

**ANIMAL COMPONENT OF RESEARCH PROTOCOL (ACORP)**  
**Main Body**  
**VERSION 4 (LOCAL REVISION 1)**

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

**A. ACORP Status.**

1. 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). Include grant title, grant #, & UW WISPER #
  - ( ) 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 briefly summarize 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 senior high school student would understand, briefly describe how this research project is intended to improve the health of people and/or other animals, or otherwise to serve the good of society, and explain how these benefits outweigh the pain or distress that may be caused in the animals that are to be used for this protocol.



C. **Experimental Design.**

1. **Lay Summary.** Using non-technical (lay) language that a senior high school student would understand, summarize the conceptual design 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. PI

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 CITIPROGRAM.ORG 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:

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

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

► ( ) 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

I. **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 / Procedure(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 <i>Guide</i> 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)



\*\*\*Use Appendix 9 to document “departures” from the standards in the *Guide*.

- 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.



- 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.



► ( ) Devices that extend chronically through the skin WILL be implanted into some or all animals on this protocol. Describe any customized routine husbandry to be provided by animal husbandry staff to 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?	
		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 accredited by AAALAC?		Building	Room Number
	Yes -- enter status*	No**		
	( )	( )**		
	( )	( )**		
	( )	( )**		

\*See ACORP Instructions, for a list of AAALAC accreditation status options.

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

**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”.

► ( ) 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.

Also answer the following:

► ( ) All compounds given to living animals will be pharmaceutical grade. --OR --

► ( ) All compounds given to living animals will be pharmaceutical grade, except for the following:  
 (provide list of compounds, justify the use of each one, and describe how it will be compounded).

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.

Add a concise statement as of the reason animals must leave the ARF and enter the VA.

►

Procedure	Surgical?		Bldg/Room Number	Requires transport through non-research areas? See policy #32, describing approved methods of animal transport	
	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.

Body Fluid, Tissue, or Device to be Collected	Collected AFTER Euthanasia	Collected BEFORE 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.) Review (Body Condition Scoring: A Rapid and Accurate Method for Assessing Health Status in Mice. Mollie H. Ullman-Culleré and Charmaine J. Foltz. *Laboratory Animal Science*. Vol 49, No 3, June 1999)



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. Describe the disposition of these animals. (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 method that may be used on this protocol	Method of Euthanasia	Species	AVMA Classification		
			Acceptable	Conditionally Acceptable	Unacceptable
( )	CO <sub>2</sub> 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:  
 ►
3. 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.

► ( ) 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.

Name of Procedure	Identify Where the Details of the Procedure are Documented		
	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.

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

(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.

1. 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.

Please use the **Animal Research Alternatives and Animal Care Guide** for online literature searches to demonstrate that you have searched for alternatives for 1) using animals in research 2) minimize painful procedures.: <http://researchguides.library.wisc.edu/animalalternatives>

Name of the database	Date of search	Period of years covered by the search	Potentially painful or distressing procedures addressed	Key words and/or search strategy used	Indicate which mandate each search 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. **Replacement**. 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. **Reduction**. 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. **Refinement**. 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 **unnecessarily** 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.

Controlled substances	Storage		Personnel Authorized to Access	Location for Use		Procurement	
	Double-locked	Not Double-locked*		VA Property	Not on VA Property	VA Pharmacy	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.



- 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. Do not check off or attach any appendices that are not applicable to this ACORP.

- ▶ ( ) 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*”
- ▶ ( ) Appendix 10 “Breeding”
- ▶ ( ) Appendix 11 “Overnight Housing in Labs”

**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.

Item	SOP		Approval Date
	Title	ID	
C.2.c	N/A		
M.1			
M.2			
U.4.a	N/A		
U.4.b	N/A		
V	N/A		

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. Do NOT include signatures for, or attach, any appendices that do NOT apply.

1. **Main Body of the ACORP.**

a. **Certification by Principal Investigator(s):**

I certify that, 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.

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

- 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 after-hours contact information 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
<b>Robert Taylor, DVM</b>		
Name of IACUC Chair	Signature	Date
<b>Thomas Pugh, PhD</b>		

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 non-study 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.

Name(s) of Principal Investigator(s)	Signature(s)	Date
Name of Institutional Veterinarian	Signature	Date
<b>Robert Taylor, DVM</b>		
Name of IACUC Chair	Signature	Date
<b>Thomas Pugh, PhD</b>		

**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
<b>Randy Wolff, PhD</b>		

**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
<b>Diane Meranda, BS</b>		

**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.
  - 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).** I certify that, 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
<b>Thomas Pugh, PhD</b>		
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 have granted approval 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
<b>Thomas Pugh, PhD</b>		
Name of Attending Veterinarian (VMO or VMC)	Signature	Date
<b>Robert Taylor, DVM</b>		
Name of the Chair of the Clinical Executive Board, or the Service Chief responsible for the Patient Care Area and Equipment	Signature	Date
Name of ACOS for R&D	Signature	Date
<b>Nasia Safdar, MD, PhD</b>		
Name of Chief of Staff	Signature	Date

<b>Alan Bridges, MD</b>		
Name of Director or CEO of the Facility (Hospital or Clinic)	Signature	Date
<b>Judy K. McKee, FACHE</b>		

**8. Appendix 8. Use of Explosive Agent(s) within the Animal Facility or in Animals.**

**a. Certification by the Principal Investigator(s).**

I certify that, 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 have granted approval.

