**Animal Use Protocol Form**

## Please Leave Blank

**Protocol #:**

Approval Date:

Expiration Date:

PROPOSAL #:

APPROVAL DATE:

EXPIRATION DATE:

P POSAL #:

ROPOSAL #:

PROPOSAL #:

APPROVAL DATE:

EXPIRATION DATE:

* One species per form.
* If you need to add more rows in a table hit the tab key.
* Please check for grammar and typo’s
* All modifications need to be added to the approved protocol using **track changes**.

#### ADMINISTRATIVE DATA

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Principal investigator: | | | |  | | | | | | | | | | | | | |
| Department: | |  | | | | | | | | Title: | | |  | | | | |
| Phone: |  | | | | MS: | |  | | | | | E-mail: | | |  | | |
| Project title: | | |  | | | | | | | | | | | | | | |
| *Put an X by the type of submission.* | | | | | | Initial: | |  | | | Renewal: | | |  | | Modification: |  |
| *Previous Protocol #* | | |  | | | | | | | | | | | | | | | |
| If this is a renewal protocol were there any unexpected complications associated with this study? If ‘yes’, how were they handled and how do you expect to address this in the future? | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | |
| *List below Funding Source* | | | | | | | | | *List below* Grant # | | | | | | | | |
|  | | | | | | | | |  | | | | | | | | |
|  | | | | | | | | |  | | | | | | | | |

#### ANIMAL REQUIREMENTS

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Genus: |  | | | | | | Species: |  |
| Strain, subspecies, or breed: | | | |  | | | Common name: |  |
| Approximate age, weight or size: | | | |  | | | Sex: |  |
| Source(s): | |  | | | | | | |
| Requested housing location(s): | | | | |  | | | |
| Laboratory Procedural Locations: *List the building, room #, species, and type of procedures that will be done. Procedures might include surgery, post-operative care, behavioral, euthanasia, non-surgical procedures, hazardous agent use, and breeding colony activities.* | | | | | | | | |
| Building | | | Room # | | | Procedure | | |
|  | | |  | | |  | | |
|  | | |  | | |  | | |
|  | | |  | | |  | | |

#### [GLOSSARY OF ACRONYMS AND ABBREVIATIONS](http://science.ksc.nasa.gov/shuttle/technology/sts-newsref/stsref-toc.html" \l "stsover-acronyms)

|  |
| --- |
| Provide a glossary of the acronyms / abbreviations used in the protocol. |
|  |

#### SUMMARY OF PROCEDURES

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| --- |
| Briefly describe the overall intent of the study in Lay Terms. Include in your description:  *a) statement of your hypothesis, the objectives and significance of the study,*  *b) the relevance to human, animal health, and/or general knowledge,*  *c) an overview of how animals will be used.* |
|  |

#### TRANSPORTATION

|  |
| --- |
| Transportation of animals must follow “The Guide”. For transport between noncontiguous buildings describe the vehicle used. If animals are transported within buildings list the route that will be used. |
|  |

#### RATIONALE FOR ANIMAL USE

|  |
| --- |
| Explain your rationale for animal use. *The rationale should include reasons why it is necessary to use animal models.* |
|  |
| Justify the appropriateness of the species selected. The species selected should be the lowest possible on the phylogenetic scale. |
|  |
| Justify the number of animals to be used. *The group size should be statistically justified with either previous experience, published data from similar experiments or power analysis. The number of animals to be used for breeding and experimentation should be delineated.  All requested animals should be linked to a specific proposed experiment.  Animals that will be euthanized prior to weaning because they are the wrong sex or genotype must also be estimated and listed as part of the animal numbers.* |
|  |

#### AUTHORIZED AMOUNTS

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| The number of animals you request in this section is the total number of animals you will require for a 3-year period.   * Please make sure you request the animals by Pain and Distress Categories. For more detail of the Pain or distress classification see Appendix A.   Category B: No pain or distress. Animals kept for breeding or holding in a colony.  Category C: No more than momentary or slight pain or distress, no use of anesthetics.  Category D: Pain or distress relieved with anesthetics, analgesics and/or tranquilizer drugs or other methods for relieving pain or distress.  Category E: Pain or distress or potential pain or distress that is not relieved with anesthetics, analgesics and/or tranquilizer drugs or other methods for relieving pain or distress.   * Include all pre weaned animals * If this is a renewal protocol and there are animals remaining on the expiring protocol these animals will need to be transferred and should be included in the number of animals requested. | | | | |
| # Category B | # Category C | # Category D | # Category E | Total # |
|  |  |  |  |  |
|  |  |  |  |  |

|  |
| --- |
| Justification for Category "E". *Describe each category “E” procedure and provide a thorough justification of why pain and distress relief cannot be provided* |
|  |

