**Instructions for completing the UC Merced protocol form for Animal Use and Care**

Please make sure to check grammar and spelling prior to submitting application. Mistakes in grammar and spelling in the application can result in misunderstanding of species, procedures, husbandry requirements, etc., by the members of the IACUC committee and IACUC staff.

**1. Contacts**

The investigator must be a UC employee with career status. Non-UC personnel, graduate students, and residents may be the alternate contact, but the responsible party must have career status employment. Please be sure to include an alternate contact along with after hours phone and/or pager numbers. If animals on this project show evidence of illness or pain, emergency care, including euthanasia, will be administered at the discretion of veterinary staff when the investigator or alternate contact person cannot be reached.

**2. Title**

Please limit the project title to 60 characters as frequently required for grant applications.

**3. Species**

Please only list species by common names such as mice, rats, dogs, rhesus or cynomolgus monkeys, or cats. List the total number of animals to be used over the three-year period covered by the submitted protocol. If you have a breeding colony producing the animals for this study, then all of the animals in the colony will need to be accounted for in the protocol. If more than three species will be used, please provide an attached list.

Assumed litter sizes: 8-10 mice/rats

**4. Procedures**

Briefly describe the procedures included in this project using language that would be understandable to those without a scientific background. This page is posted on the animal room door for animal care staff, and it is important that they understand the intent of the study. This information will help the animal care staff understand any conditions they may encounter while caring for your animals, and best serve your needs and those of the animals.

**5. Animal Location**

Please list the vivarium location as well as the study area or laboratory where ANY of the procedures described in the protocol will be performed. If animals are to be investigator-maintained, husbandry SOPs must be submitted with the protocol form or must be on file with the IACUC Office.

**6. Special Husbandry Requirements**

Describe any special requirements your animals will have with respect to food, water, temperature, humidity, light cycles, caging type, bedding, or any other conditions associated with husbandry. Be sure to identify any deviations from the Guide for the Care and Use of Laboratory Animals, such as wire bottom cages, and include the length of time animals are to be housed in the special cages. Justification for deviations from the “Guide” must also be provided. Include any special instructions with regard to disposal of dead animals, such as “bag for disposal” or “save for necropsy”. Also indicate if pest control can be performed in the animal area. The “Guide” is a document intended to assist institutions in caring for and using animals in ways judged to be scientifically, technically, and humanely appropriate. The “Guide” is also intended to assist investigators in fulfilling their obligation to plan and conduct animal experiments in accord with the highest scientific, humane, and ethical principles. It is expected that all “Guide” recommendations will be followed, unless specifically justified.

**7. Hazardous Materials**

The use of Hazardous Materials in the animal rooms and the laboratories requires the completion of the Room/Lab Safety Information sheet found at the end of the protocol form. The use of such agents may also require a Use Authorization from Environmental Health & Safety (EH&S). The Investigator is responsible for insuring that the necessary approvals are obtained from EH&S, that all personnel are appropriately trained and equipped to work safely with these hazards, and that the animal care staff has been notified of any associated risks specific to the hazardous agent(s) and its use in animals. Hazardous materials include: Infectious Agents; Radioisotopes; Chemical Carcinogens; Recombinant DNA; and Hazardous Chemicals (flammable, toxic, corrosive, or chemotherapeutic). For more information regarding specific requirements pertaining to hazardous materials, contact EH&S at (209)228-4234.

**8. Funding and Funding Source**

Please indicate if this is a NEWLY funded NIH grant. The Public Health Service (PHS) policy requires the IACUC to compare the animal portions of a newly funded grant to the submitted protocol. To accomplish this requirement, investigators are requested to submit those portions of the submitted grant that reflect any proposed procedures with live vertebrate animals. Please submit relevant animal-related pages from section D. Experimental Design and Methods. For example, if the grant contains tables describing the study groups and numbers of animals, please include. Please also attach section F. Vertebrate Animals. The pages that are submitted with the protocol as an attachment must be from the submitted grant. Please contact the IACUC staff if you have any questions associated with this section of the protocol submission and the PHS requirements. The IACUC suggests that investigators consider adding relevant information to section F. Vertebrate Animals in new grant applications. This will provide an easy method for including the necessary information for new grant-related protocol submissions.

