; see ACORP instructions.

- c. **Describe each procedure** to be performed on any animal on this protocol. (Use Appendix 9 to document any of these procedures that involve "departures" from the standards in the *Guide*. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)
- D. **Species.** Justify the choice of species for this protocol.

▶

Personnel

- E. **Current qualifications and training.** (For personnel who require further training, plans for additional training will be requested in Item F.)
 - 1. <u>Pl</u>

Name▶

Animal research experience ▶

Qualifications to perform specific procedures

| Specific procedure(s) that the PI will perform personally | Experience with each procedure in the species described in this ACORP |
|---|---|
| | |
| | |

2. Other research personnel (copy the lines below for each individual)

Name▶

Animal research experience ▶

Qualifications to perform specific procedures

| Specific procedure(s) that this individual will perform | Experience with each procedure in the species described in this ACORP |
|---|---|
| | |
| | |

3. VMU animal care and veterinary support staff personnel (copy the lines below for each individual)

Name▶

Qualifications to perform specific support procedures in the animals on this protocol

| Specific support procedure(s) assigned to this individual | Qualifications for performing each support procedure in the species described in this ACORP (e.g., AALAS certification, experience, or completion of special training) |
|---|--|
| | |

4. For each of the research personnel listed in items 1 and 2 above, enter the most recent completion date for each course

| Name of Individual | Working with the VA IACUC | ORD web-based species specific course (Identify the species) | Any other training required locally (Identify the training) |
|--------------------|---------------------------------|--|---|
| | | | |
| | | | |

- F. **Training to be provided.** List here each procedure in Item E for which anyone is shown as "to be trained", and describe the training. For each procedure, describe the type of training to be provided, and give the name(s), qualifications, and training experience of the person(s) who will provide it. If no further training is required for anyone listed in Item E, enter "N/A"
- G. Occupational Health and Safety.

1. Complete one line in the table below for each of the personnel identified in Item E:

| | | Enrollment in OHSP | Declined | Current on Interactions with OHSP? (yes/no) |
|------|---------------|---|----------------------|---|
| Name | VA program | Equivalent Alternate Program – identify the program | optional services | |
| | () | () | () | |
| | () | () | () | |
| | () | () | () | |

| 2. | Are there any non-routine OHSP measures that would potentially benefit, or are otherwise required for |
|----|---|
| pe | rsonnel participating in or supporting this protocol? |

| () 100. Booonbo mon P | ▶ (|) Yes. | Describe | them | |
|------------------------|-----|--------|----------|------|--|
|------------------------|-----|--------|----------|------|--|

► () No.

Animals Requested

H. **Animals to be Used.** Complete the following table, listing the animals on separate lines according to any specific features that are required for the study (see ACORP Instructions, for guidance, including specific terminology recommended for the "Health Status" column):

| Description (include the species and any other special features not shown elsewhere in this table) | Gender | Age/Size on Receipt | Source (e.g., Name of Vendor, Collaborator, or PI of local breeding colony) | Health Status |
|--|--------|------------------------|--|---------------|
| | | | | |
| | | | | |

 Numbers of animals requested. See ACORP Instructions, for descriptions of the categories and how to itemize the groups of animals.

USDA Category B

| Procedures► | | | | | | |
|--|--------|--------|--------|--------|--------|---------------------|
| Species / Experimental Group / Procedures(s) | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Category B TOTAL |
| | | | | | | |
| | | | | | | |

USDA Category C

| Procedures► | | | | | | |
|---|--------|--------|--------|--------|--------|---------------------|
| Species / Experimental Group / Procedure(s) | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Category C TOTAL |
| | | | | | | |
| | | | | | | |

USDA Category D

| Procedures► | | | | | | |
|---|--------|--------|--------|--------|--------|---------------------|
| Species / Experimental Group / Procedure(s) | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Category D TOTAL |
| | | | | | | |
| | | | | | | |

USDA Category E

| Procedures► | | | | | | |
|---|--------|--------|--------|--------|--------|---------------------|
| Species / Experimental Group / Procedure(s) | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Category E TOTAL |
| | | | | | | |
| | | | | | | |

TOTALS over all Categories

| Species / Experimental Group /Procedure(s) | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | GRAND TOTAL |
|--|--------|--------|--------|--------|--------|----------------|
| | | | | | | |
| | | | | | | |