#### DRUGS / AGENTS

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| List all procedural drugs such as: Anesthetics, Analgesics, Tranquilizers, Neuromuscular blocking agents, or other therapeutic drugs (i.e., antibiotics): *Provide the following information about any of these drugs that you intend to use on animals in this project. Investigators must use pharmaceutical-grade chemicals or other substances whenever they are available, even in acute/ terminal procedures. If a drug is pharmaceutical grade it will have either an NADA or ANADA number on file which is generally on the label/packaging insert of the drug. The use of non-pharmaceutical grade drugs/ agents needs to be justified below*.  For human drugs these can be searched at:  <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=orange%20book&utm_content=1>  For veterinary drugs they can be searched at:  <http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/ucm042847.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=green%20book&utm_content=1> | | | | | | | | | |
| Drug | Procedure | Dose (mg/kg) | Volume | Route | Frequency / Duration | Pharmaceutical Grade | | Controlled Substances | |
| Yes | No | Yes | No |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| List all Experimental drugs/agents/substances/cells: *Provide the following information about any of these other drugs or agents to be used with animals. Investigators are expected to use pharmaceutical-grade chemicals or other substances whenever they are available, even in acute / terminal procedures. The use of non-pharmaceutical grade agents needs to be justified in section H8.* | | | | | | | | | |
| Agent | Procedure | Dose (mg/kg) | Volume | Route | Frequency / Duration | Pharmaceutical Grade | | Controlled Substances | |
| Yes | No | Yes | No |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

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| --- |
| Pharmaceutical-grade and Non-pharmaceutical-grade Compounds. *Provide a scientific justification the use of any non-pharmaceutical drug / agent listed above. describe methods that will be used to ensure appropriate preparation and administration* |
|  |

#### DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Explain the experimental design and specify all animal procedures. All procedures to be employed in the study must be described. This description should allow the IACUC to understand the experimental course of an animal from its entry into the experiment to the endpoint of the study.  *A best practice is to provide an acceptable range of the specific items described below to allow flexibility in the use of professional judgment and avoid non-compliance due to work conducted off protocol as a result of overly restricted parameters.*  NOTE: Detail of all surgical procedures should be explained in section “J”.  Answer the following questions | | | | | | | | | | | |
| List sequentially all procedures done on animals. A flowchart may be an effective presentation of the planned procedures. | | | | | | | | | | | |
|  | | | | | | | | | | | |
| Animal identification methods: *Put an X next to all that apply* | | | | | | | | | | | |
| ear tags |  | tattoos |  | collar |  | cage card |  | implant |  | other |  |
| Genetically Engineered Animals: Describe any anticipated phenotypic consequences of the genetic manipulations to the animals including phenotypes that are not the aim of the study. *Describe any special care and describe the monitoring frequency and methods that the lab will use.* | | | | | | | | | | | |
|  | | | | | | | | | | | |
| Methods of restraint *[e.g., restraint chairs, collars, vests, harnesses, slings, etc.]*. *Describe how animals are restrained for routine procedures like blood withdrawals. Prolonged restraint must be justified with appropriate oversight to ensure it is minimally distressing. For prolonged restraint describe any sedation, acclimation or training to be used.* | | | | | | | | | | | |
|  | | | | | | | | | | | |
| Administration of substances. *Describe how drugs / agents listed in section “H” are administered. (e.g. vessel utilized, restraint, sedation)* | | | | | | | | | | | |
|  | | | | | | | | | | | |
| Blood withdrawals *[volume, frequency, withdrawal site, and methodology]*. | | | | | | | | | | | |
|  | | | | | | | | | | | |
| Radiation *[dosage and schedule]*. | | | | | | | | | | | |
|  | | | | | | | | | | | |
| Food or fluid restriction. If food, or fluid, or both food and fluid, will be restricted, describe method for assessing the health and wellbeing of the animals. Animals need to be weighted at least once a week. *[Amount earned during testing and amount freely given must be recorded and assessed to assure proper nutrition.]* If you are seeking a departure from the recommendations of the *Guide*, provide a scientific justification. | | | | | | | | | | | |
|  | | | | | | | | | | | |
| Behavioral Procedures. | | | | | | | | | | | |
|  | | | | | | | | | | | |
| Imaging. *If required describe restraint and / or inhalant anesthesia.* | | | | | | | | | | | |
|  | | | | | | | | | | | |
| Other non-surgical procedures (e.g. tail biopsy, special diet feeding, and administration of noxious stimuli). | | | | | | | | | | | |
|  | | | | | | | | | | | |
| Expected health outcomes of any experimental studies *[e.g., pain or distress, ascites production, etc.].* | | | | | | | | | | | |
|  | | | | | | | | | | | |
| Describe any procedures that will be utilized to minimize study associated pain, distress, and morbidity. *If a study is USDA Classification E, describe any non-pharmaceutical methods that will be used to minimize pain and distress.* | | | | | | | | | | | |
|  | | | | | | | | | | | |
| Humane endpoint criteria *[e.g., tumor size, percentage body weight gain or loss, inability to eat or drink, behavioral abnormalities, clinical symptomatology, or signs of toxicity]* List the criteria that will be used to determine when euthanasia is to be performed. Include the frequency of monitoring and the criteria utilized. It may be helpful to develop several criteria or a scoring system. Death as an endpoint must be scientifically justified. | | | | | | | | | | | |
|  | | | | | | | | | | | |
| Veterinary care: Indicate the plan of action in case of animal illness [e.g., initiate treatment, call investigator prior to initiating treatment, euthanize]. *Please be aware that in cases where someone in the lab cannot be reached the Attending Veterinarian is authorized to treat and/or euthanize animals.* | | | | | | | | | | | |
|  | | | | | | | | | | | |
| Other procedures not delineated already. | | | | | | | | | | | |
|  | | | | | | | | | | | |