Name of IACUC Chair	Signature	Date
<b>Thomas Pugh, PhD</b>		
Name of Attending Veterinarian (VMO or VMC)	Signature	Date

<b>Robert Taylor, DVM</b>		
Name of Safety/Biosafety Officer for the Facility	Signature	Date
<b>Randy Wolff, PhD</b>		
Name of ACOS for R&D	Signature	Date
<b>Nasia Safdar, MD, PhD</b>		
Name of VISN Regional Safety Officer	Signature	Date

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

10. **Breeding Appendix no signatures required**

11. **Appendix 11 “Over Night Housing Appendix”**

Certification by the officials responsible for housing of animals >12 hours and/or overnight in a VA Research Laboratory. Each of the following must sign to verify that they or the committee they represent have granted approval.

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

Approving officials

IACUC Chair	Signature	Date
<b>Thomas Pugh, PhD</b>		
Attending Veterinarian	Signature	Date
<b>Robert Taylor, VMC</b>		
Animal Research Facility Supervisor	Signature	Date
<b>Robin Faust, BA, rALAT</b>		
Research Environment of Care Coordinator	Signature	Date
<b>Diane Meranda, BS</b>		
Environmental Care Supervisor	Signature	Date
<b>John Butterbaugh</b>		

ACOS for R&D	Signature	Date
<b>Nasia Safdar, MD, PhD</b>		
Chief of Staff	Signature	Date
<b>Alan Bridges, MD</b>		
Hospital Director	Signature	Date
<b>Judy K. McKee, FACHE</b>		

**ACORP Appendix 1**  
**ADDITIONAL LOCAL INFORMATION**  
**VERSION 4**

(This appendix may be used to collect additional information required by the local IACUC. See ACORP App. 1 Instructions, for more detailed explanations of the information requested.)

**ACORP APPENDIX 2  
 ANTIBODY PRODUCTION  
 VERSION 4**

See ACORP App. 2 Instructions, for more detailed explanations of the information requested.

1. **Immunization.** Provide the information requested below for any animals to be used for raising antibodies specifically for use in this protocol.

a. Describe the immunization protocol in the table below, using a separate row for each day on which any agent (including primer, antigen, and/or adjuvant) will be administered. (Make sure that each primer, antigen, and adjuvant is also included in Appendix 3.)

Immunization day (e.g. day -7, 0, 7, 30, etc.)	Antigen		Adjuvant – give name, concentration, and volume (ml)	Total injection volume (ml) per animal (antigen plus adjuvant)	Divided among how many injection sites?	Injection route and location of injection site(s) on body
	Name	Total amount (mg) <u>and</u> volume (ml)				

b. Describe how each antigen will be screened to make sure that it does not harbor infectious agents that could infect other laboratory animals or people after injection.



c. List possible adverse effects that might be observed in animals receiving the proposed primer, antigen, and/or adjuvant injections, and describe the measures that will be taken if these adverse effects occur:



d. Give the justification for using any primer or adjuvant that is expected to cause pain or distress in the animals.



2. **Survival Blood Collection.** Will blood be collected as a survival procedure for the production and harvesting of antibodies on this protocol?

► ( ) No, the production and harvest of antibodies on this protocol does not involve survival collection of blood.

► ( ) Yes, this protocol requires the collection of blood in a survival procedure, before (as a “pre-bleed”) and/or after immunization. Make sure this is included in Item R of the ACORP, and complete items 2.a, 2.b, and 2.c, below.

a. Describe each survival collection of blood in the table below, including any “pre-bleeds” prior to immunizations:

Site of Blood Collection	Amount of Blood Collected at any one time, expressed as volume (ml) <u>and</u> as % of body weight (assume 1 ml = 1 gram)	Number of Blood Collections	Time Interval(s) Between Successive Collections	Volume Replacement? (yes/no)

b. Will anesthetics, tranquilizers, or analgesics be administered for blood collection?

► ( ) No anesthetics, tranquilizers, or analgesics will be administered for blood collection. Explain why it is appropriate or necessary NOT to administer pain-relieving agents:

►

► ( ) Yes. Describe the administration of pain-relieving agents, including the name of each agent, and its dose (mg/kg), volume (ml), and route and frequency/duration of administration (Make sure this information is also included in Appendix 3):

►

c. Will volume replacement be provided for blood that is collected?

► ( ) Volume will NOT be replaced for some of the blood collection listed. For each collection listed in Item 2.a, above, for which volume will NOT be replaced, explain why not.

►

► ( ) Volume WILL be replaced for some of the blood collection listed. For each collection listed in Item 2.a, above, for which volume WILL be replaced, describe the replacement(s) that will be provided (including the composition of the replacement(s), volume, and route of administration).

►

3. **Terminal Blood Collection.** Will animals be euthanatized by exsanguination, for harvest of antibodies?

- ▶ ( ) No, this protocol does NOT involve terminal blood collection for harvest of antibodies.
- ▶ ( ) Yes, this protocol DOES require terminal blood collection for the harvest of antibodies. Make sure this is included in Item R of the ACORP, and complete Items 3.a., 3. b., and 3.c., below:

a. Describe the method(s) to be used for euthanasia and exsanguination:

▶

b. Will anesthetics, tranquilizers, or analgesics be administered for exsanguination?

- ▶ ( ) No anesthetics, tranquilizers, or analgesics will be administered for the exsanguination(s). Explain why it is appropriate or necessary NOT to administer pain-relieving agents:

▶

- ▶ ( ) Yes. Describe the administration of pain-relieving agents including the name of each agent, and its dose (mg/kg), volume (ml), and route and frequency/duration of administration (Make sure this information is also included in Appendix 3):

▶

c. Describe how you will make sure that the animals are dead after collection of the blood:

▶

4. **Harvesting Feeder Cells.** Describe the exact procedures (including administration of pain-relieving agents) that will be used on any donor animals from which feeder cells will be collected for this protocol, and estimate the number of animals needed for this purpose. Make sure that these animals are included in Item I of the ACORP, and that the harvesting of feeder cells is included in Item R of the ACORP.

