PROTOCOL FOR ANIMAL USE AND CARE

E-mail to: irb@western.edu
Please use a minimum font size of 10

Office of Research USE ONLY
USDA Cat :
PROTOCOL:
EXPIRES:

1. Contacts:

	Investigator		Alternate Contact	
Last Name:				
First:		MI:	First :	MI:
E-mail:				
Department/ Affiliation:				
Phone / after hrs:				

2. Title

3. Species (common names):

	Total number for study	Name of source of the animals:

4. Procedures: Briefly describe the animal procedures and significance included in this project using language for non-scientific personnel. This page is posted on the animal room door for animal care staff and must be clear and understandable to the staff.

5. Animal Location

Overnight housing	Study area / Laboratory **(Room/Bldg.)**

Animals will be maintained by: [ ] Vivarium [ ] Investigator *(If investigator maintained, please attach husbandry SOPs.)*

6. Special Husbandry Requirements: Briefly describe any *special* food, water, temperature, humidity, light cycles, caging type, and bedding requirements. Please include any special instructions for animal care staff with regard to procedures to follow for disposal of dead animals and if pest control can be performed in the animal area.

7. Hazardous Materials (If used specifically in this protocol, please fill out the Room/Lab Safety Information Sheet):

Infectious Agents?	[ ] Yes [ ] No	Material:		[ ] Lab [ ] Vivarium
Radioisotopes?	[ ] Yes [ ] No	Material:		[ ] Lab [ ] Vivarium
Chemical Carcinogens?	[ ] Yes [ ] No	Material:		[ ] Lab [ ] Vivarium
Recombinant DNA?	[ ] Yes [ ] No	Material:		[ ] Lab [ ] Vivarium
Hazardous Chemicals?	[ ] Yes [ ] No	Material:		[ ] Lab [ ] Vivarium

Hazardous chemicals would include chemicals that are flammable, toxic, corrosive, or chemotherapeutic.

8. Funding and Funding Source

Is the protocol for **newly** funded NIH research? Yes [ ] No [ ] Funding Source:

****If this protocol is submitted for a newly funded NIH grant, please attach the relevant animal-related pages from section *D. Experimental Design and Methods* and section *F. Vertebrate Animals* that will allow a direct comparison between this protocol and the animal work proposed in your grant. This comparison of NIH grants and Animal Use and Care protocols is required by PHS policy and only applies to newly funded NIH grants. Please contact IACUC staff if you have questions associated with this requirement.**

9. What Veterinarian will provide care for your animals? (check one)

[ ] Western Colorado University Attending veterinarian

[ ] Another Veterinarian

If you checked "Another Veterinarian", please provide the following information and notify the Western Colorado University Attending Veterinarian.

Veterinarian:		Address:	
Day phone:			
Emergency phone:		E-mail:	

10. **Objective and Significance**:

Please provide a brief description of the **objectives and significance** of the study, bearing in mind your target audience may be a faculty member from an unrelated discipline.

Objective:

Significance: Please provide a statement of relevance to human or animal health, the advancement of knowledge, or the good of society.

11. Literature search for alternatives and unnecessary duplication: ***Federal law specifically requires this section.***

Alternatives should be considered for any aspect of this protocol that may cause more than momentary or slight pain or distress to the animals. Alternatives to be considered include those that would: 1) **refine** the procedure to minimize discomfort that the animal(s) may experience; 2) **reduce** the number of animals used overall; or 3) **replace** animals with non animal alternatives.

For assistance with search for alternatives, visit:

http://www.vetmed.ucdavis.edu/Animal_Alternatives/main.htm

http://altweb.jhsph.edu/searchalt.htm

**

a) Databases: List a **minimum** of **two** databases searched and/or other sources consulted. Include the years covered by the search. *The literature search must have been performed within the last three months.*

Database Name	Years Covered	Keywords / Search Strategy	Date

b) Result of search for alternatives: Please comment on the application(s) of any identified alternatives, including how these alternatives may be or may not be incorporated to modify a procedure to either lessen or eliminate potential pain and distress.

