

For IACUC Use Only:  
Rev 2: December 2000

IACUC No.:

Date of Approval:

Check all that apply:

Maj. Surv. Surgery  Primates  Cat. E studies  Haz. Agents  Dogs, cats or pigs

## ANIMAL COMPONENT OF RESEARCH PROTOCOL (ACORP) DRAFT

### General Information

**Note: Use a separate form for each species. DO NOT include individual appendices if they are not relevant to the protocol being described. Type an "x" in the box(es) next to your selection(s). Define all abbreviations the first time they are used. To add a row to a table, click inside one of the existing table cells, then select Table, Insert, Rows from the main menu of the program.**

A. **ACORP Status.** Complete items A.1.- A.8. below; then proceed to item B.

1. Name of Principal Investigator:
2. VA Station Name and Number:
3. Proposal Title:
4. Animal Species covered by this ACORP (only one):
5. Funding Source. Indicate the source(s) of funds that will be used to perform these animal procedures once approved by the VA IACUC:
  - Department of Veterans Affairs
  - U. S. Public Health Service (e.g. NIH)
  - Private or Charitable Foundation. Identify:
  - University Departmental Funds. Identify University and Department:
  - Private Company. Identify:
  - Other. Identify:
6. Is this a new ACORP for a new project?
  - Yes. Proceed to item 7.
  - No. Answer A.6.a.-c. below.
    - a. Indicate the status of this ACORP below:
      - This is an unchanged, approved ACORP intended for a new funding source.
      - This is a revised ACORP with a new funding source.
      - This is a revised ACORP that reflects changes or additional, new studies.
      - This ACORP is submitted as a three-year (3-year) renewal.
      - Other. Please specify:
    - b. Previous ACORP title:
    - c. Previous IACUC approval number (VA and affiliate, if applicable):
7. Do you plan on performing the animal procedures described in this form even if you do not receive extramural VA, PHS, NSF, or other funding?
  - Yes.
  - No.
8. Indicate the type of animal use:

- Research.
- Teaching or Training.
- Testing.
- Sentinel animal use.
- Breeding and colony management only; no experimental procedures.
- Other. Please specify:

### Proposal Overview

B. Using non-technical (lay) language that a senior high school student would understand, briefly describe how this research project might improve the health of people and/or other animals. A scientific abstract from a grant proposal is not acceptable. Once completed, proceed to item C.

#### C. **Experimental Design.**

1. Using non-technical (lay) language that a senior high school student would understand, describe the experimental design in no more than one or two paragraphs.
2. In language scientific colleagues outside of your discipline would understand, describe the experimental design for the animal experiments planned, and the sequence of events to reveal what happens to the animals. Include all procedures and manipulations, and explain why they must be performed. Give your best estimate of how many animals will undergo the procedures or manipulations described. For complicated experimental designs, a flow chart, diagram, or table is strongly recommended to help the IACUC understand what is proposed. Do not describe the details of surgical procedures, monoclonal antibody production, or behavioral training here. Such details are requested later in appendices. Once completed, proceed to item D.

D. Describe the characteristics of the selected species, strain, stock, mutant, or breed that justify its use in the proposed study. Consider such characteristics as body size, species, strain, breed, availability, data from previous studies, and unique anatomic or physiologic features. Once completed, proceed to item E.

### Personnel

E. Give the names of all research staff expected to work with the animals in this study. For each person listed, describe their education, training, and experience with experimental animals in general AND describe their experience performing the exact procedures in the species described in this ACORP. This description must help IACUC members determine if all animal manipulations, including surgery, testing, and blood collection, are performed by individuals who are qualified to accomplish the procedures skillfully and humanely. A listing of academic degrees alone is not an adequate response. (Qualifications to perform euthanasia will be requested in item U.3. and need not be given here.) Once completed, proceed to item F.

F. If personnel do not have experience with the exact procedures described in this ACORP, how will they be trained, who will train them, and what are the training experiences or qualifications of the person(s) doing the training? If not applicable, enter "N/A". Once completed, proceed to item G.

#### G. **Occupational Safety and Health.**

1. Have all personnel listed in item E. been enrolled in the Occupational Health and Safety Program for those with laboratory animal contact?
  - Yes. Proceed to item G.2.
  - No. If personnel have declined to participate, are enrolled in another equivalent program,

or will enroll before studies commence, so indicate here and then proceed to item G.2.

2. Are there any non-routine measures such as special vaccines or additional health screening techniques that would potentially benefit research, husbandry, or veterinary staff participating in or supporting this project? Routine measures included in the Occupational Health and Safety Program (vaccination for tetanus, rabies, and hepatitis B, and TB screening) need not be mentioned here.

- Yes. Describe them below; then proceed to item H.  
 No. Proceed to item H.

**Animal Information**

H. Complete the following table; then proceed to item I.

Strain, Stock, Mutant, or Breed	Gender	Age/Size	Source (Vendor)	Health Status*

\*For each strain, stock, mutant, or breed listed, provide information about the expected status of the animals:

- For rodents and rabbits, indicate specific-pathogen-free (SPF), gnotobiotic (germ-free or defined flora), conventional, feral, or other description.
- For dogs, cats, pigs, and other "large animals", indicate specific-pathogen-free (SPF), conditioned, conventional, feral, or other description.
- For non-human primates, indicate viral status (e.g., herpes B, SIV, etc.)
- Also indicate here if animals will be surgically altered by the vendor (e.g., ovariectomized rats).

- I. Complete the tables below, assigning all requested animals by breed/strain/mutant to a USDA category of pain/distress. If you have difficulty determining the appropriate category, please contact the attending veterinarian or IACUC Chair for assistance. The same animal cannot be assigned to more than one USDA category. If several different procedures are planned, the animal should be placed in a category based on the most painful/distressful procedure. You are required by VA policy to describe planned procedures for the fourth and fifth years of a submitted VA grant even though, under PHS policy, the IACUC must perform a new review three years after the initial approval date. Once completed, proceed to item J.

**USDA Category B:** List by year the number of animals that will be bred or purchased for breeding, but not used for experiments. This includes breeders, young that cannot be used because of improper genotype or gender, and any other animals that will not have any research procedures performed on them or participate in research studies. If numbers cannot be determined exactly, estimate as closely as possible. (Note: If tail snips are necessary for genotyping, this category is not appropriate.)

Breed/Strain/Mutant	Year 1	Year 2	Year 3	Year 4	Year 5

**USDA Category C:** List, by year the number of animals that will undergo procedures that involve no or only very brief pain or distress, with no need for or use of pain relieving drugs. Examples include observational studies, most intravenous and parenteral injections of non-irritating agents, most blood collections from peripheral vessels, and the collection of cells and/or tissues from animals after euthanasia has been performed.