- J. **Management of USDA Category D procedures**. Indicate which statement below applies, and provide the information requested.
 - ▶ () This protocol does NOT include any Category D procedures.
 - ▶ () This protocol INCLUDES Category D procedures. List each Category D procedure and provide the information requested. (For surgical procedures described in Appendix 5, only identify the procedure(s) and enter "See Appendix 5 for details.)

| Procedure | Monitoring (indicate the method(s) to be used, and the frequency and duration of monitoring through post-procedure recovery) | Person(s) responsible for the monitoring | Method(s) by which pain or distress will be alleviated during or after the procedure (include the dose, route, and duration of effect of any agents to be administered) |
|-----------|--|--|---|
| | | | |
| | | | |
| | | | |

- K. **Justification of Category E procedures.** Indicate which statement below applies, and provide the information requested.
 - ▶ () This protocol does NOT include any Category E procedures
 - ▶ () This protocol INCLUDES Category E procedures. Identify each Category E procedure included in this ACORP and justify scientifically why the pain or distress cannot be relieved.

Veterinary Care and Husbandry

L. Veterinary Support.

1. Identify the laboratory animal veterinarian who is responsible for ensuring that the animals on this protocol receive appropriate veterinary medical care.

Name► Institutional affiliation► email contact►

2. Veterinary consultation during the planning of this protocol.

Name of the laboratory animal veterinarian consulted ►

Date of the veterinary consultation (meeting date, or date of written comments provided by the veterinarian to the PI) ►

- M. **Husbandry.** As a reference for the animal husbandry staff, summarize here the husbandry requirements of the animals on this protocol. (Use Appendix 6 to justify the use of any special husbandry and to detail its effects on the animals. Use Appendix 9 to document any aspects of the husbandry that involve "departures" from the standards in the *Guide*. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)
 - 1. Caging needs. Complete the table below to describe the housing that will have to be accommodated by the housing sites for this protocol:

| a. Species | b. Type of housing* | c. Number of individuals per housing unit** | d. Is this housing consistent with the Guide and USDA regulations? (yes/no***) | e. Estimated maximum number of housing units needed at any one time |
|------------|---------------------|---|--|---|
| | | | | |
| | | | | |

^{*}See ACORP Instructions, for guidance on describing the type of housing needed. If animals are to be housed according to a local Standard Operating Procedure (SOP), enter "standard (see SOP)" here, and enter the SOP into the table in Item Y. If the local standard housing is not described in a SOP, enter "standard, see below" in the table and describe the standard housing here:

** The *Guide* states that social animals should generally be housed in stable pairs or groups. Provide a justification if any animals will be housed singly (if species is not considered "social", then so note)

▶

2. Enrichment. Complete the table below to indicate whether "standard" exercise and environmental enrichment will be provided to the animals on this protocol, or whether any special supplements or restrictions will be required (See ACORP Instructions, for more information on enrichment requirements. Use Appendix 9 to document any enrichments requirements that represent "departures" from the standards in the *Guide*.):

| a. Species | b. Description of Enrichment* | c. Frequency |
|------------|-------------------------------|--------------|
| | | |
| | | |

*If enrichment will be provided according to a local SOP, enter "standard (see SOP)" and enter the SOP into the table in Item Y. If the local standard enrichment is not described in a SOP, enter "standard, see below", and describe the standard species-specific enrichment here.

▶

- 3. Customized routine husbandry. Check all of the statements below that apply to the animals on this protocol, and provide instructions to the animal husbandry staff with regard to any customized routine husbandry needed.
 - ▶ () This ACORP INCLUDES genetically modified animals.

List each group of genetically modified animals, and describe for each any expected characteristic clinical signs or abnormal behavior related to the genotype and any customized routine husbandry required to address these. For genetic modifications that will be newly generated on or for this protocol, describe any special attention needed during routine husbandry to monitor for unexpected clinical signs or abnormal behavior that may require customized routine husbandry.

▶

^{***}Use Appendix 9 to document "departures" from the standards in the *Guide*.

| ▶ () Devices that extend chronically through the skin WILL be implanted into some or all animals o |
|---|
| this protocol. Describe any customized routine husbandry to be provided by animal husbandry staff t |
| minimize the chances of chronic infection where the device(s) penetrate the skin. |

▶

▶ () Some or all of the animals on this protocol WILL require other customized routine husbandry by the animal husbandry staff, beyond what has been described above. Describe the special husbandry needed.