**9. Veterinary Care**

IACUC Policy on Veterinary Care Delivered by Faculty Veterinarians:

Adequate veterinary care is an institutional responsibility. The Attending Veterinarian, Dr. Patrick Sharp, is the veterinarian of record for the UC Merced campus, as required under the Federal Animal Welfare Act, and has final responsibility to ensure that campus programs of veterinary care are adequate. Veterinarian-researchers who wish to directly provide veterinary care for their animals may do so, subject to the following:

• The investigator must demonstrate familiarity with the regulatory requirements for adequate veterinary care.

• At the beginning of the experiment, the veterinarian-researcher must consult at least once with the veterinary staff of the unit in which their animals will be housed. The purpose of this consultation is to work out any unresolved details of veterinary care, such as weekend coverage when the investigator is out of town, etc.

• The investigator will be required to keep individual medical records in the facility with the animal(s) at all times so that these records are accessible to campus veterinary staff and the IACUC. Animal records must remain with the animal facility when the project is completed.

The designated veterinary staff for the unit retains the responsibility for the adequacy of veterinary care and retains oversight responsibility for animals within their units. Animal caretakers must continue to report sick calls through the appropriate channels.

**10. Objectives and significance**

Please provide the overall objective(s) of the study, and the significance. Bear in mind your target audience may be a faculty member from an unrelated discipline, please do not use jargon. All abbreviations must be clearly defined.

**11. Literature Search**

A minimum of two database searches including *Boolean operators* that reflects an effort to address the ‘3Rs’ (refinement, replacement, reduction) is required by federal law. It is also important to show that the proposed use of animals is not unnecessarily duplicative of other studies previously performed. The ‘3Rs’ are:

• Refinement of technique to reduce or eliminate unnecessary pain and distress an animal may experience.

• Reduction, which refers to an effort to reduce the number of animals used overall within the study.

• Replacement refers to replacing animals with non-animal alternatives, non-mammalian or invertebrate species. Alternatives could include in vitro methods that utilize organ, tissue and cell culture, computer simulation models, microorganisms, plants, or chemical techniques.

UC Merced provides on-line access to databases that can be used to search for such alternatives. The literature search must have been performed within the last six months. For more information on animal alternatives please visit [USDA for guidelines on adequate literature searches for animal alternatives](http://www.aphis.usda.gov/ac/policy/policy12.pdf).

Animal Alternative Databases:

[UC Center for Animal Alternatives](http://www.vetmed.ucdavis.edu/Animal_Alternatives/main.htm)

[AWI Laboratory Animals](http://www.awionline.org/lab_animals)

[Animal Welfare Information Center](http://awic.nal.usda.gov/nal_display/index.php?info_center=3&tax_level=1)

[Center for Alternatives to Animal Testing](http://caat.jhsph.edu)

**11b.** **Result of search for alternatives.** Please indicate the results of this search for alternatives, and whether you were able to identify alternatives that are included in the studies proposed. If no alternatives have been found, and if no prior studies have been performed that indicate duplication, then state this within the framework of the objectives of the study. It is important to state the unique aspects of your study in relation to the published literature. Please also include any procedures you have performed that indicate your efforts to decrease the use of animals. This could include in vitro studies or those performed with invertebrate or non-mammalian species. This documents your efforts towards employing the concepts of the ‘3Rs’.

**11c.** **Animal numbers justification.** Please include a description of how you have arrived at the numbers of animals you are requesting for these studies. A rationale for the numbers of animals proposed is essential, and the IACUC is required by law to assess the need for the numbers of animals proposed for use. Statistical validation can be presented using a power analysis or other relevant statistical tests. Such information allows the IACUC to understand your study needs and assure that the scientific objectives of the study can be met (i.e., sufficient animals, too few animals or too many animals).