Breed/Strain/Mutant	Year 1	Year 2	Year 3	Year 4	Year 5

<b>USDA Category D:</b> List by year the number of animals that will undergo procedures involving potential pain or distress that is relieved by appropriate anesthetics, sedatives, or analgesics. Examples include major and minor surgery performed under anesthesia (survival or non-survival), tissue or organ collections <u>prior to</u> euthanasia, painful procedures performed under anesthesia (such as retro-orbital blood collection in rodents), prolonged restraint accompanied by tranquilizers or sedatives, and experiments involving infectious or other hazardous materials in animals that have provisions for immediate euthanasia if they become sick to effectively prevent pain and/or suffering. If an endpoint is used that involves significant pain or distress, consideration should be given to putting animals into Category E.					
Breed/Strain/Mutant	Year 1	Year 2	Year 3	Year 4	Year 5
<b>USDA Category E:</b> List, by year, the number of animals that will undergo procedures in which pain or stress is NOT relieved with the use of anesthetics, analgesics, tranquilizers, or by euthanasia. Examples include studies in which animals are allowed to die without intervention (e.g. LD <sub>50</sub> , mortality as an end-point), studies that allow endpoints that are painful or stressful, addictive drug withdrawals without treatment, pain research, and noxious stimulation.					
Breed/Strain/Mutant	Year 1	Year 2	Year 3	Year 4	Year 5
<b>TOTALS:</b> Bring all totals for each year down, by breed/strain/mutant.					
Breed/Strain/Mutant	Year 1	Year 2	Year 3	Year 4	Year 5

J. **Description of USDA Category D and E procedures.** Are any USDA Category D or E studies planned?

- No. Proceed to item K.
- Yes. Complete items J.1. and J.2.; then proceed to item K.

1. List and describe all category D procedures by filling out the table below. If no category D studies are proposed, enter "N/A" and proceed to item J.2. For any surgical procedures you will describe in Appendix 5, enter only a brief description in the "Procedure" column, then enter "See Appendix 5 for details."

Procedure	Frequency of monitoring after the procedure and how long animals will be monitored	Person(s) doing the monitoring	Analgesic, sedative, or anesthetic used, plus dose, route, and duration

2. Each year a report describing and justifying all category E procedures must be submitted by each facility to the USDA and the VA. If no category E studies are proposed, enter "N/A" and proceed to item K. Otherwise, describe each category E procedure, and justify completely why pain or distress relief cannot be provided for each procedure. Your description will be used in the USDA annual report. If animals will be allowed to experience natural death as a result of experimental procedures (e.g. infectious disease or oncology studies), or an endpoint is used that allows the animals to experience significant pain or distress, you must justify why

an alternate endpoint (such as weight loss, clinical signs, tumor size, etc.) prior to death or pain or distress can not be used. If animals will undergo category D procedures as well, describe them in item J.1. above.

- K. Describe how the estimated number of animals needed for the experiments was determined. When appropriate, provide the number and type of experimental and control groups in each experiment, the number of experiments planned, and the number of animals in each group. The *ILAR Guide* states that whenever possible, the number of animals requested should be justified statistically. A power analysis is strongly encouraged to justify group sizes when appropriate. Once completed, proceed to item L.

### **Animal Housing and Care**

- L. **Laboratory Animal Veterinary Support.** Complete items L.1-L.3, then proceed to item M.

1. Give the name of the laboratory animal veterinarian responsible for providing adequate care to the animals that will be used along with their institutional affiliation.
2. VA Policy requires that a laboratory animal veterinarian be consulted during the planning stages of any procedure involving laboratory animals, before IACUC review. Give the name of the laboratory animal veterinarian consulted during the planning of procedures involving animals. As an alternative to an actual meeting, the veterinarian may perform a pre-review of the ACORP and provide comments to the PI so that the ACORP may be revised prior to IACUC review.
3. Give the date of the veterinary consultation (meeting date, or date written comments were provided by the veterinarian to the PI).

- M. **Husbandry.**

1. Caging needs. To help the animal care staff with caging needs, please indicate the type of caging that you will need; then go on to question M.2:
  - Gnotobiotic (germ-free and defined flora) isolators
  - Biohazard or other special hazard containment caging
  - Sterile rodent microisolator caging, with filtered cage top
  - Non-sterile rodent microisolator caging, with filtered cage top
  - Standard rodent shoebox caging with no filter top
  - Standard non-rodent caging, appropriate for species
  - Other. Describe:
2. The *ILAR Guide for the Care and Use of Laboratory Animals* states that consideration should be given to housing social animals in groups whenever possible. Will social animals be housed singly?
  - Yes. Complete item M.3.
  - No. Proceed to item M.4.
  - Not Applicable; the species involved is not a social animal. Proceed to item M.4.
4. Please provide a justification for housing social animals singly; then proceed to question M.4.
4. The *ILAR Guide for the Care and Use of Laboratory Animals* recommends the use of contact bedding (i.e., shoebox or microisolator cages) instead of wire mesh floors for housing rodents. Will rodents be housed on suspended wire mesh floors or other flooring in which the animals do not rest on bedding?
  - Not applicable; this ACORP does not describe rodent use. Proceed to item M.6.

- No. All rodents will be housed in shoebox or other caging in which the animals rest directly on bedding. Proceed to item M.6.
- Yes. Proceed to item M.5.

5. Why is caging with wire mesh flooring necessary?

6. Indicate the appropriate response below:

- This ACORP does not address the use of dogs, primates, or transgenic mice. Proceed to item M.7.
- This ACORP addresses the use of dogs. Answer item M.6.a. below.
- This ACORP addresses the use of primates. Answer item M.6.b. below.
- This ACORP addresses the use of transgenic mice. Answer item M.6.c. below.

a. Is there any scientific justification for excluding the dogs in this study from the institutional dog exercise plan required by USDA?

- No. Proceed to item M.7.
- Yes. Provide a scientific justification for excluding the dogs; then proceed to item M.7.

b. Is there any scientific justification for excluding the primates from the institutional primate psychological enrichment plan required by USDA?

- No. Proceed to item M.7.
- Yes. Provide a scientific justification below for excluding the primates; then proceed to item M.7.

c. Do the transgenic mice planned for use exhibit any characteristic clinical signs or abnormal behavior related to their genotype?

- No. Proceed to item M.7.
- Yes. Describe here, then proceed to item M.7.:

7. Will any cannulae, acrylic implants, venous catheters, or other similar medical devices be implanted into an animal such that the device extends chronically through the skin?

- No. Proceed to item N.
- Yes. Explain what wound management measures will be taken to minimize the chances of chronic infections around the device(s) where they penetrate the skin.

#### **N. Housing Sites.**

1. Will all animals purchased with VA or VA Foundation funds be housed only in VA facilities?

- Yes. Proceed to item N.2.
- No. Complete and attach ACORP Appendix 1, "Use of Non-VA Animal Facility", then go to item N.2.

2. Give the VA location(s), inside or outside of the animal facility, where animals will be housed permanently or temporarily, then proceed to item O.