▶

5. **Expansion of Hybridoma Cell Line(s) *in vivo*.** Will any animals be used to expand hybridoma cell lines so that antibody can be harvested from ascites fluid?

- ▶ ( ) No animals will be used on this protocol for *in vivo* expansion of hybridoma cell lines.

► ( ) Yes, this protocol requires use of some animals for *in vivo* expansion of hybridoma cell lines. Make sure that the animals used for this are included in Item I of the ACORP, the priming agent and the hybridoma cells are documented in Appendix 3, and the collection of ascites fluid is included in Item R of the ACORP. Complete items 5.a, 5.b, and 5.c, below.

a. Explain why alternate research methods that do not require the use of additional animals (e.g., *in vitro* cell culture systems for harvesting monoclonal antibodies) are not adequate to meet the research objectives of this project.



b. Complete the following table to summarize the procedures to be performed in expanding the hybridoma cell lines and collecting ascites fluid:

Hybridoma cell line designation	Number of animals to be 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. Describe the exact procedures (including administration of pain-relieving agents) that will be used for the abdominal taps to be performed on this protocol



d. List the criteria for euthanasia of animals prior to the last planned abdominal tap.



(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.)

**ACORP APPENDIX 3  
 BIOSAFETY  
 VERSION 4**

See ACORP App. 3 Instructions, for more detailed explanations of the information requested.

1. **Summary of All Materials Administered to Animals on this Protocol.** Complete the table below for all materials to be administered to any animal on this protocol, indicating the nature of the material by marking EVERY box that applies, and indicating the BSL number for any infectious agents:

<b>Material</b> (Identify the specific agent, device, strain, construct, isotope, etc.)	<b>Source</b> (Identify the vendor or colleague, or specify which animals on this protocol will serve as donors)	<b>Nature of Material</b>						
		Toxic Agent (Item 4)	Infectious Agent (Item 5) -- Enter the CDC Biosafety Level (BSL 1, 2, 3, or 4)	Biological Agent (Item 6)	Radioactive Agent (Item 7)	Contains Recombinant Nucleic Acid (Item 8)	Routine Pre- or Post-Procedural Drug	Euthanasia agent
		( )	( ) BSL_	( )	( )	( )	( )	( )
		( )	( ) BSL_	( )	( )	( )	( )	( )
		( )	( ) BSL_	( )	( )	( )	( )	( )
		( )	( ) BSL_	( )	( )	( )	( )	( )
		( )	( ) BSL_	( )	( )	( )	( )	( )
		( )	( ) BSL_	( )	( )	( )	( )	( )

2. **Summary of How Materials will be Administered.** Complete the table below for each of the materials shown in the table in Item 1 above:

<b>Material*</b> (Identify the specific agent, device, strain, construct, isotope, etc.)	<b>Dose</b> (e.g., mg/kg, CFU, PFU, number of cells, mCi) and <b>Volume</b> (ml)	<b>Diluent* or Vehicle*</b>	<b>Route of admin</b>	<b>Frequency or duration of admin</b>	<b>Reason for Administration and Expected Effects</b>	<b>Location of Further Details in this ACORP (specify "Main Body" or "App #", and identify the item)</b>	<b>Administration Under Anesthesia, sedation, or tranquilization (Y/N)</b>

\*Each material, diluent, or vehicle that is listed as FDA approved or is labeled "USP" is pharmaceutical grade. Check on-line for formulations that are FDA approved for administration to humans (<http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm>) or animals (<http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/UCM042847>). Designate with a \* each material and each diluent or vehicle to be used that is not pharmaceutical grade. For each of these, explain here why the use of a non-pharmaceutical grade formulation is necessary, and describe how it will be ensured that the material is suitable for use. (See ACORP App. 3 Instructions, for specifics about the level of detail required.)

3. **Anesthesia, Sedation, or Tranquilization.** Complete 3.a. and 3.b. below:
- a. For each material with "Y" entered in the last column of the table in Item 2 above, describe the anesthesia, sedation, or tranquilization to be used, identifying the anesthetic, sedative, or chemical tranquilizer, and detailing the dose, volume, and route of administration (Make sure that these agents are also included in Item 1 of this appendix, as materials to be administered):
  - b. For each material with "N" entered in the last column of the table in Item 2 above, explain why no anesthesia, sedation, or tranquilization is necessary, or can be provided, and describe any alternate methods of restraint that will be used.

4. **Toxic Agents.** Complete the table below for each of the materials listed as a “toxic agent” in the table in Item 1 above, checking the all of the properties that apply (see ACORP App. 3 Instructions, for details).

Name of Toxic Agent	a. Mutagen	b. Carcinogen	c. Teratogen	d. Select Agent?			e. Other – specify toxic properties
				Not a Select Agent	Select Agent Used in Sub-threshold Quantities	Select Agent that Requires Registration/Approval	
	( )	( )	( )	( )	( )	( )*	( ) ►
	( )	( )	( )	( )	( )	( )*	( ) ►
	( )	( )	( )	( )	( )	( )*	( ) ►
	( )	( )	( )	( )	( )	( )*	( ) ►
	( )	( )	( )	( )	( )	( )*	( ) ►
	( )	( )	( )	( )	( )	( )*	( ) ►

\*For each “select agent” that requires registration/approval (copy the lines below for each agent):

Name of agent ►

Registered with CDC or USDA ►

Registration Number ►

Registration Date ►

Expiration Date of Registration ►

Name of official who granted approval on behalf of VACO ►

Date of approval ►

5. **Infectious Agents.** Complete the table below for each of the materials listed as an “infectious agent” in the table in Item 1 above (see ACORP App. 3 Instructions, for details).