#### SURGERY

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| * Major Surgeries generally penetrate and expose a body cavity or permanently alter physiologic function. (e.g. laparotomy, craniotomy, thoracotomy, limb amputation) * Minor surgeries are those that do not penetrate and expose a body cavity and do not permanently alter physiologic function. (e.g. muscle biopsy, Arthroscopy, endoscopic biopsy) Procedures which are routinely done on an outpatient basis at a veterinary practice are generally considered minor. (e.g. castration). * Non-survival surgery is a procedure from which an animal is euthanized before recovery from anesthesia. | | | | | | | | |
| Put an “X” next to the types of surgery(s) in the protocol and describe the following: | Minor |  | Major |  | Multiple Major Survival |  | Non-Survival |  |
| Induction and maintenance of anesthesia. | | | | | | | | |
|  | | | | | | | | |
| Assessment and monitoring of animal and anesthesia. | | | | | | | | |
|  | | | | | | | | |
| Aseptic methods/techniques. | | | | | | | | |
|  | | | | | | | | |
| Surgical site preparation. | | | | | | | | |
|  | | | | | | | | |
| Methods to prevent dehydration and hypothermia. | | | | | | | | |
|  | | | | | | | | |
| Identify the individual(s) that will perform surgery and their qualifications, training, and/or experience. | | | | | | | | |
|  | | | | | | | | |
| Identify the location where surgery will be performed. [building(s) and room(s)] | | | | | | | | |
|  | | | | | | | | |
| Surgical procedures. | | | | | | | | |
|  | | | | | | | | |
| Duration of the individual procedures being performed on the animal. | | | | | | | | |
|  | | | | | | | | |
| If survival surgery, describe postoperative care that will be provided and frequency of observation. Identify the responsible individual(s) and location(s) where care will be provided. [building(s) and room(s)] Include detection and management of postoperative complications during work hours, after hours, weekends and holidays. Include experimental endpoint criteria. | | | | | | | | |
|  | | | | | | | | |
| If non-survival surgery, describe how euthanasia will be provided and how death will be determined. | | | | | | | | |
|  | | | | | | | | |
| Are paralytic agents used during surgery? If yes, please describe how ventilation will be maintained and how pain will be assessed. | | | | | | | | |
|  | | | | | | | | |
| Has major or minor survival surgery been performed on any animal prior to being placed on this study? [Major survival surgery penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic functions or involves extensive tissue dissection or transection (such as laparotomy, thoracotomy, craniotomy, joint replacement, or limb amputation)]. If yes, please explain. | | | | | | | | |
|  | | | | | | | | |
| Will more than one survival surgery be performed on an animal while on this study? If yes, please justify. | | | | | | | | |
|  | | | | | | | | |