▶

- ▶ () This ACORP does NOT include use of any animals that will require customized routine husbandry.
- N. **Housing Sites**. Document in the tables below each location where animals on this protocol may be housed.
 - ▶ () Housing on VA property. Identify each location on VA property where animals on this protocol will be housed, and indicate whether or not each location is inside the VMU.

| Building | Room number | Inside of VMU? | | |
|----------|-------------|----------------|-----|--|
| g | | Yes | No | |
| | | () | () | |
| | | () | () | |
| | | () | () | |

▶ () Housing in non-VA facilities. Identify each location not on VA property where animals on this protocol will be housed, and provide the information requested in the table.

| Name of Non-VA Facility | Is this facility accred AAALAC? | ited by | Building | Room Number |
|-------------------------|---------------------------------|---------|----------|----------------|
| | Yes enter status* | No** | | |
| | () | ()** | | |
| | () | ()** | | |
| | () | ()** | | |

^{*}See ACORP Instructions, for a list of AAALAC accreditation status options.

Special Features

- O. Antibody Production. Will any of animals on this protocol be used for the production of antibodies?
 - ▶ () Some or all of the animals on this protocol WILL be used in the production and harvesting of antibodies. Check "Appendix 2" in Item Y, below, and complete and attach Appendix 2, "Antibody Production".

^{**}For any facility listed above that is not accredited by AAALAC, attach documentation that a waiver has been granted by the CRADO.

- ▶ () NO animals on this protocol will be used in the production and harvesting of antibodies.
- P. **Biosafety.** Will any substances (other than those used in routine husbandry or veterinary care) be administered to the animals on this protocol?
 - ▶ () This protocol INVOLVES administration of substances to the animals other than those used in routine husbandry and veterinary care. Check "Appendix 3" in Item Y, below, and complete and attach Appendix 3, "Biosafety".
 - ▶ () This protocol does NOT involve administration of any substances to the animals other than those used in routine husbandry and veterinary care.
- Q. **Locations of procedures.** Complete the table below, listing the location(s), inside or outside of the animal facility, for each of the procedures to be performed on animals on this protocol.

| Procedure | Surg | ical? | Bldg/Room Number | Requires transport through non-research areas? | | | | |
|-----------|------|-------|---------------------|--|-----|--|--|--|
| | Yes | No | | Yes – describe method of discreet transport | No | | | |
| | () | () | | () | () | | | |
| | () | () | | () | () | | | |
| | () | () | | () | () | | | |
| | () | () | | () | () | | | |

R. **Body Fluid, Tissue, and Device Collection.** List each body fluid, tissue, or device to be collected, and complete the table below to indicate the nature of the collection. Check the relevant Appendices in Item Y, below, and complete and attach them, as shown in the column headings.

| | | Collected | d BEFORE Euth | nanasia |
|--|----------------------------------|--|---|---|
| Body Fluid, Tissue, or Device to be Collected | Collected AFTER Euthanasia | Blood Collection Associated with Antibody Production (Appendix 2, "Antibody Production") | Collected as Part of a Surgical Procedure (Appendix 5, "Surgery") | Other Collection from Live Animals (Appendix 4, "Antemortem Specimen Collection") |
| | () | () | () | () |
| | () | () | () | () |
| | () | () | () | () |

- S. Surgery. Does this protocol include any surgical procedure(s)?
 - ▶ () Surgery WILL BE PERFORMED on some or all animals on this protocol. Check "Appendix 5" in Item Y, below, and complete and attach Appendix 5, "Surgery".
 - ▶ () NO animals on this protocol will undergo surgery.

- T. **Endpoint criteria.** Describe the criteria that will be used to determine when animals will be removed from the protocol or euthanatized to prevent suffering. (Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these criteria. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)
- U. **Termination or removal from the protocol**. Complete each of the following that applies:
 - ▶ () Some or all animals will NOT be euthanatized on this protocol. <u>Describe the disposition of these animals</u>. (Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these methods of disposition. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