Name and BSL	a. ABSL	b. Drug Sensitivity Panel Available? (Describe)	c. Select Agent?
--------------	---------	---	------------------

Number of Infectious Agent	Number *		Not a Select Agent	Select Agent used in Sub-threshold quantities	Select Agent that Requires Registration/Approval
		(Yes/No)	( )	( )	( ) **
		(Yes/No)	( )	( )	( ) **
		(Yes/No)	( )	( )	( ) **
		(Yes/No)	( )	( )	( ) **
		(Yes/No)	( )	( )	( ) **
		(Yes/No)	( )	( )	( ) **

\*Complete the following for each agent for which the ABSL Number given is less than the BSL Number shown (copy the lines below for each agent):

- Name of agent ►
- Justification for applying ABSL measures that are less protective than those recommended ►

\*\*For each “select agent” that requires registration/approval (copy the lines below for each agent):

- Name of agent ►
- Registered with CDC or USDA ►
  - Registration Number ►
  - Registration Date ►
  - Expiration Date of Registration ►
- Name of official who granted approval on behalf of VACO ►
- Date of approval ►

6. **Biological Agents.** Complete the table below for each of the materials listed as a “biological agent” in the table in Item 1 above (see ACORP App. 3 Instructions, for details).

Name of Biological Agent	Screening for Infectious Agents

7. **Radioactive Agents.** Complete the table below for each of the agents listed as a “radioactive agent” in the table in Item 1 above (see ACORP App. 3 Instructions, for details).

Name of Radioactive Agent (specify the isotope)	Authorized Individual	Approving Committee or Official

8. **Agents Containing Recombinant Nucleic Acid.** For each of the materials checked in the table in Item 1, above, as “contains recombinant nucleic acid”, indicate which of the conditions applies (see ACORP App. 3 Instructions, for details).

Name of Agent that Contains Recombinant Nucleic Acid	Subject to the <i>NIH Guidelines for Research Involving Recombinant DNA Molecules</i>	Exempt
	( )	( )
	( )	( )
	( )	( )
	( )	( )
	( )	( )
	( )	( )

9. **Potential for Pain or Distress.** Complete the table below for each of the agents listed in Item 1, above, that is expected to have potentially painful or distressing effects on the animals (see ACORP App. 3 Instructions, for details).

Name of Agent	Nature of Potential Pain/Distress	Measures to Alleviate Pain/Distress

10. **Protection of Animal Facility Staff from Hazardous Materials.** Complete Items 10.a and 10.b, below, for each of the agents listed in the table in Item 1, above, as “toxic”, “infectious”, “biological”, “radioactive”, or “contains recombinant nucleic acid” (detailed in Items 4 – 8). This item specifically addresses members

of the animal facility staff; protection of the research staff from each of these agents must be addressed in Item G of the main body of the ACORP. See ACORP App.3 Instructions, for details.

a. Complete the table below.

Name of Hazardous Agent	Approving Committee or Official	Institution (VA or affiliate)	Names of Animal Facility Staff Members at Risk

b. Detail how the individuals listed in the table above (Item 10.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.



11. **Signatures.** Provide the applicable signatures on the signature pages (Item Z.3) of the main body of this ACORP.

**ACORP Appendix 4**  
**ANTEMORTEM SPECIMEN COLLECTION**  
**VERSION 4**

See ACORP App. 4 Instructions, for more detailed explanations of the information requested.

1. **Summary.** Complete the table below for each specimen to be collected from a live animal on this protocol (see ACORP App. 4 Instructions, for details).

Specimen Collected	Site and Method of Collection	Anesthesia (Yes/No)	Amount Collected Each Time	Volume Replacement (Yes/No/NA)	Total Number of Collections per Animal	Time Intervals Between Successive Collections

2. **Use of Anesthetics, Tranquilizers, or Analgesics.**

- a. For each specimen described in Item 1, above, as being collected WITHOUT anesthesia, complete Items 2.a(1) and 2.a(2), below:

(1) Explain why no measures will be taken to prevent pain (e.g., because of scientific requirements described here, or because the collection method involves no more than minor or momentary pain).



(2) Completely describe any method of physical restraint that may be used.



- b. For each specimen described in Item 1, above, as being collected WITH anesthesia, complete the following table:

Anesthetic, tranquilizer, or analgesic agent	Dose (mg/kg) and volume (ml)	Route of administration	Frequency of administration

3. **Volume Replacement for Fluid Collections.**

- a. For each fluid specimen described in Item 1, above, for which NO volume replacement will be provided, explain why not.



- b. For each fluid specimen described in Item 1, above, for which volume replacement WILL be provided, describe the replacement fluids that will be administered (including their composition, volume, and route of administration).
- 

4. **Monitoring the animals.** Detail how the animals will be monitored after collection of specimens to ensure that they recover appropriately (see ACORP App. 4 Instructions, for details).
- 

**ACORP Appendix 5**  
**SURGERY**  
**VERSION 4**

See ACORP App. 5 Instructions, for more detailed explanations of the information requested.

1. **Surgery Classification.** Complete the table below for each surgery included in this protocol, and indicate how it is classified (terminal, minor survival, major survival, one of multiple survival). See ACORP App. 5 Instructions, for details.