#### CONSIDERATION OF ALTERNATIVES

|  |  |
| --- | --- |
| **Note:** **Do not do a literature search for category B or C** **animals.** If any procedures fall into USDA's Classification D or E, causing more than momentary or slight pain or distress to the animals, describe your consideration of alternatives and your determination that alternatives are not available. Delineate the methods and sources used in the search. Database references must include databases searched, the date of the search, period covered, and the keywords used. Your search and accompanying narrative should specifically address each of the following:  refine existing tests by minimizing animal distress,  reduce the number of animals necessary for an experiment, or  replace whole‑animal use with *in vitro* or other tests.  If you use ascites production to produce antibodies, you must provide the reason for not using an *in vitro* system. Note that you must certify in Section Q.5 that no valid alternative was identified to any described procedures which may cause more than momentary pain or distress, whether relieved or not. | |
| Index(es) Searched: |  |
| Dates covered in search: |  |
| Identify Key words and how they are combined: (e.g. ‘Animal welfare’ AND ‘Mice’ AND ‘Tumors’): | |
|  | |
| Search Results: | |
|  | |
| Describe any other methods and sources used to determine that alternatives are not available for the procedures/study: | |
|  | |

#### METHOD OF EUTHANASIA OR DISPOSITION OF ANIMALS AT END OF STUDY

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Indicate the proposed method of euthanasia with an “X”. If a chemical agent is used specify the dosage, volume and route of administration under the section “G” – Drugs. | | | | |
|  | Anesthesia followed by cervical dislocation |  | Anesthesia followed by decapitation | |
|  | Anesthesia followed by euthanasia solution |  | Anesthesia followed by exsanguinations | |
|  | Anesthesia followed by perfusion with chemical |  | Anesthesia gas followed by perfusion with chemical | |
|  | Cervical dislocation without anesthesia (must provide justification) |  | CO2 inhalation followed by cervical dislocation | |
|  | CO2 inhalation followed by decapitation |  | CO2 inhalation followed by exsanguinations | |
|  | CO2 inhalation followed by perfusion with chemical |  | CO2 inhalation followed by pneumothorax | |
|  | CO2 inhalation followed by removal of vital organs |  | Cranial concussion followed by pithing | |
|  | Decapitation followed by pithing |  | Decapitation without anesthesia | |
|  | Euthanasia solution |  | Ice bath followed by cervical dislocation | |
|  | Ice bath followed by decapitation |  | MS222 | |
|  | MS222 followed by decapitation and double pithed |  | Other ( describe) |  |
| If the method(s) of euthanasia include those not recommended by the AVMA Guidelines on Euthanasia *[e.g., decapitation or cervical dislocation without anesthesia]*, provide scientific justification as to why such methods must be used. | | | | |
|  | | | | |

#### HAZARDOUS AGENTS

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Use of hazardous agents requires the approval of Environmental Health and Safety (EH&S). Attach documentation of approval for the use of recombinant DNA or potential human pathogens. Please make sure you fill out the appropriate Hazard appendix. | | | | |
| Hazardous Agent | Yes | No | Agent(s) | Date of EH&S Approval |
| Human / Animal Tumors or Tissue |  |  |  |  |
| Infectious or Biological Agents |  |  |  |  |
| Hazardous Chemicals / Drugs |  |  |  |  |
| Radiation |  |  |  |  |
| Recombinant DNA |  |  |  |  |

#### 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. |
|  |
| For animals which are imported from other states or countries Indicate if federal, state, and/or local permits are required and whether they have been obtained. |
|  |

#### List of Appendix

|  |  |  |  |
| --- | --- | --- | --- |
| Mark an “X” next to all the appendices that will be submitted with this protocol. | | | |
|  | Appendix A - USDA Classifications and Examples |  | Appendix B1 - Hazards - Infectious or Biological Agents |
|  | Appendix B2 - Hazards - Chemical |  | Appendix B3 - Hazards - Radiation |
|  | Appendix C - Special Needs Summary Sheet |  | Appendix D- Personnel Sheet / Instructions for CCMR staff |
|  | Appendix E - Exemption from Standard Care |  | Appendix F - Antibody Production |