### **Experimental Procedures**

O. **Antibody Production.** Will animals be used to produce monoclonal or polyclonal antibodies, or will existing hybridoma cell lines be injected into animals to harvest antibody?

- No. Proceed to item P.
- Yes. Complete and attach Appendix 2, "Antibody Production," then proceed to item P.

P. **Test Substances.** Will test substances be administered to animals? For the purposes of this question, test substances are defined as materials administered to animals. This includes, but is not limited to, radioisotopes, toxins, antigen, pharmacological agents, infectious agents,

carcinogens or mutagens, biomaterials, prosthetic devices, and cells, tissues, or body fluids. (Note: The following substances do not need to be entered in Appendix 3 unless they are hazardous: routine pre- or post-operative drugs described in the Surgery Appendix [Appendix 5], antigens, adjuvants, hybridomas described in the Antibody Production Appendix [Appendix 2], and euthanasia agents entered in item U, Euthanasia.)

- No. Proceed to item Q.
- Yes. Complete and attach Appendix 3, "Test Substances;" then proceed to item Q.

Q. **Location of procedures.** Complete the table below, indicating where all non-surgical procedures will be performed. Be sure to include the sites of procedures such as radiography, fluoroscopy, computed axial tomography (CT), or magnetic resonance imaging (MRI) that may be performed outside the animal facility.

Non-surgical Procedure	Building and Room Number	Method of discreet transport, if required through <u>non-research</u> areas (enter N/A if not applicable)*

\*Describe how animals will be transported to and from these sites. Transportation must be in accordance with the *Guide*, USDA regulations, and PHS policy in climate-controlled vehicles and sanitizable transport cages when appropriate. Transport through non-research areas must be discreet. Once completed, proceed to item R.

R. **Body Fluid, Tissue, and Device Collection.**

1. Will any body fluids, tissues, or devices be collected from animals AFTER euthanasia?
  - No. Proceed to item R.2.
  - Yes. List the fluids, tissues, and/or devices here; then proceed to item R.2.
2. Will any body fluids, tissues, or implanted devices or materials be collected from animals BEFORE euthanasia?
  - No. Proceed to item S.
  - Yes. Proceed to item R.3.
3. Is collection in live animals limited to blood collection associated with antibody production?
  - No. Complete and attach Appendix 4, "Antemortem Specimen Collection." Then proceed to item S. If the body fluid, tissues, or devices are collected as a surgical procedure, please be sure to also describe these collections as part of the surgical protocol in the Appendix 5, "Surgery."
  - Yes. Because blood collection associated with antibody collection is already described in Appendix 2, "Antibody Production", DO NOT complete Appendix 4, "Antemortem Specimen Collection." Proceed to item S.

S. **Surgery.** Will survival or non-survival surgery be performed?

- No. Proceed to item T.
- Yes. Complete and attach Appendix 5, "Surgery;" then proceed to item T.

T. **Endpoint Criteria.** What specific endpoint criteria will be used for determining when sick animals, both on and off study, will be euthanatized or otherwise removed from a study? Examples of appropriate criteria that should be considered include a weight loss limit as a percentage of initial or expected body weight, allowable durations of anorexia, allowable tumor size or total tumor burden expressed as a percentage of body weight, the presence of health problems refractory to

medical intervention, and severe psychological disturbances. Other criteria appropriate for the species under consideration should also be considered. When complete, proceed to item U.

**U. Euthanasia.** Will animals be euthanatized as part of the planned studies?

- No. Describe the final disposition of the animals here, then proceed to item U.4:
- Yes. Complete items U.1. - U.4. below; then proceed to item V.

1. Describe the exact method of euthanasia for each animal used. Include the agents used, dose (as applicable), and route of administration.
2. Justify any method that is not considered “acceptable” by the latest report of the AVMA Panel on Euthanasia. (More info- item U.2) If you are unsure how to answer, contact your veterinarian or IACUC for guidance. If all methods are considered acceptable by the Panel, enter “All methods meet AVMA Panel recommendations” below:
3. List the personnel who will perform euthanasia and indicate their training and experience with the method of euthanasia and the species involved. If personnel are not yet trained, indicate so and explain how they will be trained before performing euthanasia themselves.
4. Should the animal care staff find an animal dead, how should the carcass be handled (e.g. refrigerated or frozen), and should a member of your staff be contacted immediately?

**V. Special Procedures.** Are any experimental procedures or special husbandry procedures planned that are NOT described in the local standard operating procedures (SOP) manual or elsewhere in this ACORP? Special procedures can include special restraint practices (including non-human primate chairing), special animal health monitoring, special diets, caging, environmental control, exercise, environmental enrichment, means of identification, use of noxious stimuli, forced exercise, or behavioral manipulation.

- Yes. Complete and attach Appendix 6, “Special Husbandry and Procedures;” then proceed to item W.
- No. Proceed to item W.

**Mandatory Considerations**

**W. Consideration of Alternatives and the Prevention of Unnecessary Duplication.** Complete items W.1 through W.5 below; then proceed to item X. Keep copies of computer database search results in your files to demonstrate your compliance with the law if regulatory authorities or the IACUC should choose to audit your project.

1. Investigators must consider less painful or less stressful alternatives to procedures, and provide assurance that proposed research does not unnecessarily duplicate previous work. You should perform one or more database searches to meet these mandates unless compelling justifications can be made without doing so. Complete the table below for each database search you conduct to answer items W.2 through W.5 below. You must provide complete information in the first four columns of the table to comply with USDA Policy #12.

Name of the database (s)	Date performed	Period (years) covered by each search	Key words and/or search strategy used	Indicate below for which mandate each search was conducted by placing an “X” in the proper column			
				Alternative computer models or <i>in vitro</i> techniques (item W.2)	Alternative use of less-sentient species (item W.3)	Alternative use of less stressful model or methods, or fewer animals (item W.4)	Lack of unnecessary duplication (item W.5)


2. Could any of the animal procedures described in this ACORP be replaced by computer models or *in vitro* techniques? Indicate below if such replacement is or is not possible, and provide a narrative on how you came to your conclusion.

3. Could a smaller, less sentient mammalian species or a non-mammalian species (e.g. poultry, fish, invertebrates) substitute for the mammals in any of the experiments planned? Indicate below if such substitution is or is not possible and provide a narrative on how you came to your conclusion.

4. Could a different animal model or different animal procedure that involves 1) less distress, pain, or suffering, or 2) fewer animals substitute for any proposed animal model or animal procedure planned? Indicate below if such replacement is or is not possible, and provide a narrative on how you came to your conclusion.

5. Does the proposed research unnecessarily duplicate previous work? Indicate below if the proposed work unnecessarily duplicates previous work and provide a narrative on how you came to your conclusion.

X. **Other Regulatory Considerations.** Complete items X.1, X.2, and X.3 below; then proceed to item Y.

1. **Controlled drugs.**

a. Will all drugs used in animals and classified as controlled substances by the DEA or your state drug enforcement authority be stored in a double-locked cabinet, and be accessible only to authorized personnel in accordance with DEA regulations?