Surgery		Terminal	Survival		
#	Description (specify the species, if ACORP covers more than one)		Minor	Major	One of Multiple*
1		( )	( )	( )	( )*
2		( )	( )	( )	( )*
3		( )	( )	( )	( )*
4		( )	( )	( )	( )*

\*If survival surgery (including major surgeries and any minor surgeries that may induce substantial post-procedural pain or impairment) will be performed as part of this protocol in addition to any other such surgery (on this or another protocol) on the same individual animal, complete items 1.a and 1.b, below:

- a. Provide a complete scientific justification for performing the multiple survival surgeries on an individual animal:
- 

- b. Give the interval(s) between successive surgeries, and the rationale for choosing the interval(s):
- 

2. **Description of Surgeries.** Describe each surgery listed in Item 1, providing enough detail to make it clear what the effects on the animal will be. (Pre-operative preparation, anesthesia, and post-operative recovery will be covered in items 5, 6, and 7, below.)

Surgery 1 ►

Surgery 2 ►

Surgery 3 ►

Surgery 4 ►

3. **Personnel.** Complete the table below for each individual who will be involved in any of the surgeries on this protocol.

Name	Surgery # (s) (see Item 1)	Role in Surgery			
		Surgeon	Assistant	Manage Anesthesia	Other (describe)
		( )	( )	( )	( )
		( )	( )	( )	( )
		( )	( )	( )	( )
		( )	( )	( )	( )
		( )	( )	( )	( )

4. **Location of surgery.** Complete the table below for each location where surgery on this protocol will be performed.

Building	Room Number	Surgery # (s) (see Item 1)	Type of Space		
			Dedicated Surgical Facility	Other Dedicated Surgical Space	Other Space not Dedicated to Surgery
			( )	( )*	( )*
			( )	( )*	( )*
			( )	( )*	( )*
			( )	( )*	( )*

\*For each space that is not in a dedicated surgical facility, provide the justification for using this space for surgery on this protocol



5. **Pre-operative protocol.**

- a. **Pre-operative procedures.** Complete the table below for each pre-operative procedure that will be performed to prepare the animal(s) for surgery.

Surgery # (s) (see Item 1)	Fast (Specify Duration)	Withhold Water (Specify Duration)	Place Intravenous Catheter(s) (Specify Site(s))	Other – Describe
1	( ) --	( ) --	( ) --	( ) --
2	( ) --	( ) --	( ) --	( ) --
3	( ) --	( ) --	( ) --	( ) --
4	( ) --	( ) --	( ) --	( ) --

b. **Pre-operative medications.** Complete the table below. Include agent(s) for induction of anesthesia, as well as any other pre-treatments that will be administered prior to preparation of the surgical site on the animal.

Agent	Surgery # (s) (see Item 1)	Dose (mg/kg) & volume (ml)	Route of administration	Frequency of administration (e.g., times/day)	Pre-operative period of treatment (e.g., immediate, or # of days)

c. **Pre-operative preparation of the surgical site.** For each surgery, identify each surgical site on the animals, and describe how it will be prepared prior to surgery.

Surgery 1 ►

Surgery 2 ►

Surgery 3 ►

Surgery 4 ►

6. **Intra-operative management.**

a. **Intra-operative medications.** Complete the table below for each agent that will be administered to the animal during surgery.

Agent	Paralytic*	Surgery # (s) (see Item 1)	Dose (mg/kg) & volume (ml)	Route of administration	Frequency of dosing
	( )*				
	( )*				

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

\* For each agent shown above as a paralytic, explain why its use is necessary, and describe how the animals will be monitored to ensure that the depth of anesthesia is sufficient to prevent pain.



b. **Intra-operative physical support.** For each surgery, describe any physical support that will be provided for the animals during surgery (e.g., warming, cushioning, etc.).



c. **Intra-operative monitoring.** Describe the methods that will be used to monitor and respond to changes in the state of anesthesia and the general well-being of the animal during surgery. Include how frequently intra-operative monitoring will occur.



7. **Survival surgery considerations.** For each survival surgical procedure indicated in Item 1 and described in Item 2, complete Items 7.a. – 7.g.

a. Complete the table below for each survival surgery listed in Item 1, above.

Surgery # (see Item 1)	Survival Period	Measures for Maintaining Sterility							
		Sterile Instruments	Surgical Cap	Sterile Gloves	Surgical Scrub	Sterile Drapes	Sterile Gown	Face Mask	Other*
		( )	( )	( )	( )	( )	( )	( )	( )*
		( )	( )	( )	( )	( )	( )	( )	( )*
		( )	( )	( )	( )	( )	( )	( )	( )*
		( )	( )	( )	( )	( )	( )	( )	( )*

\* Describe any “other” measures to be taken to maintain sterility during surgery.



b. For each surgery, describe the immediate post-operative support to be provided to the animals.

Surgery 1 ►

Surgery 2 ►

Surgery 3 ►

Surgery 4 ►

c. Post-operative analgesia. Complete the table below for each surgery listed in item 1, above.

Surgery # (see Item 1)	Agent*	Dose (mg/kg) & Volume (ml)	Route of Administration	Frequency of Dosing (e.g., times/day)	Period of treatment (e.g. days)
1					
2					
3					
4					

\*For each surgery for which NO post-operative analgesic will be provided, enter “none” in the “Agent” column, and explain here why this is justified:



- d. Other post-operative medications. Complete the following table to describe all other medications that will be administered as part of post-operative care.