#### PRINCIPAL INVESTIGATOR CERTIFICATIONS

|  |
| --- |
| Please read and sign below.   * I certify that I have completed all required institutional training. * I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research. * I certify that the individuals listed on the Personnel sheet are authorized to conduct procedures involving animals under this proposal, have attended the institutionally required courses, and received training in: the biology, handling, and care of this species; aseptic surgical methods and techniques (if necessary); the concept, availability, and use of research or testing methods that limit the use of animals or minimize distress; the proper use of anesthetics, analgesics, and tranquilizers (if necessary); and procedures for reporting animal welfare concerns. * For all USDA Classification D and E proposals (see section H): I certify that I have reviewed the pertinent scientific literature and the sources and/or databases as noted in Section H. and have found no valid alternative to any procedures described herein which may cause more than momentary pain or distress, whether it is relieved or not. * I certify that I will obtain approval from the IACUC before initiating any changes in this study * I certify that I will notify the IACUC regarding any unexpected study results that impact the animals. Any unanticipated pain or distress, morbidity or mortality will be reported to the attending veterinarian and the IACUC. * I certify that I am familiar with and will comply with all pertinent institutional, state, and federal rules and policies. |

**Principal Investigator** (electronic signature is accepted)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name: | Signature: |  | Date: |  |

#### CONCURRENCES

**Department Chair**

All research with animals must receive some form of peer review (the IACUC does NOT provide this function). Normally, peer review takes place during the processing of a grant application. If corporate or departmental funds will be used, the Department must perform peer review, and the chair of the department must sign below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name: |  | Signature: |  | Date: |  |

**IACUC Approval**

Certification of review and approval by the Institutional Animal Care and Use Committee:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name: |  | Signature: |  | Date: |  |