- Not applicable- no controlled drugs will be used. Proceed to item X.2.
- No. Please explain here, then go to item X.1.b.:
- Yes. Complete item X.1.b.

b. List the controlled substances that will be used in vivo for this project, and include the building and room number where they will be stored.

2. Will any human patient procedural areas be used for these animal studies?

- No. Proceed to item X.3.
- Yes. Complete and attach Appendix 7, "Request to Use Patient Procedural Area;" then proceed to item X.3.

3. Will an explosive anesthetic or other explosive agent be used in any portion of these animal studies? (More info- item X.3)

- No. Proceed to item Y.
- Yes. Complete and attach Appendix 8, "Request to Use Explosive Agent;" then proceed to item Y.

Y. Please indicate which of the following Appendices are completed and attached. Do not attach blank appendices which are not applicable to this ACORP. Check with your IACUC to see if an optional Appendix 9, "Additional Local Information", is required.

- Appendix 1, "Use of Non-VA Animal Facility" (reference item N)
- Appendix 2, "Antibody Production" (reference item O)
- Appendix 3, "Test Substances" (reference item P)
- Appendix 4, "Antemortem Specimen Collection" (reference item R)
- Appendix 5, "Surgery" (reference item S)

- Appendix 6, "Special Husbandry and Procedures" (reference item V)
- Appendix 7, "Request to Use Patient Care Procedural Areas for Animal Studies" (reference item X)
- Appendix 8, "Request to Use Explosive Agent" (reference item X)
- Appendix 9, "Additional Local Information"

Z. **Certifications.** Signatures of the Principal Investigator(s), IACUC Chair, veterinarian, and R&D Committee Chair are mandatory; others may NOT sign for them. Copies (including FAX transmissions) of original signatures are fine, but stamps and digital graphics file reproductions are not acceptable. Note: Signatures must be less than one year old if this form is part of an application submission to VA Headquarters.

1. **Certification by Principal Investigator(s).**

To the best of my knowledge, I certify that the information provided in this Animal Component of Research Protocol (ACORP) is complete and accurate. I understand that IACUC approval is valid for one year only, that approval must be renewed annually, that every third year the IACUC must perform a new review of my protocol, and that I might be required to complete a newer version of the ACORP and provide additional information at the time of the triennial review. I also understand that IACUC approval must be obtained before I:

- Use additional animal species, increase the number of animals used, or increase the number of procedures performed on individual animals;
- Change procedures in any way that might increase the pain/distress category in which the animals are placed, or might otherwise be considered a significant departure from the written protocol;
- Perform additional procedures not described in this ACORP;
- Allow other investigators to use these animals on other protocols, or use these animals on another of my IACUC-approved protocols.

I further certify that

- No personnel will perform any animal procedures until they have been approved by the IACUC. When new or additional personnel become involved in these studies, I will submit their qualifications, training, and experience to the IACUC and seek IACUC approval before they are involved in animal studies;
- I will ensure that all personnel are enrolled in the institutional Occupational Health and Safety Program prior to their contact with animals;
- I will provide my after-hours telephone numbers to the VMU in case of emergency.

Name of Principal Investigator(s)	Signature	Date

6. **Minority Opinions (For IACUC Use).** IACUC members must be given the opportunity to submit minority opinions on this form. Enter any written minority opinions here (or attach separate pages labeled "IACUC Minority Opinion"). If there are no minority opinions, leave this space blank.

3. **Approval Signatures.**

a. To the best of their abilities, the undersigned have evaluated the care and use of the animals described in 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, and find the procedures in this ACORP to be appropriate.

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

- b. The VA Research and Development Committee concurs with approval of the procedures described in this ACORP, and has approved the overall scientific merit of this project.

Name of R&D Committee Chair	Signature	Date

### ACORP Appendix 1, DRAFT USE OF NON-VA ANIMAL FACILITY

1. Indicate which non-VA facilities will house animals purchased with VA or VA Foundation funds for this project, and give the current AAALAC International accreditation status for each. Be sure to consider affiliated institutions and contract facilities that purchase and house animals on your behalf to make custom antibodies or other biological products. Consult with your veterinarian or IACUC to determine which institutions must be entered. USDA policies and PHS policy clarifications may also be helpful. Once completed, proceed to item 2.

Non-VA Facility Name	Is this facility accredited by AAALAC?	
	Yes	No*
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>

\*According to VHA Handbook 1200.7, "Use of Animals in Research", section 6.d., all VA animal facilities and affiliate or other animal facilities that house animals purchased with VA (including VA Foundation) funds must be accredited by AAALAC. Under exceptional circumstances, a waiver may be requested in writing from the CRADO (Chief Research and Development Officer) or designee through the CVMO (Chief Veterinary Medical Officer). See Appendix A of VHA Handbook 1200.7 for information on how to contact the CVMO.

2. In what non-VA building(s) and room(s) will the animals be housed?
3. Return to item N.2. on the ACORP.

## ACORP Appendix 2, DRAFT ANTIBODY PRODUCTION

1. **Monoclonal Antibody Production.** Will monoclonal antibodies be produced in animals or harvested from hybridoma cell lines as part of this project?

- No. Proceed to item 3.  
 Yes. Complete item 1.a.

a. Is antibody harvest limited to existing hybridoma cell lines with no further immunizations or lymphocyte fusions planned?

- Yes. Proceed to item 2 below.  
 No. Fill out items 1.b and 1.c below; then proceed to item 2.

b. Complete the following table regarding the immunization protocol for the animals prior to lymphocyte harvest for hybridoma creation. For each antigen for which multiple immunization days will be used, use a separate row in the table for each immunization day.

<u>Injection day (e.g. day 0, 7, 30, etc.)</u>	<u>Antigen</u>	Total amount (mg) and volume (ml) of antigen injected	Identity and volume (ml) of adjuvant injected	Total injection volume per animal (antigen plus adjuvant; ml)	Divided into how many injections?	Injection route and location of injections on body

c. If feeder cells for supporting hybridoma colony growth will be collected from animals, describe the exact procedures that will be used to collect the feeder cells and the number of animals needed for this purpose.

2. You must consider alternate research methods that can replace the use of animals. Will any animals be used to expand hybridoma cell lines so that antibody can be harvested from ascites fluid?

- No. Proceed to item 2.d.  
 Yes. Complete items 2.a-2.c below; then proceed to item 2.d.

a. Explain why *in vitro* cell culture systems for harvesting monoclonal antibodies are not adequate to meet the research objectives.

b. Complete the following table.

Hybridoma cell line designation	Number of animals used for ascites production	Priming agent and volume	Number and timing of priming injections	Volume of injected hybridoma cells	Number of abdominal taps before euthanasia

c. What criteria will be used to determine if animals should be euthanatized prior

to the last planned abdominal tap?