Surgery # (see Item 1)	Medication	Dose (mg/kg) & Volume (ml)	Route of Administration	Frequency of dosing (e.g. times/day)	Period of treatment (e.g. days)

1. Post-operative monitoring. After-hours contact information for the personnel listed must be provided to the veterinary staff for use in case of an emergency. Include what signs are monitored.

e.

1. Immediate post-operative monitoring

Surgery # (see Item 1)	Methods Of Monitoring	Frequency of Monitoring	Duration at this Frequency	Name(s) of Responsible Individual(s)

2. Post-operative monitoring after the immediate post-operative period. Include what signs are monitored.

Surgery # (see Item 1)	Methods Of Monitoring	Frequency of Monitoring	Duration at this Frequency	Name(s) of Responsible Individual(s)

a. Post-operative consequences and complications.

1. For each surgery, describe any common or expected post-operative consequences or complications that may arise and what will be done to address them.

Surgery 1 ►

Surgery 2 ►

Surgery 3 ►

Surgery 4 ►

2. List the criteria for euthanasia related specifically to post-operative complications:

Surgery 1 ►

Surgery 2 ►

Surgery 3 ►

Surgery 4 ►

3. In case an emergency medical situation arises and none of the research personnel on the ACORP can be reached, identify any drugs or classes of drugs that should be avoided because of the scientific requirements of the project. (If the condition of the animal requires one of these drugs, the animal will be euthanated instead.)

►

- b. Maintenance of post-surgical medical records. Complete the table below for each surgery, specifying where the records will held, and identifying at least one individual who will be assigned to maintain accurate, daily, written post-surgical medical records. Indicate whether the named individuals are research personnel involved in this project, or members of the veterinary staff.

Surgery # (see Item 1)	Location of Records	Name(s) of Individual(s) Responsible for Maintaining Written Records	Research Personnel	Veterinary Staff
1			( )	( )
2			( )	( )
3			( )	( )
4			( )	( )

**Certification.** The PI must sign the certification statement in Item Z.5 of the main body of the ACORP.

**ACORP APPENDIX 6  
 SPECIAL HUSBANDRY AND PROCEDURES  
 VERSION 4**

See ACORP App. 6 Instructions, for more detailed explanations of the information requested.

1. **Description of Procedures.** Complete the table below for each procedure listed in Item V of the main body of the ACORP that is not detailed in a SOP or in another item or Appendix of the ACORP. For each special procedure, check all features that apply.

Special Procedure		Features							
Number	Brief Description	Husbandry	Restraint	Noxious Stimuli	Exercise	Behavioral Conditioning	Irradiation	Imaging	Other**
1		( )	( )	( )	( )	( )	( )	( )	( )
2		( )	( )	( )	( )	( )	( )	( )	( )
3		( )	( )	( )	( )	( )	( )	( )	( )
4		( )	( )	( )	( )	( )	( )	( )	( )

\*Husbandry refers to all aspects of care related to the maintenance of the animals, including (but not limited to) provision of an appropriate diet, access to water, control of environmental conditions, and the selection of primary and secondary enclosures.

\*\*Describe any "Other" features that are involved.



- a. Provide a complete description of each special procedure listed above, including the duration of the procedure, how frequently it will be repeated in any one animal, and any effects it is expected to have on the animal:

Special Procedure 1 ►

Special Procedure 2 ►

Special Procedure 3 ►

Special Procedure 4 ►

b. Explain why each of these special procedures is necessary:

Special Procedure 1 ►

Special Procedure 2 ►

Special Procedure 3 ►

Special Procedure 4 ►

2. **Personnel.** Complete the table below for each special procedure listed in Item 1, above. Identify the individual(s) who will be responsible for carrying out the procedures, and those who will be responsible for monitoring the condition of the animals during and after the procedures. After-hours contact information for the personnel listed must be provided to the veterinary staff for use in case of an emergency.

Procedure Number (see Item 1)	Responsible Individual(s)	
	Carrying Out Procedure	Monitoring the Animals
1		
2		
3		
4		

3. **Potential Pain or Distress.** Complete the table below for each special procedure identified in Item 1, above, indicating for each procedure, whether potential pain and/or distress is expected, and, if so, describing the potential pain and/or distress and indicating whether any measures are to be taken to prevent or alleviate it.

Procedure Number (see	Expected Potential Pain and/or Distress	
	No	Yes

Item 1)		Description	To Be Relieved	Not to Be Relieved
1	( )		( ) <sup>a</sup>	( ) <sup>b</sup>
2	( )		( ) <sup>a</sup>	( ) <sup>b</sup>
3	( )		( ) <sup>a</sup>	( ) <sup>b</sup>
4	( )		( ) <sup>a</sup>	( ) <sup>b</sup>

a. For each procedure for which potential pain and/or distress is expected, but WILL be prevented or alleviated by administration of the analgesic(s) or stress-relieving agents, complete the table below:

Procedure Number (see Item 1)	Agent	Dose (mg/kg) & vol (ml)	Route of admin	Freq of admin (times/day)	Duration of admin (days post-procedure)
1					
2					
3					
4					

Describe any non-pharmacological measures to be taken to address the potential pain and/or distress:

- Special Procedure 1 ►
- Special Procedure 2 ►
- Special Procedure 3 ►
- Special Procedure 4 ►

b. For each procedure for which potential pain and/or distress is expected and will NOT be prevented or alleviated, provide the scientific justification for this:

- Special Procedure 1 ►
- Special Procedure 2 ►
- Special Procedure 3 ►
- Special Procedure 4 ►

4. **Monitoring.** Describe how the condition of the animals will be monitored during and after each of the special procedures, and list the criteria that will be used to determine when individual animals will be removed from groups undergoing these procedures, because of pain or distress (see ACORP App. 6 Instructions, for details):

Procedure Number (see Item 1)	Monitoring Methods	Endpoint Criteria
1		
2		
3		
4		

**ACORP APPENDIX 7  
USE OF PATIENT CARE EQUIPMENT AND/OR AREAS  
FOR ANIMAL STUDIES  
Version 4**

See ACORP App. 7 Instructions, for more detailed explanations of the information requested.