c) Animal numbers justification: Please describe the consideration given to reducing the number of animals required for this study; this could include any *in vitro* studies performed prior to the proposed animal studies. Please also provide information on how you arrived at the number of animals required. If preliminary data is available and if relevant, please provide a power analysis or other statistical method used to determine the number of animals necessary. For studies where a statistical method such as a power analysis is not appropriate (such as pilot studies, tissue collection), please provide a brief narrative describing how the requested animal numbers were determined to be necessary. Please site all references.

d) Species rationale: Please provide the rationale for the species chosen, and any consideration given to the use of non-mammalian or invertebrate species, or the use of non-animal systems (e.g., cell or tissue culture, computerized models).

e) Has this study been previously conducted? [ ] Yes [ ] No

If the study has been previously conducted, please provide scientific justification for why it is necessary to repeat the experiment.

12. Summary of Procedures:

a) Describe the use of animals in your project in detail. Using terminology that will be understood by individuals outside your field of expertise. Please write a detailed description of all animal procedures in a logical progression, beginning with receipt of the animals and ending with euthanasia or the study endpoint. **List each study group and describe all the specific procedures that will be performed on each animal in each study group.**

Please provide a complete description of the surgical procedure(s) including **Anesthesia, Analgesia, and/or Neuromuscular blocking agents**. If the procedure(s) will be performed by vivarium or veterinary staff with an established, IACUC-approved SOP, please identify the SOP title and number.

Field Studies: If animals in the wild will be used, describe how they will be observed, any interactions with the animals, whether the animals will be disturbed or affected, and any special procedures anticipated. Indicate if Federal or State permits are required and whether they have been obtained.

This cell will expand, but please try to be concise. Please define all abbreviations.

b) Study Groups and Numbers Table: Define the numbers of animals to be used in each experimental group described above. The table may be presented on a separate page as an attachment to this protocol if preferred. This table must account for all animals proposed for use under this protocol.

Group	Procedures / Treatments	Number of Animals

c) Is death an endpoint in your experimental procedure? [ ] Yes [ ] No

(Note: "Death as an endpoint" refers to acute toxicity testing, assessment of virulence of pathogens, neutralization tests for toxins, and other studies in which animals are not euthanized, but die as a direct result of the experimental manipulation). If death is an endpoint, explain why it is not possible to euthanize the animals at an earlier point in the study. If you can euthanize the animals at an earlier point, based on defined clinical signs, then death is not an endpoint.

d) Surgery: This project will involve: **Survival surgery** [ ] Yes [ ] No **Terminal surgery** [ ] Yes [ ] No

Location: Building:

Room:

Name of the surgeon:

e) This project will involve **Multiple Major Surgical Procedures** [ ] Yes [ ] No

Please provide scientific justification for multiple major surgical procedures:

f) Drugs to be used (except for euthanasia) - anesthetics, analgesics, tranquilizers, neuromuscular blocking agents or antibiotics:

Post-procedural analgesics should be given whenever there is possibility of pain or discomfort that is more than slight or momentary.

Provide the following information about any of these drugs that you intend to use in this project.

Species	Drug	Dose (mg/kg)	Route	When and how often will it be given?	Pharmceutical grade? (Y/N)

Please provide justification below for use of all non-pharmaceutical grade drugs you intend to use in this project

g) Anesthesia monitoring: Please complete the following:

Please identify the physiologic parameters monitored during the procedure to assess adequacy of anesthesia and when additional anesthesia will be administered.

h) Neuromuscular blocking agents can conceal inadequate anesthesia and, therefore, require special justification. If you are using a neuromuscular blocking agent, please complete the following:

Why do you need to use a neuromuscular blocking agent?

What physiologic parameters are monitored while under a neuromuscular block to assess adequacy of anesthesia?

Under what circumstances will incremental doses of anesthetics-analgesics be administered while under a neuromuscular block?

i) Post-surgical monitoring: please complete the following:

Please identify the physiologic parameters monitored, and interval(s) and for what duration of monitoring.

When will analgesics be administered and at what interval(s)?

If post-operative analgesics cannot be given, please provide scientific justification.