- d. **Blood collection.** Will survival blood collections be obtained from animals following immunization or as a “pre-bleed” prior to immunization?
- No. Proceed to item 3.
- Yes. Complete items 1) and 2) below; then proceed to item 3.

1) Complete the following table; include any “pre-bleeds” prior to immunizations.

Site of blood collection	Amount of blood collected expressed as volume (ml) and % of body weight (assume 1 ml weighs 1 gram)	Number of blood collections	Interval between collections

2) Will anesthetics, tranquilizers, or analgesics be used prior to blood collection?

- No. Justify the omission of pain-relieving agents below; then proceed to item 3.
- Yes. Describe the administration of pain-relieving agents including dose (mg/kg), volume (ml), route, and frequency/duration; then proceed to item 3.

3. **Polyclonal Antibody Production.** Will polyclonal antibodies be produced in this species of animal as a part of this project?
- No. **Do not** complete items 3.a.-3.c. Go to item 4 below.
- Yes. Complete items 3.a.-3.c., then go to item 4.

a. Complete the following table. For each antigen for which multiple immunization days will be used, use a separate row in the table for each day.

<u>Injection day (e.g. day 0, 7, 30, etc.)</u>	<u>Antigen</u>	Total amount (mg) and volume (ml) of antigen injected	Identity, concentration and volume (ml) of adjuvant injected	Total injection volume per animal (antigen plus adjuvant; ml)	Divided into how many injections?	Injection route, and location of injections on body

b. List possible adverse effects in animals that might be seen from the proposed antigen or adjuvant injections and what measures will be taken should these adverse effects occur.

- c. **Blood collection.** Will survival blood collections be obtained from animals following immunization or as a “pre-bleed” prior to immunization?
- No. Proceed to item 4.
- Yes. Complete items 3.c.1) and 2); then proceed to item 4.

1) Complete the following table; include any “pre-bleeds” prior to

immunizations.

Site of blood collection	Amount of blood collected expressed as volume (ml) and % of body weight (assume 1 ml weighs 1 gram)	Number of blood collections	Interval between collections

2) Will anesthetics, tranquilizers, or analgesics be used prior to blood collection?

- No. Justify the omission of pain-relieving agents below; then proceed to item 4.  
 Yes. Describe the administration of pain-relieving agents including dose (mg/kg), volume (ml), route, and frequency/duration below; then proceed to item 4.

4. **Terminal blood collection.** Will animals used for antibody production be exsanguinated as a method of euthanasia?

- No. Go to item 5.  
 Yes. Complete items 4.a, b., and c. below, then go to item 5.

a. Describe the method of exsanguination.

b. Will anesthetics, tranquilizers, or analgesics be used prior to exsanguination?

- No. Justify the omission of pain-relieving agents below; then proceed to item 5.  
 Yes. Describe the administration of pain-relieving agents including dose (mg/kg), volume (ml), route, and frequency/duration here; then proceed to item 5.

c. How will you make sure that the animals are dead following blood withdrawal?

5. How will the antigens or cell lines listed in items 1.b., 2.b., and 3.a. be screened to make sure they do not harbor infectious agents that could infect other laboratory animals or people after injection?

6. Return to the main ACORP form and continue with item P.

### ACORP Appendix 3, DRAFT TEST SUBSTANCES

1. **Toxic Agents.** Will toxic chemicals, toxic pharmacologic agents, known or suspected mutagens, carcinogens, teratogens, DNA-binding, or other similar agents be used in animals?

- No. Proceed to item 2.  
 Yes. Complete items 1.a, 1.b, 1.c, and 1.d, then proceed to item 2.

a. Table of toxic agents.

Agent	Diluent	Route of admin.	Dose (e.g. mg/kg) and Volume (ml)	Frequency and duration of administration	Reason for admin., and expected effects

- b. Indicate which of the above agents, if any, are known or suspected mutagens, carcinogens, or teratogens.
- c. Are any of the agents above on the CDC list of “select agents” that might have bioterrorism uses? Check the appropriate response below and proceed to item 2.d.
  - No.
  - Yes. Ask your research office to contact the VAHQ Biosafety Officer for further instructions as soon as possible. You will have to obtain a CDC license and HQ approval before beginning your studies with this agent.
- d. Will the animals be anesthetized or sedated when these agents are administered?
  - No. Proceed to item 2.
  - Yes. Detail the method of anesthetic, sedative, or tranquilizer administration including agent, dose and volume, and route; then proceed to item 2.

2. **Infectious Agents.** Will bacterial, viral, rickettsial, fungal, protozoal, or other infectious agents be used in animals? If the agent will have a radioactive label added, also complete item 4 below. Likewise, if the infectious agent contains recombinant nucleic acid, fill out item 6 below for the agent as well.

- No. Proceed to item 3.
- Yes. Complete items 2.a, 2.b, 2.c, and 2.d; then proceed to item 3.

a. Complete the table below.

Agent and strain or construct	CDC Biosafety Level of agent (BSL1, 2, 3, 4)	Route of admin.	Dose (e.g. CFU, PFU) and volume administered (ml)	Frequency of administration

- b. Has an antibiogram, anti-viral drug sensitivity screen, or other appropriate drug sensitivity panel been determined for the agent(s) listed to assist physicians in selecting proper therapy if an inadvertent human infection occurs?
- c. Will the animals be anesthetized or sedated when these agents are administered?
  - No. Proceed to item 2.d.
  - Yes. Detail the method of anesthetic, sedative, or tranquilizer administration including agent, dose and volume, and route; then proceed to item 2.d.
- d. Are any of the agents on the CDC list of “select agents” that might have bioterrorism uses? Check the appropriate response below and proceed to item 3.
  - No.
  - Yes. Ask your research office to contact the VAHQ Biosafety Officer for further instructions as soon as possible. You will have to obtain a CDC license and HQ approval before beginning your studies with this agent.

3. **Biological Materials.** Will serum, cell lines, tissue, nucleic acid or other biological materials be administered to animals? If any of the agents are radioactive or will have a radioactive label added, also complete item 4 for that agent.

- No. Proceed to item 4.
- Yes. Complete items 3.a., 3.b., and 3.c.; then proceed to item 4.

a. Table of biological materials.

Material (e.g. fluid, cells, tissues)	Diluent	Source (e.g. vendor, other animals, colleague)	Route of admin.	Dose (e.g. ml/kg, mg/kg, cells/kg) and volume (ml)	Frequency and duration of admin.	Reason for admin., and expected effects

b. Will the animals be anesthetized or sedated when these agents are administered?

- No. Proceed to item 4.  
 Yes. Detail the method of anesthetic, sedative, or tranquilizer administration including agent, dose and volume, and route; then proceed to item 4.

c. How will these materials be screened to make sure they do not harbor infectious agents that could infect other laboratory animals or people?

4. **Radioactive Agents.** Will radioactive compounds or agents be administered to animals?