1. **Full Name(s) of Principal Investigator(s) ►**
2. **Equipment to be Used.**
  - a. Identify the equipment ►
  - b. Procedure(s) to be performed with this equipment ►
  - c. Describe how contamination of the human patient care equipment will be prevented and how the equipment will be cleaned/sanitized before its subsequent use for human patients.  
►
3. **Human Patient Care Procedural Areas to be Used.**
  - a. Location(s) ►
  - b. Animal species to be studied or treated ►
  - c. Number of individual animals to be studied or treated ►
  - d. Date(s) ►
  - e. Time(s) of day ►
  - f. Procedure(s) to be performed on the animals in these areas ►
  - g. Protection and cleaning of patient care room surfaces ►
  - h. Benefits to VA patients. Briefly describe how this use of the human patient care areas for research on animal subjects potentially benefits VA patients.  
►
  - i. Necessity for use of human patient care areas. Explain why this work on animal subjects cannot be performed within the animal facility or a research laboratory area.  
►
  - j. Animal transport. Describe how the animals will be transported back and forth between the animal housing area and the human patient care areas.  
►
  - k. Preventing human patients and patient care personnel from being affected by the presence of the animals. Provide detailed descriptions of the measures to be taken to address noises and odors, allergens, and zoonotic pathogens associated with the animals.



4. **Signatures.** Provide the signatures required on the signature pages (Item Z.7) of the main body of this ACORP.

**ACORP APPENDIX 8  
 USE OF EXPLOSIVE AGENT(S) WITHIN THE VMU OR IN ANIMALS  
 VERSION 4**

See ACORP App. 8 Instructions, for more detailed explanations of the information requested.

1. **Full name(s) of Principal Investigator(s) ►**
2. **Explosive agents to be used.**
  - a. Identify the explosive agents. Complete the table below.

Agent Number	Name(s) Used to Refer to the Agent in This ACORP	Name Shown for this Agent on the MSDS on File	CAS number	Location of the MSDS on File
1				
2				
3				
4				

- b. Locations where the explosive agents will be used. Complete the table below.

Agent Number	Location Where Agent Will Be Used			
	Building	Room Number	Within the VMU	Outside of VMU
1			( )	( )
2			( )	( )
3			( )	( )
4			( )	( )

- c. Procedure(s) to be performed. Briefly describe the use of each of the explosive agents on this protocol and explain why it is necessary to use these agents (why non-explosive replacements cannot be used instead).  
 ►
- d. Precautions to be taken to prevent explosions. Describe the measures to be taken to store, use, and dispose of safely each explosive agent and any materials contaminated with it, and to prevent the generation of sparks in its presence. See ACORP App. 8 Instructions, for a list of commonly used precautions.  
 ►
- e. Period of use.  
 Beginning no earlier than (date) ►  
 Ending no later than (date) ►
- f. Animals that will be administered explosive agents:  
 Species ►  
 Approximate weights of individual animals ►  
 Approximate number of animals ►

3. **Personnel.** Complete the table below for each individual who will handle any of the explosive agents as part of this protocol.

Name of Individual	Explosive Agent(s) to be Handled	Training and Experience Pertinent to Handling Explosive Agents

4. **Signatures.** Provide the signatures required on the signature pages (Item Z.8) of the main body of this ACORP.

**ACORP Appendix 9**  
**DEPARTURES FROM “MUST” AND “SHOULD” STANDARDS IN THE *GUIDE* (2011)**  
**VERSION 4**

See ACORP App. 9 Instructions, for more detailed explanations of the information requested.

For each IACUC-approved “departure” of this protocol from a “Must” or “Should” standard in the *Guide*, provide the following information. (Consult the IACUC or the Attending Veterinarian for help in determining whether any “departures” are involved.):

Copy the lines below for each departure.

Briefly summarize the “Must” or “Should” standard, and provide the number(s) of the page(s) on which it appears in the *Guide*



Describe the specific alternate standard(s) that will be met on this protocol, and how they will be monitored.



Provide the scientific, veterinary medical, or animal welfare considerations that justify this departure



## ACORP Appendix 9 Madison VAMC Rodent Breeding Appendix

(Compiled using UW RARC Breeding Policy and Stratton VAMC Breeding Appendix)  
**ACORP VERSION 3**

The purpose of this appendix is to account for rodents used as part of a breeding colony. Please follow the instructions carefully. **Bold all answers.**

**NOTE: An example of a breeding scheme is at the end of the form.**

1. Fill out the following table for each strain you plan to breed:

Strain	Mutation, transgene, or other genotypic manipulation	Source of breeders (e.g., commercial suppliers, institution, etc.)	Microbial status – <b>MUST</b> be SPF (specific-pathogen-free) – <b>Helicobacter Positive Animals will NOT be accepted at the VA Animal Research Facility.</b>

2. Describe the breeding scheme for each strain. Indicate how many females per male will be housed, and the mating system planned (brother-sister mating, back-cross, etc.)

3. Who will be responsible for maintaining the breeding colony? What is the minimum number of times the breeding colony will be checked by PI and staff?