For protocols that do not require statistical significance such as a pilot study, please include a justification for the numbers of animals that includes potential variability that may be anticipated and how that affects the study. Animal number justification is also required for teaching protocols, demonstrations, or for breeding stock. For other studies, such as those that focus on specific cell types or tissue analysis, include a detailed breakdown identifying the amount of material required to accomplish the goals, how much can be obtained from each individual animal, and how this is reflected in the animal numbers requested. This will allow the IACUC to understand your study needs.

**11d.** **Assign Pain/Distress Classification.** According to regulatory agencies, all vertebrate animals used in research, teaching or testing must be assigned to an appropriate pain category. Please assign each animal under the highest pain/distress category that will apply to the animal at any time while on the protocol. The chart in this section outlines the Pain/Distress categories.

**11e.** **Species rationale**. Please include your rationale for the species chosen and why in vitro methods cannot be used to meet the stated objectives.

**11f.** **Has this study been previously conducted?** If you are proposing to repeat a study that has been previously conducted, it is necessary to provide justification for this need. The IACUC is required to insure that no unnecessary duplication is performed, and your justification will allow the IACUC to understand why duplication is necessary.

**12. Summary of Procedures**

**12a. Describe the use of animals in your project in detail.**

In this section please clearly and succinctly state all of the procedures that you propose to perform with the animals. Please include in your description terminology that will be understood by individual outside of your area of expertise, and only use abbreviations after they have been defined. Please be concise and describe the procedures in a manner that can easily be followed. For complicated experimental designs, a flow chart or diagram is strongly recommended to help the IACUC understand the experiments you propose. Please provide full descriptions of any surgical procedures. If the procedures proposed will be performed by a vivarium veterinarian and is described in an IACUC approved SOP, then it is only necessary to state the title of the SOP and SOP number. See individual vivarium veterinary staff to obtain this information.

Specifically address the following:

• Experimental injections (substances, e.g., infectious agents, adjuvants, etc.; dose, sites, volume, route, and schedules).

• Blood collection (volume, frequency, withdrawal sites, and methodology).

• Surgical procedures (animal prep, approach, procedure, closure and post-op care).

• Radiation (dosage and schedule).

• Methods of restraint (e.g., restraint chairs, collars, vests, harnesses, slings , cones, etc.). Include how the animals are restrained for routine procedures such as blood collection. Prolonged restraint must be justified with appropriate oversight to insure it is minimally distressing. Describe any sedation, acclimation or training to be utilized.

• Experimental endpoint criteria (e.g., tumor size, percent body weight gain or loss, inability to eat or drink, behavioral abnormalities, clinical symptoms, or signs of toxicity) must be specified when the administration of tumor cells, biologics, infectious agents, radiation or toxic chemicals are expected to cause significant clinical symptoms or are potentially lethal. List the criteria to be used to determine when euthanasia is to be performed. Death as an endpoint must always be justified. Provide details in sections 12c and 13.

• 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. Please attach copies of permits if applicable.

If your protocol includes antibody production, please include the Antibody Production Project Description.

**12b. Study Groups and Numbers Table**

As identified by the columns, in this table please include the group number, the procedures for each of the animals in each group, and the number of animals per group. A separate table can be included if this is preferred. This table must fully account for all animals used in the proposed studies, and the total number of animals proposed needs to match the total number of animals shown on page 1, Section 3: Species.

**12c. Death as an Endpoint**

“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. The use of death as an endpoint is discouraged and must always be justified. Endpoints other than death must always be considered and should be used whenever the research objective can be attained with non-lethal endpoints. 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, death is not an endpoint.

**12d. Surgery**

Please identify if the surgical procedure(s) proposed are survival or terminal, the surgery location, and personnel involved. If both survival and terminal procedures are indicated in this protocol, please clarify both groups.