|  |  |
| --- | --- |
| **Appendix A** | **USDA Classifications and Examples** |
| **Classification B:** Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes.  **Examples:**   * Breeding colonies of any animal species (USDA does not require listing of rats, mice, birds) that are handled in accordance with IACUC approval, the *Guide* and other applicable regulations. Breeding colony includes parents and offspring. * Newly acquired animals that are handled in accordance with IACUC approval and applicable regulations. * Animals held under proper captive conditions or wild animals that are being observed.   **Classification C:** Animals upon which teaching, research, experiments, or tests will be conducted involving no pain or distress, or not more than momentary pain or distress.  **Examples:**   * Procedures performed correctly by trained personnel such as the administration of electrolytes/fluids, administration of oral medication, blood collection from a common peripheral vein per standard veterinary practice [dog cephalic, cat jugular] or catheterization of same, standard radiography, parenteral injections of non-irritating substances. * Manual restraint that is no longer than would be required for a simple exam; short period of chair restraint for an adapted nonhuman primate.   **Classification D:** Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will be used.  **Examples:**   * Surgical procedures conducted by trained personnel in accordance with standard veterinary practice such as biopsies, gonadectomy, exposure of blood vessels, chronic catheter implantation, and laparotomy or laparoscopy. * Blood collection by more invasive routes such as intracardiac or periorbital collection from species without a true orbital sinus *[e.g., guinea pigs and rats]*. * Administration of drugs, chemicals, toxins, or organisms that would be expected to produce pain or distress but which will be alleviated by analgesics, anesthetics, tranquilizers, or supportive care.   **Classification E:** Animals upon which teaching, experiments, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs will adversely affect the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests.  **Examples:**   * Procedures producing pain or distress unrelieved by analgesics such as toxicity studies, microbial virulence testing, radiation sickness, and research on stress, shock, or pain. * Surgical and postsurgical sequella from invasion of body cavities, orthopedic procedures, dentistry or other hard or soft tissue damage that produces unrelieved pain or distress. * Negative conditioning via electric shocks that would cause pain in humans. * Chairing of nonhuman primates not conditioned to the procedure for the time period used.   **NOTE REGARDING CLASSIFICATION E:** An explanation of the procedures producing pain or distress in these animals and the justification for not using appropriate anesthetic, analgesic or tranquilizing drugs must be provided on **Attachment 1**. This information is required to be reported to the USDA, will be available from USDA under the Freedom of Information Act (FOIA), and may be publicly available through the Internet via USDA’s website. | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Appendix B1. | | | | | Hazards - Infectious or Biological Agents | | | | | | | | |
|  | | | | | | | | | | PROTOCOL #:  (# to be given by IACUC) | | | |
| **Please use a separate hazard page for each hazard.**   * Work with biological agents (including all work with human source materials, pathogens, and rDNA) requires registration and consultation with EHS and prior Institutional Biosafety Committee (IBC) approval. Contact EHS for assistance in completing this appendix. * All work with human pathogens must be handled as Biological safety Level 2 (BSL-2) or higher. Use of human pathogens in animals requires ABSL-2 or higher practices and procedures:   <http://www.cdc.gov/biosafety/publications/bmbl5/>   * All researchers with exposure to human pathogens must complete Introduction to Laboratory Safety and Introduction to Biological Safety Level 2 (BSL-2) training. In addition, researchers must also complete annual BSL-2 refresher training online. * Complete all parts of the appendix; include N/A if section is not relevant. * It is the responsibility of the research staff to label all hazards administered to animals on the cage card. This should include the agent used, date/route/dose of administration and | | | | | | | | | | | | | |
| 1. Complete the following table | | | | | | | | | | | | | |
| Animal Species | | Biohazard Agent  (genus species) | | Biosafety Level of the Agent | | | | | Dose | | | | Route of administration |
|  | |  | |  | | | | |  | | | |  |
| 1. Date of IBC approval for use of above agent? (Approval must be within 3 years) | | | |  | | | | | | | | | |
| 1. Has this agent undergone any recombinant DNA manipulation? If Yes, describe rDNA activity. | | | | Yes | | No | |  | | | | | |
|  | |  | |
| 1. Where will agent be prepared for inoculation (room #)? | | | |  | | | | | | | | | |
| 1. Where will the agent be administered to the animal (room #)? | | | |  | | | | | | | | | |
| 1. Frequency and duration of administration | | | |  | | | | | | | | | |
| 1. How long is animal maintained after administration? | | | |  | | | | | | | | | |
| 1. Will infected animals be returned to or housed in the CCMR? | | | |  | | | | | | | | | |
| 1. Is the Agent infectious to humans or animals? *Please describe* | | | |  | | | | | | | | | |
| 1. Could the bedding be potentially contaminated? *If Yes, describe disposal*: | | | | Yes | | | No |  | | | | | |
|  | | |  |
| 1. Is the carcass contaminated? If Yes, describe disposal: | | | | Yes | | | No |  | | | | | |
|  | | |  |
| 1. After administration, how long are animals and/or bedding/cages considered hazardous? | | | |  | | | | | | | | | |
| 1. Briefly describe the research goals associated with using this agent: | | | |  | | | | | | | | | |
| 1. How is the agent potentially shed? Put an “X” next to all that apply | | | | | | | | | | | | | |
|  | Feces/Urine | |  | Saliva or bite | | | | | | |  | Bloodborne | |
|  | Aerosol/droplet/respiration | |  | Fomite/bedding | | | | | | |  | Other | |
| 1. List any special considerations or precautions beyond standard BSL2 practices that would be recommended for working with this agent: | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | |
| 1. Is a vaccine or therapeutic available for humans? *If yes, please describe (include options for vaccination, prophylaxis and/or post exposure treatment):* | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | |
| 1. List any antibiotic resistance markers that the agent carries (this includes resistance for selectable markers): | | | | | | | | | | | | | |
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| Appendix B2. | | | | Hazards - Chemical | | | | |
|  | | | | | | PROTOCOL #:  (# to be given by IACUC) | | |
| * Hazardous chemicals, as defined here, must be identified when used in animals to ensure the protection of researchers and CCMR staff. * Check the EHS web site for MSDS search engines, links to the NTP/IARC and toxicology information. * Hazardous chemicals include but are not limited to acutely toxic materials (LD50≤50mg/kg), teratogens/reproductive toxins, neurotoxins, antineoplastics or carcinogens designated by the National Toxicity Program (NTP) or the International Agency for Research on Cancer (IARC) as having a moderate to high potential for causing cancer in humans or animal models. * Experimental drugs or substances with limited toxicology data must be handled as if hazardous using this process. * Work in KSC laboratories must follow the procedures for “Particularly Hazardous Substances” outlines in the College’s Chemical Hygiene. * Studies involving chemicals added to food/water require additional review and procedures * At a minimum all researchers must have completed Introduction to Laboratory Safety training and Hazardous Waste Management training. The College’s Chemical Hygiene Plan outlines basic training requirements and procedures for chemical work including work with high hazard chemicals. * Complete all parts of the appendix; include N/A if section is not relevant. * It is the responsibility of the research staff to label all hazards administered to animals on the cage card. This should include the agent used, date/route/dose of administration and include any special husbandry and personal protection requirements. | | | | | | | | |
| 1. 2Complete the following Drug/Agent/Substance Information. If you need to add more rows in a table hit the tab key. | | | | | | | | |
| Drug/Substance name and CAS# | Dose (mg/kg) | Volume per dose | Route of admin.  (IV, IP, Food) | | Frequency and duration of admin. | | Hazard Class (i.e. carcinogen, acute toxin, teratogen) | Duration and route of excretion (i.e. 48 hours in urine and feces) |
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| Risk assessment statement: Please respond to each question | | |
| 1. What are the research goals for using hazardous or experimental substances/drugs? Are you looking for toxic outcomes, therapeutic benefits, drug candidate screening, adverse effects, lethality testing or dose/response data? | | |
|  | | |
| 1. List the therapeutic and lethal dose data for the drugs/chemicals you will use (express doses in mg/kg). | | |
|  | | |
| 1. What risks do these drugs/chemicals pose to researchers opening, weighing, diluting or preparing stock solutions or injections? | | |
|  | | |
| 1. Describe precautions for researcher opening, weighing, diluting, preparing stock solutions or injections or transporting this chemical. (i.e. gloves, lab coat, splash goggles, chemical fume hood, etc.) | | |
|  | | |
| 1. Where will the chemical be prepared (room #)? |  | |
| 1. Where will chemical be administered (room #)? |  | |
| 1. Will drugs/chemicals be added to food/water? |  | |
| 1. Are inhalation studies proposed? |  | |
| 1. Will select agent toxins be used? |  | |
| 1. Will dioxins, PCB or heavy metals be used? |  | |
| 1. List procedures and precautions that research personnel will use when administering this agent (i.e. protective equipment, gloves, lab coat, splash goggles, ventilation, chemical fume hood, etc.): | |
|  | | |
| Recommend precautions for personnel handling dosed/exposed animals: | | |
| 1. Ventilation/Engineering Controls (i.e. vented dump station, negative pressure room) | | |
|  | | |
| 1. Protective Equipment (i.e. nitrile gloves, head/foot covers, safety glasses): | | |
|  | | |
| 1. Bedding disposal (i.e. normal disposal in trash or bag for incineration): | | |
|  | | |
| 1. Other – work area or cage decontamination recommendations etc. | | |
|  | | |
| 1. Is an antidote or specialized treatment indicated for those handling chemicals (i.e. tetanus vaccine for tetanus toxin, calcium gluconate for HF use)? | | |
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| Appendix C. | Special Needs Summary Sheet | |
|  | | PROTOCOL #:  (# to be given by IACUC) |