4. What age will breeders be started and retired? Will breeders be euthanized?

5. What age will rodents be weaned (local policy states no more than 24 days without IACUC approval)?  
 (NOTE: If a new litter is born, and a previous litter is still present, the previous litter **MUST** be weaned).

6. Describe the characteristics of each particular strain that result from the genotype, including any detrimental impact on the immune system or other clinical problems or anomalies.
7. Personnel and Qualifications. Give the name(s) of all individuals who will work with the breeding colony, and describe their relevant education, training, and experience with breeding animals.
8. If personnel do not have experience, how will they be trained?
9. Will tail snips or other genetic testing be required to maintain colony? If so, describe all tissue collection procedures related to genotyping, including the use of local or general anesthesia used prior to tissue collection (or reference Appendix 6; Special Husbandry Procedures)
10. According to ARC Policy #07-09, Use and Management of Rodent Breeding Colonies, in the absence of genetic monitoring, the number of generations the colony will be permitted to run must be defined and should not exceed three or four. If genetic testing is not being done, what is the maximum number of generations that will be bred?
11. Complete the following table, using your best estimates of yearly needs. In reality, the genetics don't always cooperate and it is unlikely that all of the females will get pregnant. To account for these issues, it is a good idea to increase the number of rodents you want to produce (a 10-20% increase is reasonable). Numbers of breeders, number of weanlings euthanized due to wrong genotype, number of weanlings used in experiments, and number of animals used for future breeders should all be accounted for in the ACORP in Item I.

Strain	Number of breeders needed per year	Average expected litter size	Number of weanlings that will be euthanized because of improper genotype or gender per year	Number of weanlings that will be used in experiments per year	Number of animals used for future breeding

**Guidance for the correct USDA Pain and Distress Category Designation in Item I of ACORP for breeders:**

USDA Category B: Breeders and weanlings 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, category B is NOT appropriate. Breeders and weanlings that will experience potentially painful tissue collections (e.g., Tail Snips or ID Chip Implants) that will be relieved by anesthesia or analgesia should be placed in USDA pain/distress category D in Item I.)

USDA Category C: Breeders, weanlings, and any other 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.

USDA Category C, D, E: Rodents in the last column (those that will be used for experiments) should be placed in the USDA pain/distress category appropriate for them based upon experimental procedures and any potentially painful tissue collections for genotyping. Please see the definition for Category C above and refer to definitions for Category D & E in the text of the ACORP, Item I USDA Category Table.

**BREEDING EXAMPLE:**

*You want to produce 100 female mice heterozygous for a transgene for your experiment. You cross wild-type females with transgenic males. The transgenic females are expected to account for 25% of each litter. Thus, to produce 100 of these mice you will need to produce about 400 mice. If the expected litter size is 8, you will need to produce about 50 litters. If you want the experimental mice born within a short time, you will need at least 50 females and at least 25 males*

to produce these mice. If you can produce them over time, you can expect to get more than one litter from each female and thus decrease the number of breeder females and males. Now, you need to calculate how many mice will be needed to produce the breeder mice, unless you plan to purchase them. **REMEMBER:** In reality, genetics don't always cooperate and it is unlikely that all of the females will get pregnant. To account for these issues, it is a good idea to increase the number of mice you want to produce. A 10-20% increase is reasonable.

Filling out the spaces below will help in determining the number of animals needed. Completing the blanks below is not required but is included to help guide PIs in setting up a breeding scheme:

1. In order to produce \_\_\_\_\_ (number) experimental animals, we must produce \_\_\_\_\_ total animals which will require \_\_\_\_\_ (number) litters.
2. To produce this number of litters, we will need \_\_\_\_\_ (number) females and \_\_\_\_\_ (number) males.
3. To produce these breeding animals, we will need to produce \_\_\_\_\_ (number) litters using \_\_\_\_\_ (number) females and \_\_\_\_\_ (number) males.

**ACORP Appendix 10**  
**REQUEST TO HOUSE ANIMALS >12 HOURS AND/OR OVERNIGHT**  
**IN A VA RESEARCH LABORATORY**  
Version II (9/2007)

1. Name(s) of Principal Investigator(s):  
Office Phone Number:  
e-mail:
2. Room number of the lab to be used.
3. Species and total number of animals to be used.
4. Concise statement of the reason animals must be housed >12 hours and/or overnight in a Research lab. Include reasons why the Animal Research Facility cannot be used for the proposed procedures and overnight housing.

5. Duration of housing in the lab for each animal, the maximum number of animals proposed to be housed at one time, and the estimated final date for which housing will be needed.
6. Describe the measures to be taken to prevent the escape of animals from their housing while in the lab. Be specific about extra precautions, such as locks, that will be used.
7. Describe the measures to be taken to prevent disturbances (e.g., noise, odors) to other personnel.
8. Describe methods to be employed to minimize levels of allergens such as rodent urine proteins and animal dander. Some options are keeping cages in or near an operating fume hood, using micro-filter tops on cages and documented negative air pressure.
9. Details and frequency of the procedures to be followed by lab staff in maintaining sanitation, including disposal of bedding and waste materials. (Applicant should consult ARF Supervisor (ext. 17875) for instruction on proper bedding disposal and cage return to the ARF.)
10. List measures for monitoring climate control (temperature and humidity) as required by federal animal welfare regulations. (Applicant should consult ARF Supervisor (ext. 17875) for advice on meeting all regulatory requirements.)
11. Describe oversight during weekends or holidays.
12. List the names and emergency phone numbers of personnel who should be contacted by Housekeeping, Police or Engineering personnel if necessary outside of normal business hours.
13. Provide the signatures required on the signature pages (Item Z.11) of the main body of this ACORP.