- No. Proceed to item 5.  
 Yes. Complete items 4.a., 4.b., and 4.c.; then proceed to item 5.

a. Table of radioactive agents.

Radioactive Agent (include isotope)	Diluent	Agent dose (mg/kg) and Vol. (ml)	Activity (e.g. mCi/kg)	Route of admin.	Frequency and duration of admin.	Reason for admin., and expected effects

b. Which investigator has been given permission by the Radiation Safety Committee or equivalent committee to utilize the isotope(s) indicated above?

c. Will the animals be anesthetized or sedated when these agents are administered?

- No. Proceed to item 5.  
 Yes. Detail the method of anesthetic, sedative, or tranquilizer administration including agent, dose and volume, and route; then proceed to item 5.

5. **Other Agents.** Will other substances not listed previously in this appendix be administered to animals? Do not include anesthetics/analgesics/sedatives you will describe elsewhere in the ACORP as part of surgery and postoperative care.

- No. Proceed to item 6.  
 Yes. Complete items 5.a. and 5.b.; then proceed to item 6.

a. Table of other agents.

Agent	Diluent	Agent dose (e.g. mg/kg) and Vol. (ml)	Route of admin.	Frequency and duration of admin.	Reason for admin., and expected effects



- b. Will the animals be anesthetized or sedated when these agents are administered?
  - No. Proceed to item 6.
  - Yes. Detail the method of anesthetic, sedative, or tranquilizer administration including agent, dose and volume, and route; then proceed to item 6.

6. **Recombinant nucleic acid and recombinant infectious agents.**

- a. Do any of the agents noted above in items 1-5 above have recombinant nucleic acid in them?
  - No. Proceed to item 7.
  - Yes. Answer item 6.b.
- b. Are the recombinant constructs exempt from the animal research guidelines included in the latest version of the *NIH Guidelines for Recombinant DNA and Gene Transfer* publication?
  - No. You must conduct the animal experiments involving recombinant nucleic acid according to the *NIH Guidelines for Recombinant DNA and Gene Transfer*. Consult with your Biosafety Committee and veterinarian to make sure you comply. Go to item 7.
  - Yes. Go to item 7

7. **Pain or Distress.** Will animals potentially experience pain and/or distress as a result of the administration of agents listed above in items 1, 2, 3, 4, 5, or 6?

- No. Proceed to item 8.
- Yes. Describe the nature of the pain and/or distress that animals might experience and describe measures that will be taken to alleviate any pain and/or distress. Then proceed to item

8. **Hazardous/Toxic Agents.** Are any of the agents listed above in items 1-6 hazardous or toxic to humans or animals, or covered by the *NIH Guidelines for Recombinant DNA and Gene Transfer*?

- No. **You have completed this appendix; no further information is required in this appendix. Go to item Q on the ACORP. YOU DO NOT NEED TO GET SIGNATURES IN ITEM 9. BELOW!**
- Yes. Complete items 8.a., 8.b., and 9; then return to item Q on the ACORP.

a. Table of hazardous agents, committee approvals, and personnel exposed.

Toxic or hazardous agent(s) from items 1-5 above, or non-exempt agent(s) from item 6.	Safety, biosafety, or radiation safety committee that has approved the use of this hazardous agent	Is this a VA or affiliate committee?	List all animal facility staff who will come in contact with animals given these agents or with contaminated bedding, cages, or other items.

- b. Discuss how the individuals listed in the table above (item 8.a.) have been (or will be) informed of the possible risks of exposure, and have been (or will be) trained to avoid exposure to these agents.

9. **Signatures.** By our signatures, we certify that:

- a. Before any animal experiments involving the agents listed in item 8.a. are performed, SOPs designed to protect all animal facility staff as well as non-study animals will be developed and approved by the appropriate VA or affiliated university safety committee and the IACUC; and
- b. All staff that might be exposed to these agents will be informed of possible risks and will be

properly trained to follow the SOPs to minimize the risk of exposure. As is appropriate, concurrence signatures from biosafety or radiation safety personnel are also required as shown.

Principal Investigator(s)	Signature(s)	Date
Institutional Veterinarian	Signature	Date
Biosafety Officer or Chair, Research Safety or Biosafety Committee (typed)	Signature	Date
Radiation Safety Officer, or Chair, Radiation Safety or Isotope Committee (typed)	Signature	Date
IACUC Chair (typed)	Signature	Date

### **ACORP Appendix 4, DRAFT ANTEMORTEM SPECIMEN COLLECTION**

- Blood Collection.** Will blood be collected from live animals (anesthetized or awake) as a part of this proposal?

No. Proceed to item 3.

Yes, but all collections are described in Appendix 2, “Antibody Production”, so no further information need be provided here; proceed to item 3.

Yes. Complete the table below; then proceed to item 2.

Site and Method of blood collection	Amount of blood collected, expressed as volume (ml) and % of body weight (assume 1 ml of blood weighs 1 gram)	Number of blood collections	Interval between collections

- Use of Anesthetics, Tranquilizers, or Analgesics for Blood Collection.** Will anesthetics, tranquilizers, or analgesics be used to prevent pain or stress during collection of blood described in item 1 above?

- No. Justify the omission of pain-relieving agents (either scientifically or because the collection method involves no or momentary pain) and completely describe the physical restraint that will be used during collection here:
- Yes. Complete the following table, then proceed to item 3.

Anesthetic, tranquilizer, or analgesic agent	Dose (mg/kg) & volume (ml)	<u>Route</u>	<u>Frequency</u>

3. **Other Tissue Collection.** Will other body fluids (e.g. cerebrospinal fluid, peritoneal fluid, urine) or tissues be collected from live animals (awake or anesthetized) as a part of this protocol?
- No. Proceed to item 5.
  - Yes. Complete the following table; then proceed to item 4.

Tissue or fluid collected	Site & method of collection	Amount (g) or volume (ml)	Number of collections	Interval between collections

4. **Use of Anesthetics, Tranquilizers, or Analgesics for Collection of Fluids or Tissues.** Will anesthetics, tranquilizers, or analgesics be used to prevent pain or stress during collection of body fluids or tissues described in item 3 above?
- No. Justify the omission of pain-relieving agents (either scientifically or because the collection method involves no or momentary pain) and completely describe the physical restraint that will be used during collection here, then go to item 5:
  - Yes. Complete the following table, then go to item 5

Anesthetic, tranquilizer, or analgesic agent	Dose (mg/kg) & volume (ml)	<u>Route</u>	<u>Frequency</u>

5. Proceed to item S on the ACORP.

## ACORP Appendix 5, DRAFT SURGERY

1. **Major survival surgery.** The *Guide* defines a major survival surgery as a surgery in which a major body cavity is penetrated and exposed or surgery in which substantial impairment of physical or physiological functions is produced. Examples of such surgeries provided in the *Guide* include laparotomy, thoracotomy, craniotomy, joint replacement, and limb amputation.
- a. Will more than one major survival surgery be performed on any animal as part of the proposed experimental plan?