▶ () Some or all animals MAY be euthanatized as part of the planned studies. Complete the table below to describe the exact method(s) of euthanasia to be used. (Use Appendix 9 to document any departures from the standards in the *Guide* represented by these methods. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

| Check each | | | Cla | AVMA assification | on |
|---|---|---------|------------|-----------------------------|--------------|
| method that may be used on this protocol | Method of Euthanasia | Species | Acceptable | Conditionally Acceptable | Unacceptable |
| () | CO₂ from a compressed gas tank Duration of exposure after apparent clinical death Method for verifying death Secondary physical method | | () | () | () |
| () | Anesthetic overdose Agent► Dose► Route of administration► | | () | () | () |
| () | Decapitation under anesthesia Agent ► Dose ► Route of administration ► | | () | () | () |

| () | Exsanguination under anesthesia Agent▶ Dose▶ Route of administration▶ | () | () | () |
|-----|---|-----|-----|-----|
| () | Other (Describe) ► | () | () | () |
| () | Other (Describe) ► | () | () | () |

| 1. | For each of the methods above that is designated as "Conditionally Acceptable" by the AVMA, describe |
|----|--|
| | how the conditions for acceptability will be met: |

▶

2. For each of the methods above that is designated as "Unacceptable" by the AVMA, give the scientific reason(s) that justify this deviation from the AVMA Guidelines:

Identify all research personnel who will perform euthanasia on animals on this protocol and describe their training and experience with the methods of euthanasia they are to use in the species indicated.

▶

- 4. Instructions for the animal care staff in case an animal is found dead.
 - a. Describe the disposition of the carcass, including any special safety instructions. If disposition is to be handled according to a local SOP, enter "according to local SOP" and enter the information requested about the SOP into the table in Item Y.

▶

- b. Describe how the PI's staff should be contacted.
 - \blacktriangleright () Please contact a member of the PI's staff immediately. (Copy the lines below for each individual who may be contacted)

Name▶

Contact Information ▶

▶ () There is no need to contact the PI's staff immediately. Describe the routine notification procedures that will be followed. If the routine notification procedures are described in a local SOP, enter "according to local SOP" and enter the information requested about the SOP into the table in Item Y.

▶

V. **Special Procedures.** List each special procedure (including special husbandry and other special procedures) that is a part of this protocol, and specify where the details of the procedure are documented. See ACORP Instructions, for examples.

| | Identify Where the Details of | of the Procedure are Docu | mented |
|-------------------|-------------------------------|--|---------------|
| Name of Procedure | SOP (title or ID number)* | Other Items in this ACORP specify the Item letter(s) | Appendix 6 |
| | | Items: | ()** |

^{*}If any special procedure is detailed in a SOP, identify the SOP and enter the information requested about the SOP in the table in Item Y.

(Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these procedures. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

- W. Consideration of Alternatives and Prevention of Unnecessary Duplication. These are important to minimizing the harm/benefit to be derived from the work.
 - Document the database searches conducted.
 List each of the potentially painful or distressing procedures included in this protocol.

Then complete the table below to document how the database search(es) you conduct to answer Items W.2 through W.5 below address(es) each of the potentially painful or distressing procedures.

| Name of the | Date of | Period of | Potentially | Key words and/or | Indicate which mandate |
|-------------|---------|-----------|-------------|----------------------|------------------------|
| database | search | years | painful or | search strategy used | each search addressed |

^{**}If any special procedure is detailed in Appendix 6, check "Appendix 6" in Item Y, below, and complete and attach Appendix 6.

| | covered by the search | distressing procedures addressed | Replacement of animals (item W.2) | Reduction in numbers of animals used (item W.3) | Refinement to minimize pain or distress (item W.4) | Lack of unnecessary duplication (item W.5) |
|--|--------------------------|--|-----------------------------------|---|--|--|
| | | | () | () | () | () |
| | | | () | () | () | () |
| | | | () | () | () | () |
| | | | () | () | () | () |

2. <u>Replacement</u>. Describe the replacements that have been incorporated into this work, the replacements that have been considered but cannot be used, and the reason(s) that further replacements are not acceptable.

3. <u>Reduction</u>. Describe how the number of animals to be used has been minimized in this protocol and explain why further reduction would disproportionately compromise the value of the data.

4. <u>Refinement</u>. Describe the refinements that have been incorporated into this work and explain why no further refinements are feasible.

5. Describe how it was determined that the proposed work does not <u>unnecessarily</u> duplicate work already documented in the literature.