13. Adverse effects:

Describe **all significant** adverse effects that may be encountered during the study (such as pain, discomfort; reduced growth, fever, anemia, neurological deficits; behavioral abnormalities or other clinical symptoms of acute or chronic distress or nutritional deficiency). If genetically-altered animals are used, please describe any potential adverse effects that could be associated with the desired genotype, if known.

Describe criteria for monitoring the well-being of animals on study and criteria for terminating/modifying the procedure(s) if adverse effects are observed.

How will the signs listed above be ameliorated or alleviated? Please provide scientific justification if these signs cannot be alleviated or ameliorated.

Note: If any significant adverse effects not described above occur during the course of the study, a complete description of these unanticipated findings and the steps taken to alleviate them must be submitted to the IACUC as an amendment to this protocol.

14. Methods of euthanasia: Even if your study does not involve euthanizing the animals, please provide a method that you would use in the event of unanticipated injury or illness. If anesthetic overdose is the method, please provide the agent, dose, and route.

Species	Method	Drug	Dose (mg/kg)	Route

15. Disposition of animals: What will you do with any animals not euthanized at the conclusion of the project?

16. Project Roster: Please provide the names of all the individuals who will work with animals on this project. Please provide either the University Employee ID number **OR** a valid Western Colorado University e-mail address in order for the IACUC to confirm that the requirements of training and occupational health for regulatory agencies have been met. Include all investigators, student employees, post-doctoral fellows, staff research associates, post-graduate researchers, and laboratory assistants who will actually work with the animals. You do not need to include the staff of the vivarium in which your animals will be housed, or staff members that are only working with tissues or animals post-euthanasia. **This roster is specifically for individuals working with live vertebrate animals.**

Occupational Health Program: Supervisors must enroll their employees in the campus Occupational Health Program. Primate Center personnel are automatically enrolled; for all other departments, please enroll personnel by having them complete a "Risk Assessment/Animal Contact Health Surveillance Questionnaire", available from Employee Health Services,

Training: Supervisors are responsible for insuring that their employees are adequately trained, both in the specifics of their job and in the requirements of the Federal Animal Welfare Act. Please contact the IRB Chair Dr Lindsey Fast, lfast@western.edu for more information.

The PI is responsible for keeping this roster current. If staff is added or removed from this project, please amend the protocol to reflect this change.

Last Name	First Name	Middle Initial	Title/Degree
UC ID Number **OR** E-mail address:			
Describe training and experience relevant to the procedures described in this protocol:			

Last Name	First Name	Middle Initial	Title/Degree
UC ID Number **OR** e-mail address:			
Describe training and experience relevant to the procedures described in this protocol:			

Last Name	First Name	Middle Initial	Title/Degree
UC ID Number **OR** e-mail address:			
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Last Name	First Name	Middle Initial	Title/Degree
UC ID Number **OR** E-mail address:			

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Last Name	First Name	Middle Initial	Title/Degree
UC ID Number **OR** e-mail address:			
Describe training and experience relevant to the procedures described in this protocol:			
Last Name	**First Name**	**Middle Initial**	**Title/Degree**
UC ID Number **OR** E-mail address:			
Describe training and experience relevant to the procedures described in this protocol:			

Assurance for the Humane Care and Use of Vertebrate Animals
Principal Investigator's Statement:

This project will be conducted in accordance with the ILAR Guide for the Care and Use of Laboratory Animals,

and the Western Colorado Univesrity Animal Welfare Assurance on file with the US Public Health Service. I will abide by all Federal, state and local laws and regulations dealing with the use of animals in research.

I will advise the Institutional Animal Care and Use Committee in writing of any significant changes in the procedures or personnel involved in this project.

Principal Investigator	Rank/Title	Date

Committee Use Only Below

**** Conditions necessary for Committee Approval:**

Final Disposition of this protocol:

_____ Approved

_____ Not Approved

_____ Withdrawn by Investigator

Date of Action: _____/_____/_____

I verify that the Institutional Animal Care and Use Committee of the Western Colorado University, acted on this protocol as shown above.

IACUC Administrator	*Date*

Antibody Production Project Description

If your project involves only antibody production, either polyclonal or monoclonal, you may complete this page in lieu of section 12a (Summary of Procedures).