- No. Proceed to item 2.
- Yes. Complete item 1.b. and 1.c. below.

- b. Provide a complete scientific justification for performing more than one major survival surgery on individual animals.
- c. Give the interval(s) between the multiple surgeries, and the rationale for choosing the interval(s), then proceed to item 2.

2. **Description of Procedure(s).** Describe the surgical procedure(s) in enough detail so that the IACUC reviewers can determine what procedure(s) are actually being performed. If several different surgeries are being performed, be sure to describe each one. When finished, proceed to item 3.
3. Provide the names of the personnel who will perform the surgery; then proceed to item 4. Note that the surgical experience of each person involved in surgery should be listed in item E of the ACORP.
4. Provide the names of the personnel who will perform the anesthetic induction and monitor the animal during surgery. Then proceed to item 5.
5. Provide the building and room number(s) where the surgical procedure(s) will be performed. A dedicated surgical facility must be used for major survival surgeries on non-rodent species (the definition of a major survival surgery is provided in item 1 above). If allowed by local policy, non-survival surgery on non-rodent species and survival surgery on rodent species may be performed in a procedure room or laboratory. Then proceed to item 6.
6. **Pre-operative procedures.** Pre-operative procedures should include all preparations of the animal(s) for surgery. Check and describe which of the following procedures will be performed. Then proceed to item 7.
  - Fasting (rarely used in rodents or rabbits). Indicate the length of the fasting period.
  - Withhold water. Indicate the length of time that water will be withheld.
  - Catheter placement. Indicate the site(s) in which venous catheter(s) will be placed for vascular access during surgery.
  - Other. Describe other pre-operative procedures.
7. **Pre-operative medications.** Complete the following table. Include any antibiotics, sedatives, or tranquilizers, and the anesthetic agent(s) that will be used to induce anesthesia prior to surgical site preparation; then proceed to item 8.

Agent	Dose (mg/kg) & volume (ml)	<u>Route</u>	Frequency (e.g. times/day)	Duration (e.g. days)

8. **Preparation of the surgical site.** Describe how the surgical site(s) will be prepared prior to surgery. Include details of hair-clipping, skin disinfection, and the use of surgical drapes. Then proceed to item 9.
9. **Intraoperative medications.** Complete the following table including any anesthetic agents, paralyzing agents, fluids, or other pharmaceuticals that will be administered to the animal during surgery. Also include experimental pharmaceuticals. Then proceed to item 10.

Agent	Dose (mg/kg) & volume (ml)	Route	Frequency

10. **Paralyzing agents.** Are any of the above medications considered paralyzing agents?
- No. Proceed to item 11.
- Yes. Federal regulations prohibit the use of paralytics (neuromuscular blocking agents) for surgery unless other appropriate anesthetic agents are used to induce a surgical plane of anesthesia. Paralytics do not provide any pain relief; therefore, animals are unable to respond physically to pain because motor reflexes are paralyzed. Justify the use of these agents and indicate how the animals will be monitored to ensure that the depth of anesthesia is sufficient to prevent pain. Then proceed to item 11.
11. **Physical support.** Indicate any physical methods used to support patients during surgery (e.g. heating pads, blankets, etc.); then proceed to item 12.
12. **Intra-operative monitoring.** Describe methods used to monitor the state of anesthesia and general well-being of the animal during surgery. Then proceed to item 13.
13. Will the animals regain consciousness following surgery?
- No. You have completed this appendix. *No further information is required in this appendix. Return to item T on the ACORP itself.*
- Yes. Proceed to item 14.
14. **Survival surgery considerations and post-operative care.** Complete items 14.a-f. below. Then proceed to item 15.
- a. How long will the animal(s) survive after surgery? (If multiple surgeries are planned, answer for the last surgery before euthanasia.)
- b. Is the room where the procedures will be performed (listed in item 5 above) suitable for sterile/aseptic surgery?
- c. Indicate which of the following procedures will be used to maintain a sterile field during surgery:
- Sterile instruments.
- Surgeon cap.
- Sterile gloves.
- Surgeon scrub.
- Sterile drapes.
- Sterile gown.
- Face mask.
- Other. Describe:
- d. List any physical methods used to support the patients in the immediate post-operative period (e.g., heating pads, blankets, fluids, etc.).
- e. Unless scientifically or otherwise justified to the IACUC's satisfaction, you are obligated to routinely provide post-operative pain relief for all vertebrate animals undergoing survival surgery. Do you plan to use analgesics to provide postoperative pain relief to the animals following surgery?

- No. Provide a justification for not using postoperative analgesics.
- Yes. Complete the following table listing post-operative analgesics agent(s) that will be used after surgery to control pain.

Agent	Dose (mg/kg) & Volume (ml)	Route	Frequency (e.g. times/day)	Duration (e.g. days)

- f. Complete the following table for other medications (such as fluids, antibiotics, anti-coagulants, and other pharmacological agents) that will be administered post-operatively.

Agent	Dose (mg/kg) & Volume (ml)	Route	Frequency (e.g. times/day)	Duration (e.g. days)

15. **Frequency and Responsibility for post-operative care.** Complete items 15.a. and 15.b. below. Then proceed to item 16. The names and after-hours telephone (or other contact) numbers of the personnel listed below must be provided to the VMU staff in case of an emergency.

- a. Give the frequency of postoperative monitoring and how long the monitoring will continue.
- b. Who will be responsible for post-operative care until the animal can ambulate without danger to itself?
- c. Who will be responsible for post-operative care thereafter (including after-hours, weekends, and holidays)?

16. **Post-operative complications.** Complete items 16.a. - d. below; then proceed to item 17.

- a. Describe any possible or expected post-operative complications and what will be done if these complications arise.
- b. Provide criteria by which a decision to euthanize a surgical patient post-operatively will be made.
- c. In case there is an emergency medical situation and you or your staff cannot be reached, identify drugs or classes of drugs that should not be used as part of the treatment plan.
- d. In the event that emergency euthanasia must be performed or an animal is unexpectedly found dead, how should the carcass be handled?

17. **Responsibility for maintaining animal post-surgical medical records.** Who will be responsible for maintaining accurate, daily, post-surgical written medical records?

- My research staff or I will be responsible. Proceed to item 18 below.

- The veterinary staff will be responsible. Proceed to item 18 below.
- Local policy does not mandate that postoperative medical records be maintained for the species covered by this ACORP. **You have completed this Appendix. Do not answer item 18 or sign under item 18. Instead, go to item T on the ACORP.**
- Other. Please explain, then proceed to item 18 below.

18. **Certifications.** Complete the following; then return to item T on the ACORP and continue.