▶

X. Other Regulatory Considerations.

1. Controlled drugs.

 a. Complete the table below for each drug that is used in animals on this protocol and that is classified as a controlled substance by the DEA. See ACORP Instructions, for explanations about the information requested.

| | Sto | rage | | Location | for Use | Procur | ement |
|-----------------------|-------------------|---------------------------|--------------------------------|----------------|--------------------------|---------------------|------------|
| Controlled substances | Double- locked | Not Double- locked* | Personnel Authorized to Access | VA Property | Not on VA Property | VA Phar- macy | Non- VA |
| | () | ()* | | () | () | () | () |
| | () | ()* | | () | () | () | () |

| | | () | ()* | | () | () | () | () |
|--|--|-----|------|--|-----|-----|-----|-----|
|--|--|-----|------|--|-----|-----|-----|-----|

*For any controlled substance that will NOT be stored under double lock, with limited access, describe how it will be stored, and explain why this is necessary.

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- b. Check each statement below that applies, to confirm that all controlled substances used on this protocol will be procured according to VA pharmacy policies:
 - ▶ () Some controlled substances will used on VA property, and all of these will be obtained through the local VA pharmacy.
 - ▶ () Some controlled substances will not be obtained through the local VA pharmacy, but none of these will be used on VA property. See the ACORP Instructions, for further information.
 - ► () Other. Explain ►
- 2. **Human patient care equipment or procedural areas**. Does this protocol involve use of any human patient care equipment or procedural areas?
 - ▶ () Yes, some human patient care equipment or procedural area(s) will be used for the animal studies on this protocol. Check "Appendix 7" in Item Y, below, and complete and attach Appendix 7, "Use of Patient Procedural Areas for Animal Studies".
 - ▶ () No human patient care equipment or procedural areas will be used for the animal studies on this protocol.
- 3. Explosive agents. Does this protocol involve use of any explosive agent?
 - ▶ () Yes, some explosive agent(s) will be used on this protocol. Check "Appendix 3" and "Appendix 8" in Item Y, below, and complete and attach Appendix 8, "Use of Explosive Agent(s) within the Animal Facility or in Animals", as well as Appendix 3, "Biosafety".
 - ▶ () No explosive agent(s) will be used as part of this protocol.
- Y. **Summary of Attachments.** To assist the reviewers, summarize here which of the following apply to this ACORP.

Appendices. Indicate which of the Appendices are required and have been completed and attached to this protocol. <u>Do not check off or attach any appendices that are not applicable to this ACORP.</u>

- ► () Appendix 1, "Additional Local Information"
- ► () Appendix 2, "Antibody Production"
- ► () Appendix 3, "Biosafety"
- ▶ () Appendix 4, "Ante-mortem Specimen Collection"
- ▶ () Appendix 5, "Surgery"
- ▶ () Appendix 6, "Special Husbandry and Procedures"
- ▶ () Appendix 7, "Use of Patient Care Equipment or Areas for Animal Studies"
- ▶ () Appendix 8, "Use of Explosive Agent(s) within the VMU or in Animals"

▶ () Appendix 9, "Departures from "Must" and "Should" Standards in the Guide"

Standard Operating Procedures (SOPs). List in the table below, each of the SOPs referred to in this protocol, providing the information requested for each one. The approved SOPs must be included when the approved ACORP and Appendices are submitted for Just-in-Time processing before release of VA funding support.

| Itom | SOP | Approval Data | |
|-------|-------|---------------|---------------|
| Item | Title | ID | Approval Date |
| C.2.c | | | |
| M.1 | | | |
| M.2 | | | |
| U.4.a | | | |
| U.4.b | | | |
| V | | | |
| | | | |
| | | | |

- Z. Certifications. Signatures are required here for any ACORP that is to be submitted to VA Central Office in support of an application for VA funding. Include the typed names and dated signatures as shown below for the Main Body of the ACORP and for each of the Appendices that apply to this protocol. <u>Do NOT</u> include signatures for, or attach, any appendices that do NOT apply.
 - 1. Main Body of the ACORP.
 - a. Certification by Principal Investigator(s):

<u>I certify that</u>, to the best of my knowledge, the information provided in this ACORP is complete and accurate, and the work will be performed as described here and approved by the IACUC. I understand that IACUC approval must be renewed at least annually, and that the IACUC must perform a complete *de novo* review of the protocol at least every three years, if work is to continue without interruption. I understand further that I am responsible for providing the information required by the IACUC for these annual and triennial reviews, allowing sufficient time for the IACUC to perform the reviews before the renewal dates, and that I may be required to complete a newer version of the ACORP that requests additional information, at the time of each triennial review.