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| --- | --- | --- | --- |
| Primary Investigator | | Primary Animal Contact *(if other than Investigator)* | |
| Name |  | Name |  |
| Email |  | Email |  |
| Phone |  | Phone |  |
| Emergency # |  | Emergency # |  |

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| 1. Feeding. Put an “X” next to all that apply | | | |
|  | PI will feed |  | ARC Staff will feed |
|  | PI will water |  | ARC Staff will water |
| 1. Please Describe special feeding and/or watering requirements: | | | |
|  | | | |
| 1. Caging: Please describe special caging requirements: | | | |
|  | | | |
| 1. Light Cycle: Please describe light cycle requirement. Please include the room numbers. | | | |
|  | | | |
| 1. Other | | | |
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| Appendix D. | | | | | Personnel Sheet | |
|  | | | PROTOCOL #:  (# to be given by IACUC) | | | |
| **NOTE:** This sheet will be used by CCMR staff to contact you in the event of animal emergencies. Incomplete or inaccurate information on this sheet will delay and potentially necessitate treatment/euthanasia of animals without contacting lab members | | | | | | |
| 1. List below all personnel associated with this protocol (in the order in which they should be notified about animal health issues): If you need to add more rows in a table hit the tab key. | | | | | | |
| Name: Last Name, First | Work #: | After hours #: | | Permitted to Order Animals? | | |
| Yes | | No |
|  |  |  | |  | |  |
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| 1. List the employee’s specific role in the project (i.e. injections, surgery, euthanasia, etc…) and specific training and or experience in handling, manipulating or maintaining animals which qualify them to perform the procedures on the species described in this protocol. If the employee has not been trained, state how the individual will be trained. If you need to add more rows in a table hit the tab key. | | |
| Name: (Last Name) | Role in Protocol | Training/Experience |
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| 1. Instructions for CCMR Staff   **NOTE**: Every effort will be made to follow the instructions on this sheet. However, the Attending Veterinarian has the authority to treat and or euthanize animals to alleviate pain and suffering without first notifying the Investigator. *Put an X next to all that apply* | | | | | |
| Sick Animals | | Dead Animals | | Special Husbandry (refer to Appendix C) | |
|  | Notify Investigator |  | Notify Investigator |  | Husbandry/Caging |
|  | Veterinarian to treat |  | Save for Investigator |  | Feeding/water |
|  | Euthanize |  | Bag for disposal |  | Other |