By my signature, I certify that

- Each patient under observation or treatment will be identified such that care for individual animals can be documented.
- Daily postoperative medical records of the patient will be maintained, including an evaluation of overall health, a description of any complications noted, treatment provided, and the removal of sutures, staples, wound clips, or other such devices.
- Records will document administration of all medications and treatments given to animals, including those given to reduce pain or stress.
- As a minimum, daily records will cover the postoperative period as defined by local policy.
- Each entry in the records will include a signature or the initials of the person making the observation or treatment.
- All records will be readily available to the veterinary staff or the IACUC for review.
- The names and contact numbers of persons to notify or consult in case of emergencies will be provided to the facility manager and veterinarian.

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

### **ACORP Appendix 6, DRAFT SPECIAL HUSBANDRY AND PROCEDURES**

1. **Special Husbandry.** Are special husbandry practices required for this protocol that are not described in the local Standard Operating Procedures (SOP) manual? Examples of special husbandry practices include temperature extremes, food or water deprivation, dietary manipulations, calorie restrictions, special housing/caging, modified light cycle, special health monitoring, and unusual means of identification.
  - No. Proceed to item 2.
  - Yes. Complete items 1.a. and 1.b.; then proceed to item 2.
  - a. Provide a complete description of all non-standard practices or procedures. Make sure that the frequency and duration of these practices or procedures are stated.
  - b. Justify the use of these non-standard practices or procedures.
  
2. **Other Procedures.** Are special procedures such as prolonged physical restraint, use of noxious stimuli, forced exercise, behavioral manipulations, total or partial body irradiation, radiography or other imaging studies planned but not described elsewhere in the ACORP?
  - No. Proceed to item 3.
  - Yes. Complete items 2.a. and 2.b.; then proceed to item 3.
  - a. Check which of the following procedures are proposed:

- Prolonged physical restraint, including chairing.
- Noxious stimuli.
- Forced exercise.
- Behavioral manipulations.
- Other. Describe:

c. Describe each procedure and the expected outcome(s) in detail. Make sure that the frequency, duration, and interval between repeated manipulations are described.

3. Identify the personnel who will perform the procedures and practices listed in items 1 and 2 and the personnel that will be responsible for monitoring the condition of these animals. After-hours telephone (or other contact) numbers of the personnel listed must be provided to the veterinary staff in case of an emergency.
4. Do the practices or procedures have the potential to cause more than momentary pain and/or discomfort?
  - No. You have completed this appendix; **no further information is required in this appendix. Go to item W on the ACORP.**
  - Yes. Describe the potential pain and/or discomfort below; then proceed to item 5.
5. Will pain or stress-relieving agents be administered to the animals that experience pain and/or discomfort? Then proceed to item 6.
  - No. Provide a scientific justification for not using pain or stress relieving agents.
  - Yes. Fill out the table below.

Agent	Dose (mg/kg) & volume (ml)	<u>Route</u>	Frequency (e.g. times/day)	Duration (e.g. days)

6. Describe the methods used to monitor the condition of the animals during and after the practices or procedures and the criteria that will be used to remove individual animals from these practices and/or procedures should pain or suffering be present.
7. Proceed to item W on the ACORP.

**ACORP Appendix 7, DRAFT**  
**REQUEST TO USE PATIENT CARE PROCEDURAL AREAS FOR ANIMAL STUDIES**

1. Name of Principal Investigator(s):
2. Provide a concise statement of the potential benefit to VA patients if a patient care area is used for research involving animals.
3. Why can't the animal facility or a laboratory area be utilized for the proposed procedures?
4. Identify the species and number of animals to be used.
5. Discuss the potential pain and/or distress to animal subjects during the procedures to be conducted in a patient procedural area, and interventions planned for the prevention or alleviation of such pain/distress.
6. Identify the equipment and location (building and room numbers) of the patient care area(s) to be used.

7. List the date(s) and time of day that the procedure(s) will be performed.
8. Discuss the method of transporting the animals to and from the procedural area. Include a description of the transport containers, any vehicles used, and precautions to be taken to avoid contact with patients, visitors, and other non-research personnel.
9. Provide a complete description of the measures to be taken to prevent the transmission of diseases or parasites from animals to patients and patient care personnel.
10. Provide a complete description of the measures to be taken to prevent disturbances (e.g., noise, odors) to patients and patient care personnel.
11. Provide a complete description of methods to be employed to prevent contamination of equipment and room surfaces by animal feces, urine, saliva, blood, or other body fluids.
12. Provide details of the procedures to be followed in cleaning and disinfecting equipment and room surfaces following use.
13. Required signatures. (If this appendix is part of an ACORP, return to item X.3. on the ACORP.)

a. Principal Investigator(s) submitting this request.

Name(s) of Principal Investigator(s) (typed)	Signature(s)	Date

b. Approving officials.

Name of IACUC Chair (typed)	Signature	Date
Name of Attending Veterinarian (VMO or VMC, typed)	Signature	Date
Chair, Clinical Executive Board or Service Chief responsible for the patient care equipment (typed)	Signature	Date
ACOS for R&D (typed)	Signature	Date
Chief of Staff (typed)	Signature	Date
Facility (Hospital or Clinic) Director or CEO (typed)	Signature	Date

## ACORP Appendix 8, DRAFT REQUEST TO USE EXPLOSIVE AGENT

1. Principal Investigator(s):
2. Give the name(s), title(s), and prior pertinent training and experience of individuals who will administer the explosive agent.
3. Name of the explosive agent(s), and the Material Safety Data Sheet number(s):
4. Why can't a non-explosive agent or agents be used instead?
5. Give the beginning and ending dates during which the explosive agent(s) will be used.
6. Give a brief description of the studies for which the use of an explosive agent is proposed.
7. Give the species, weight, and approximate number of animal subjects that will be administered the explosive agent(s).
8. Give the building and room number in which agent(s) will be used.
9. Give a detailed description of the procedure(s) involving the explosive agent(s) including assurance that: a) procedures are performed within a properly operating, ventilated safety hood, b) all electrical equipment used with the agent are placed and powered outside the hood, c) once the seal is broken on containers of ether or other explosive anesthetic agents, they will be placed into a safety hood throughout use, stored in an explosion proof refrigerator, or safety hood, and discarded properly once used up, and d) that proper disposal procedures for items (including carcasses) containing traces of the agent will be safe and appropriate. (When finished, proceed to item Y on the ACORP.)
10. Required signatures.

a. Principal Investigator(s) submitting this request.

Name(s) of Principal Investigator(s) (typed)	Signature(s)	Date

b. Approving officials.

Name of IACUC Chair (typed)	Signature	Date
Name of Attending Veterinarian (VMO or VMC, typed)	Signature	Date
Facility Safety Officer (typed)	Signature	Date
ACOS for R&D (typed)	Signature	Date

VISN Regional Safety Officer (typed)	Signature	Date

**ACORP Appendix 9, DRAFT  
ADDITIONAL LOCAL INFORMATION**

(This appendix may be used to collect additional information needed by the local IACUC)