**12e. Multiple Major Surgical Procedures**

Federal Law requires scientific justification for multiple major surgical procedures. Major surgery penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic function. Multiple major survival surgical procedures on a single animal are discouraged but may be permitted if scientifically justified by the investigator and approved by the IACUC. For example, multiple major survival surgical procedures can be justified if they are related components of a research project, if they will conserve scarce animal resources per the National Research Center 1990, or if they are needed for clinical reasons. If multiple major survival surgery is approved, the IACUC must pay particular attention to animal well-being through evaluation of the outcome(s) of the animals through regular updates provided by the investigator. Cost savings is not an accepted justification for performing multiple major survival surgical procedures.

**12f. Drugs to be used (except for euthanasia)** - Anesthetics, analgesics, tranquilizers, neuromuscular blocking agents, antibiotics and other drugs.

The Animal Welfare Regulations and Public Health Service Policy state that procedures which may cause more than momentary or slight pain or distress to the animals will:

• be performed with appropriate sedatives, analgesics or anesthetics unless

withholding such agents is justified for scientific reasons, in writing, by the Principal Investigator and any withholding will continue for only the necessary period of time.

• involve in their planning, consultation with the Attending Veterinarian.

• not include the use of paralytics without anesthesia.

Please provide information about anesthetics, analgesics, tranquilizers, neuromuscular blocking agents and antibiotics according to species, drug, dose, route, and timeline that you intend to use in this project. Please consult with vivarium veterinary staff relevant to the species under consideration to insure drugs and dosages are appropriate.

**12g. Anesthesia Monitoring**

Please describe the physiologic parameters you will monitor during the procedure to assess adequacy of anesthesia and indicate the circumstances when incremental doses of anesthetics will be administered. If vivarium staff are responsible for anesthesia monitoring, please state.

**12h. Neuromuscular Blocking Agents**

Neuromuscular blocking agents can conceal inadequate anesthesia and therefore requires justification. Please describe the physiologic parameters to be monitored while under a neuromuscular blocking agent to assess adequacy of anesthesia.

**12i. Post-Surgical Monitoring**

Please describe the physiologic parameters you will monitor during the recovery period as well as how often these parameters are monitored. Also indicate when post-operative analgesics will be given or provide scientific justification if postoperative analgesics cannot be given. If vivarium staff are responsible for post-procedural monitoring, please state.

**13. Adverse Effects**

Describe all significant adverse effects of the experiment on the animals (such as pain, discomfort; reduced growth, fever, anemia, neurological deficits, behavioral abnormalities, nutritional deficiency or other clinical symptoms of acute or chronic distress). For genetically altered animals it is essential to include any adverse findings that may be directly associated with the desired genotype. Describe criteria for monitoring the well-being of animals and criteria for terminating/modifying the procedure if adverse effects are observed. Describe how the signs listed above can be ameliorated or alleviated. Please provide scientific justification if signs are not to be alleviated or ameliorated.

Even if pain or distress is not anticipated, the protocol must contain a contingency plan for dealing with unexpected situations that may arise. The plan should include detailed written criteria for the humane endpoints that will be used to determine when animals will be removed from the study, treated, or euthanized. The Animal Welfare Regulations and Public Health Service Policy state that animals that would otherwise suffer severe or chronic pain and distress that cannot be relieved should be painlessly euthanized at the end of the procedure, or if appropriate, during the procedure.

It is important to note that if any unanticipated adverse effects not described in the protocol 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 the protocol.

**14. Method of euthanasia:**

Even if your study does not involve euthanizing the animals, you must show a method that would be used in the event of unanticipated injury or illness. If anesthetic overdose is the method, show the agent, dose, and route.

Recommended Methods

The 2020 Report of the AVMA Panel on Euthanasia categorizes methods of euthanasia (see below). A copy of the AVMA report can be accessed at [http://www.avma.org/issues/animal\_welfare/euthanasia.pdf](https://www.avma.org/resources-tools/avma-policies/avma-guidelines-euthanasia-animals)

**Acceptable**

o Barbiturates (most species)

o Carbon dioxide (CO2) – compressed gas only (most species)

o Inhalant anesthetics (most species)

o Tricane methane sulfate (TMS, MS222) (fish, amphibians)

o Benzocaine hydrochloride (fish, amphibians)

o Ether and carbon monoxide are acceptable for many species, but relatively dangerous to personnel.

o Captive penetrating bolt (horse, ruminant, swine)

**Conditionally Acceptable (Requires Scientific Justification and IACUC approval)**

o Cervical dislocation (birds, small rodents and rabbits)

o Decapitation (birds, rodents, some other species)

o Pithing (some ectotherms)

o Various pharmacological and physical methods

**Unacceptable**

o Chloral hydrate, chloroform and cyanide

o Decompression

o Neuromuscular blockers

o Various pharmacological and physical methods

o Dry ice – generated CO2.

**15. Disposition of animals**

Please describe what will happen to the animals at the end of the study. If they will not be euthanized, then please include this statement. Specifically describe study end points and indicate the time point, if any, when animals will be euthanized. Please note: The Raptor Center can only accept healthy rodents that have not been infected with pathogens or treated with drugs, anesthetics, or toxins.

**16. Project Roster**

The protocol form provides substantial information on the requirements associated with training, occupational health, and documenting all individuals associated with the animal protocol. Please follow each of the steps identified, indicating for each person: name, employee number OR e-mail address, and training and experience relevant to the procedure described in this protocol, for example, classes attended, hands on training, years of experience, or surgical experience. Only those individuals that will be working with live vertebrate animals need to be included. If individuals are working with animal tissue only or after the animal has been terminated, then they need not be included. Animal care and vet staff associated with the vivarium do not need to be individually listed. Failure to provide this information may significantly delay approval of your protocol.

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| |  | | --- | |  |   **PROTOCOL FOR ANIMAL USE AND CARE**  *Submit via e-mail to:* [*rci@ucmerced.edu*](mailto:rci@ucmerced.edu)   |  | | --- | |  | | | | | | | | |  | | --- | | **Office of Research USE ONLY**  PROTOCOL:  EXPIRES: |   **USDA Category:**  Please assign a USDA category in the BOX provided. For information on USDA categories please click on the following link: [USDA pain and distress categories](https://rci.ucmerced.edu/sites/rci.ucmerced.edu/files/documents/usda_pain_and_distress_categories.pdf) | | |
| *Please use a minimum font size of 10* | | | | | | |
|  | | | | | | |
| **1. Contacts: Investigator** | | | | | **Alternate Contact** | | | | | |
| Last Name: |  | | | | Last Name: |  | | | | |
| First: | MI: | | |  | First: | MI: | | |  | |
| E-mail: |  | | | | E-mail: |  | | | | |
| Department/Affiliation: |  | | | | Department/  Affiliation: |  | | | | |
| Phone / after hrs: | |  |  | | Phone / after hrs: | |  |  | | |

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| --- | --- |
| **2. Title** |  |

|  |  |  |
| --- | --- | --- |
| **3. Species** (common names): | Total number for study | Name of source of the animals: |
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**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.

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| --- | --- | --- | --- |
| **5. Animal** | Overnight housing | | Study area / Laboratory **(Room/Bldg.)** |
| **Location** |  | |  |
| Animals will be maintained by: | | [ ] Vivarium [ ] Investigator *(If investigator maintained, please attach husbandry SOPs.)* | |

If a study conducted in the field, the Investigator has completed a field safety plan:

[ ] Yes (*Please attach*) [ ] No *(Please visit the* [*Risk Services website*](http://risk.ucmerced.edu/risk-resources/field-operational-planner) *for instructions and to access the form)*

**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.

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

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| --- | --- | --- | --- | --- |
| Biohazardous/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.

|  |
| --- |
| [ ] Yes [ ] No |

If you check ‘Yes’ to Recombinant DNA/Biohazardous material/Infectious Agents use above, please answer the following question:

Is there a Biological Use Authorization (BUA) associated with the bio-work approved by the IBC?

**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)**

|  |  |
| --- | --- |
| [ ]  [ ] | UC Merced Attending veterinarian  Another Veterinarian |

If you checked “Another Veterinarian”, please provide the following information and notify the UC Merced 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:

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

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**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://altweb.jhsph.edu/>

<http://guides.lib.ucdavis.edu/alternatives-searching>

\*\*

**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.*

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| --- | --- | --- | --- |
| **Database Name** | **Years Covered** | **Keywords / Search Strategy** | **Date** |
|  |  |  |  |
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**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.

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**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.

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**d) Pain/ Distress Classification:** Please assign each animal listed on the protocol to one of the following USDA pain and distress categories: B, C, D or E. Also include the number of animals in each category. See the example in red on how to complete the table.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Species | Category B | Category C | Category D | Category E |
| Number of Animals | Rats | 0 | 12 | 0 | 0 |
| Number of Animals |  |  |  |  |  |

|  |  |
| --- | --- |
| **Category** | **Description** |
| **B** | Animals reported in Column B should be those animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.  Animals used for research purposes during the reporting year must be reported in Column C, D, or E, as appropriate. |
| **C** | Animals used in teaching, research, experiments, or tests which involve no pain, distress, or use of pain-relieving drugs |
| **D** | Animals used in teaching, research, experiments, or tests which involve accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.  A painful procedure is defined as “any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure is applied, that is, pain in excess of that caused by injections or other minor procedures”.  These animals are monitored and would receive appropriate and timely administration of anesthetics, analgesics, medications, treatments, refinements, or euthanasia to eliminate or cap pain/distress to mild and transient levels. |
| **E** | Animals used in teaching, research, experiments, or tests which involve accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would adversely affect the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. |

For examples of USDA pain and distress categories, see [**USDA pain and distress categories**](file:///C:\Users\cxiong51\Downloads\usda_pain_and_distress_categories.pdf)**.**

**\*Category E research, testing, or procedures require strong scientific justification as to why pain-relieving drugs or other methods for relieving pain cannot be used on animals. Provide justification for category E procedures below. Include attachments, if needed.**

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**e) 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).

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| **f)** 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.

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**12.**  **Summary of Procedures:**

1. **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.

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**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** |
|  |  |  |
|  |  |  |
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|  |  |  |
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**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.*

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**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? | Pharmaceutical grade? (Y/N) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
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|  |  |  |  |  |  |
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|  |  |  |  |  |  |

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. *This page is not subject to FOIA requests.* Please provide either the University Employee ID number **OR** a valid UC Merced 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 Roy Hoglund at [rhoglund@ucmerced.edu](mailto:rhoglund@ucmerced.edu) 209-228-4189 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. Please contact the Office of the Research at 209-383-8655 for more information.

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

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

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

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

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Last Name** | **First Name** | **Middle Initial** | **Title/Degree** |
|  | | |  |
| UC ID Number **OR** e-mail address: | | | |
| Describe procedures this individual will perform and describe the training and experience relevant to the procedures in this protocol: | | | |
| **Last Name** | **First Name** | **Middle Initial** | **Title/Degree** |
|  | | |  |
| UC ID Number **OR** E-mail address: | | | |
| Describe procedures this individual will perform and describe the training and experience relevant to the procedures 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 UC Merced Animal Welfare Assurance on file with the US Public Health Service. These documents are available from the UC Merced Office of Research. Please call 209-383-8655 to obtain these documents. 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: \_\_\_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_ |
|  |

**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 (ext. 4639). | | | | |
| [ ] | | 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 (ext. 4639). | | | | |
| **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 | | | | | | | | | | | | |
| **]** | | **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**