<u>I understand that further IACUC approval must be secured before any of the following may be implemented:</u>

- Use of additional animal species, numbers of animals, or numbers of procedures performed on individual animals;
- Changing any procedure in any way that has the potential to increase the pain/distress category
 to which the animals should be assigned, or that might otherwise be considered a significant
 change from the approved protocol;
- Performing any additional procedures not already described in this ACORP;
- Use of any of these animals on other protocols, or by other investigators.

I further certify that:

- No personnel will perform any animal procedures on this protocol until the IACUC has confirmed that they are adequately trained and qualified, enrolled in an acceptable Occupational Health and Safety Program, and meet all other criteria required by the IACUC. When new or additional personnel are to work with the animals on this protocol, I will provide this information to the IACUC for confirmation before they begin work;
- I will provide my <u>after-hours contact information</u> to the animal care staff for use in case of emergency.

| Name(s) of Principal Investigator(s) | Signature | Date |
|--------------------------------------|-----------|------|
| | | |
| | | |

b. Certification by IACUC Officials.

We certify that:

- We, with the IACUC, have evaluated the care and use of animals described on this ACORP, in accordance with the provisions of the USDA Animal Welfare Act Regulations and Standards, PHS Policy, the *Guide for the Care and Use of Laboratory Animals*, and VA Policy;
- The IACUC has determined that the care and use of animals described in this ACORP is appropriate, and has therefore approved the protocol;
- The full text of any minority opinions is documented here as indicated below:
 - ▶ () No minority opinions were submitted by any IACUC participant for inclusion.
 - ▶ () Minority opinions submitted by IACUC participants are copied here
 - ► () Minority opinions submitted by IACUC participants are attached on separate pages labeled "IACUC Minority Opinion" (indicate the number of pages ►)

| Name of Attending Veterinarian (VMO or VMC) | Signature | Date |
|---|-----------|------|
| | | |
| Name of IACUC Chair | Signature | Date |
| | | |

- 2. Appendix 2. Antibody Production. No signatures required.
- 3. Appendix 3. Biosafety.
 - a. Certification by PI(s) and IACUC Officials:

We certify that:

- Before any animal experiments involving hazardous agents (identified in Item 10.a of Appendix 3) are performed, SOPs designed to protect all research and animal facility staff as well as nonstudy animals will be developed and approved by the appropriate VA or affiliated university safety committee and by the IACUC;
- All personnel who might be exposed to the hazardous agents (identified in Item 10.a of Appendix 3) will be informed of possible risks and will be properly trained ahead of time to follow the SOPs to minimize the risks of exposure.

| Signature | Date |
|-----------|------|
| | |
| Signature | Date |
| | |
| | - |

b. Certification by Biosafety Official. I certify that:

- Each agent to be administered to animals on this protocol has been properly identified in Item 1 of Appendix 3 as to whether it is "toxic", "infectious", "biological", or "contains recombinant nucleic acid":
- The use of each of the agents thus identified as "toxic", "infectious", or "biological", or "contains recombinant nucleic acid" is further documented as required in Items 4, 5, 6, and/or 8, as applicable, and in Item 10.a of Appendix 3;
- The use of each of these agents has been approved by the appropriate committee(s) or official(s), as shown in Item 10.a of Appendix 3.

| Name of the Biosafety Officer, or of the Chair of the Research Safety or Biosafety Committee | Signature | Date |
|--|-----------|------|
| | | |
| | | |

c. Certification by Radiation Safety Official. I certify that:

- Each agent to be administered to animals on this protocol has been properly identified in Item 1
 of Appendix 3 as to whether it is "radioactive";
- The use of each radioactive agent is further documented as required in Items 7 and 10.a of Appendix 3;
- The use of each radioactive agent has been approved by the appropriate committee(s), as shown in Item 10.a of Appendix 3.

| Name of the Radiation Safety Officer, or of the Chair of the Radiation Safety or Isotope Committee | Signature | Date |
|---|-----------|------|
| | | |
| | | |

4. Appendix 4. Ante-mortem Specimen Collection. No signatures required.

5. Appendix 5. Surgery. Certification by the PI(s). I certify that:

- To the best of my knowledge, the information provided in Appendix 5 of this ACORP is complete and accurate:
- The surgical procedures will be performed and the post-operative care (including administration of post-operative analgesics) will be provided as described;
- The spaces where any survival surgical procedures will be performed (listed in Item 4 of Appendix 5) are suitable for sterile/aseptic surgery;
- The names and contact information for research personnel to notify or consult in case of emergencies will be provided to the VMU supervisor and veterinary staff;
- Post-operative medical records will be maintained and readily available for the veterinary staff and the IACUC to refer to, and will include the following:

- Identification of each animal such that care for individual animals can be documented.
- Daily postoperative medical records for each animal, that include documentation of daily evaluation of overall health and descriptions of any complications noted, treatments provided, and removal of devices such as sutures, staples, or wound clips;
- Documentation of the administration of all medications and treatments given to the animals, including those given to reduce pain or stress.
- o Daily records covering at least the period defined as "post-operative" by local policy.
- The signature or initials of the person making each entry.

| Name(s) of Principal Investigator(s) | Signature(s) | Date |
|--------------------------------------|--------------|------|
| | | |
| | | |

- 6. Appendix 6. Special Husbandry and Procedures. No signatures required.
- 7. Appendix 7. Use of Patient Care Equipment or Areas for Animal Studies.
 - a. **Certification by the Principal Investigator(s).** <u>I certify that</u>, to the best of my knowledge, the information provided in Appendix 7 of this ACORP is complete and accurate, and the use of patient care equipment or areas for these animal studies will be as described.

| Name(s) of Principal Investigator(s) | Signature(s) | Date |
|--------------------------------------|--------------|------|
| | | |
| | | |

b. Certification by the officials responsible for the use of any human patient care equipment in animal procedural areas. Each of the following must sign to indicate that they have granted approval for the human patient care equipment to be moved to the VMU or other animal procedural area to be used on animals and then returned to the human patient care area, as described in Appendix 7. Leave this section blank, if not applicable.

| Name of IACUC Chair | Signature | Date |
|---------------------|-----------|------|
| | | |
| | | |

| Name of the Manager of the Human Patient Care Equipment | Signature | Date |
|--|-----------|------|
| | | |

c. Certification by the officials responsible for the use of the equipment in human patient care areas for these animal studies. Each of the following must sign to indicate that they <u>have granted approval</u> for animals to be transported into human patient care areas for study or treatment, as described in Appendix 7. Leave this section blank, if not applicable.

| Name of IACUC Chair | Signature | Date |
|---|-----------|------|
| | | |
| | | |
| Name of Attending Veterinarian (VMO or VMC) | Signature | Date |
| | | |
| Name of the Chair of the Clinical | | |
| Executive Board, or the Service Chief responsible for the Patient Care Area and Equipment | Signature | Date |
| Odro / trod drid Equipment | | |
| | | |
| Name of ACOS for R&D | Signature | Date |
| | | |
| Name of Chief of Staff | Signature | Date |
| | | |
| Name of Director or CEO of the Facility (Hospital or Clinic) | Signature | Date |
| | | |
| | | |

- 8. Appendix 8. Use of Explosive Agent(s) within the Animal Facility or in Animals.
 - a. Certification by the Principal Investigator(s).

<u>I certify that</u>, to the best of my knowledge, the information provided in Appendix 8 of this Animal Component of Research Protocol (ACORP) is complete and accurate, and the use of explosive agents in these animal studies will be as described.

I further certify that:

- Procedures involving explosive agent(s) will be performed within a properly operating, ventilated safety hood;
- All electrical equipment operating when explosive agent(s) are in use will be positioned and powered outside of the hood;
- Once the seal is broken on any containers of explosive agents, they will be kept in a safety hood throughout use, stored in an explosion-proof refrigerator or other approved storage area, and discarded properly once completely emptied;
- Proper procedures will be used for safe and appropriate disposal of items (including animal carcasses) that may contain residual traces of the explosive agent(s).

| Name(s) of Principal Investigator(s) | Signature(s) | Date |
|--------------------------------------|--------------|------|
| | | |
| | | |

b. Certification by the officials responsible for overseeing the use of explosive agent(s) in this protocol. Each of the following must sign to verify that they or the committee they represent heave-granted-approval.

| Name of IACUC Chair | Signature | Date |
|---|-----------|------|
| | | |
| Name of Attending Veterinarian (VMO or VMC) | Signature | Date |
| | | |
| Name of Safety/Biosafety Officer for the Facility | Signature | Date |
| | | |
| Name of ACOS for R&D | Signature | Date |
| | | |
| | | |

| Name of VISN Regional Safety Officer | Signature | Date |
|---|-----------|------|
| | | |

9. Departures from "Must" and "Should" Standards in the *Guide*. No signatures required.