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| Appendix E. | **Exemption from Standard Care** | |
|  | | PROTOCOL #:  (# to be given by IACUC) |

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| --- | --- | --- | --- |
| Primary Investigator | | Primary Animal Contact *(if other than Investigator)* | |
| Name |  | Name |  |
| Email |  | Email |  |
| Phone |  | Phone |  |
| Emergency # |  | Emergency # |  |

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| --- |
| 1. Exemption from Environmental Enrichment: Provide scientific justification of why environmental enrichment should not be provided to the animals on your study. |
|  |
| 1. Exemption from Social Housing: Social animals must be housed in stable pairs or groups of compatible individuals unless they must be housed alone for experimental reasons, social incompatibility resulting from inappropriate behavior, or veterinary concerns regarding animal well-being. Provide a scientific justification for single housing. |
|  |
| 1. Exemption from “The Guide” on animal space requirements. For guidelines on mouse exceptions refer to the IACUC Mouse Cage Density policy: Provide a scientific justification for a change in space requirements. |
|  |
| 1. Exemption - Other: If you are asking for an exception to the "The Guide" or “a KSC IACUC policy” that is not otherwise noted please describe and scientifically justify the requested exemption below. |
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| Appendix F. | **Antibody Production** | |
|  | | PROTOCOL #:  (# to be given by IACUC) |

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| 1. Answer the questions below. For yes / no questions put a “X” next to the box that applies. | | | | | | | | |
| 1. Polyclonal antibodies? | | |  | Yes | |  | No | |
| 1. Monoclonal antibodies? | | |  | Yes | |  | No | |
| 1. Identify the type of antigen that will be used? | | |  | | | | | |
| 1. Will the antigens be sterile? | | |  | Yes | |  | No | |
| 1. How will the antigen(s) be purified? | | |  | | | | | |
| 1. What adjuvant will be used for the initial injection? | | |  | | | | | |
| 1. What adjuvant will be used for subsequent injections? | | |  | | | | | |
| 1. What route will be used for injections? | | |  | | | | | |
| 1. What anatomical location will be injected? | | |  | | | | | |
| 1. How many injections at one time? | | |  | | | | | |
| 1. How frequently will injections be given? | | |  | | | | | |
| 1. What volume will be injected at each site? | | |  | | | | | |
| 1. Polyclonal Blood Collection Procedures | | | | | | | | |
| 1. Who will collect the blood? | | |  | | | | | |
| 1. From what anatomical location? | | |  | | | | | |
| 1. How frequently will blood be collected? | | |  | | | | | |
| 1. What volume of blood will be collected? | | |  | | | | | |
| 1. Will the animals be sedated? | | |  | Yes | |  | No | |
| 1. Monoclonal antibodies Collection Procedures | | | | | | | | |
| 1. Will monoclonal antibodies be produced in mice bearing ascites tumors? | | |  | Yes | |  | No | |
| 1. How often will the animals be assessed for abdominal distention? | | |  | | | | | |
| 1. What is the length of time between taps? | | |  | | | | | |
| 1. How many times will they be tapped? | | |  | | | | | |
| 1. Will the animals be sedated for tapping? | | |  | Yes | |  | No | |
| 1. If you are producing monoclonal antibodies using ascites tumors in mice, explain why an in-vitro system is not suitable for your study. | | |  | | | | | |
| 1. Sedation / Anesthesia for blood or ascites collection: If the animals will be sedated for either injections or collections, please indicate the species, drug, dose, vol. and route: If you need to add more rows in a table hit the tab key. | | | | | | | | |
| Species | Drug | Dose (mg/kg) | | | Volume | | | Route |
|  |  |  | | |  | | |  |
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| 1. What criteria will be used to determine that the animals should be euthanized rather than continue to be used? |
|  |