Will these animals be used for antibody production? [ ] Yes [ ] No

1. Polyclonal or Monoclonal antibodies?

   If Monoclonal, will you be producing ascites tumors in the animals? [ ] Yes [ ] No

2. What type(s) of antigen will be used?

   Will the antigens be sterile?

3. What adjuvant will be used for the initial injection?

   What adjuvant will be used for subsequent injections?

4. What route will be used for injections?

   What anatomical location will be injected?

   How many injections at one time?

   How frequently will injections be given?

   What volume will be injected at each site?

5. Polyclonal Blood collection Procedures:

   Who will collect the blood?

   From what anatomical location?

   How frequently will blood be collected? Volume?

   Will the animals be sedated? [ ] Yes [ ] No

6. Will monoclonal antibodies be produced in mice bearing ascites tumors? [ ] Yes [ ] No

   How often will the animals be assessed for abdominal distention? [ ] 1x/day **or** [ ] 2x/day

   Will the animals be sedated for tapping? [ ] Yes [ ] No

Note: Only 1 tap is permitted per animal. *If you are producing monoclonal antibodies using ascites tumors in mice, section **11b, alternatives**, must explain why an **in vitro** system is not suitable for your study.*

7. Sedation / Anesthesia for blood or ascites collection: If the animals will be sedated for either injections or collection, please indicate the species, drug, dose and route:

Species	Drug	Route	Dose (mg / kg)

8. What criteria will be used to determine that the animals should be euthanized rather than continue to be used?

ROOM /LAB SAFETY INFORMATION

Complete this form if you will be using infectious agents, radioisotopes, chemical carcinogens, recombinant DNA or hazardous chemicals .

PROTOCOL #_____
EXPIRES: _____

RUA#: _____ BUA#: _____ CCA#: _____

Identity of Hazard:			
Investigator Last Name:		Department:	
First Name:		Phone:	
E-mail:		Fax:	

Provide a short description of the agent:

This agent / material is hazardous for: [ ] Humans only [ ] Animals only [ ] Humans and Animals
For which Animal Species?

The agent can be spread by:
[ ] Blood [ ] Feces/urine
[ ] Saliva/nasal droplets [ ] Does not leave animal
[ ] Other:

Describe any human health risk associated with this agent:

The precautions checked below apply to this experiment:

[ ] The researcher or his/her technicians are responsible for the feeding and care of these animals.
[ ] The following items must be assumed to be contaminated with hazardous material and must be handled only by the researcher or his/her technicians.
- [ ] Cage [ ] Stall [ ] Water Bottle [ ] Animal Carcasses
- [ ] Bedding [ ] Other:

[ ] Cages must be autoclaved before cleaning.
[ ] Label cages and remove label after decontamination.
[ ] Animal carcasses must be labeled and disposed of as follows:
- [ ] Incineration [ ] Biohazardous Waste Container
- [ ] Bag and Autoclave [ ] EH&S will pick-up (2-1493).

[ ] All contaminated waste (soiled bedding or other animal waste) must be properly labeled and disposed of as follows
- [ ] Incineration [ ] Biohazardous Waste Container
- [ ] Bag and Autoclave [ ] EH&S will pick-up (2-1493).

Personal Protective Equipment Required:

[ ] The following personal protective equipment must be worn/used in the room:
- [ ] Lab Coat/Coveralls [ ] Shoe Covers/Booties
- [ ] Disposable Gloves [ ] Head Cover
- [ ] NIOSH Certified Dust Mask [ ] Disinfectant footbath
- [ ] Eye Protection/Face Shield [ ]
- [ ] Fitted Respirator Type:
- [ ] Other: Describe:

[ ] Personal protective equipment must be removed before leaving the room.
[ ] Personal protective equipment must be discarded or decontaminated at the end of the project
[x] Hands and arms must be thoroughly washed upon leaving the room
[ ] Full shower, including washing of hair, must be taken upon leaving the room.
[ ] Decontaminate Room (Inform ARS area supervisor when cage and/or room can be returned to general use).

Provide any other information needed to safely work in this room: