**IACUC PROTOCOL NARRATIVE** (version 31 July 2017)

Investigator must submit **most recent** **application**, **protocol narrative**, and **any accompanying documents** via email to [iacuc@chapman.edu](mailto:iacuc@chapman.edu).

Protocol Narrative must be submitted in a **Word** document.

If you have questions about completing the narrative or about the IACUC process in general, contact the IACUC Staff at [iacuc@chapman.edu](mailto:iacuc@chapman.edu) or (714) 628-2833 or 714-628-2844.

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| **Section 1: Project Overview** | | | | | | | | | | |
| *Provide a non-technical, lay language summary of the proposed project. Discuss the potential relevance (e.g., benefits) of research findings to human or animal health, advancement of knowledge, and/or for the good of society.*   * *Lay language is defined as language that can be understood by a non-scientific audience.* * *Avoid using scientific terminology, jargon or unexplained abbreviations – where use of such language is unavoidable, define the term where it is first used.* * *DO NOT cut and paste from a grant application, journal article or abstract.* * ***This summary should not exceed 250 words.*** | | | | | | | | | | |
| Click here to enter text. | | | | | | | | | | |
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| **Section 2: Justification for the Use of Animals** | | | | | | | | | | |
| *Federal regulations require that investigators provide a narrative describing the rationale for using animals, the appropriateness of the species, and the methods and specific sources used to determine that alternatives (e.g., replacement, reduction, refinement) to the use of animals and to the procedures have been considered.* | | | | | | | | | | |
| 1. **Rationale for the Use of Animals** | | | | | | | | | | |
| * + 1. Explain why animals are requiredfor these studies, and why non-animal model replacements, such as cell culture or computer modeling, cannot fully replace animals: | | | | | | | | | |
| Click here to enter text. | | | | | | | | |
| * + 1. Explain why the proposed speciesare the most appropriate: | | | | | | | | | |
| Click here to enter text. | | | | | | | | |
| 1. **Consideration of Alternatives to Live Animal Use, Painful Procedures and Unnecessary Duplication** | | | | | | | | | | |
| *The Animal Welfare Act regulations require researchers to consider alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and to provide a written narrative of the methods used and sources consulted to determine the availability of alternatives, including refinements, reductions and replacements.*  *Alternatives should be considered during the planning phase of all animal use proposals. Federal regulatory agencies recommend a database search as the most effective and efficient method for demonstrating compliance with the requirement to consider alternatives to painful/distressful procedures. (Refer to* [*USDA Animal Care Policy #12*](http://www.aphis.usda.gov/animal_welfare/policy.php?policy=12)*)* | | | | | | | | | |
| * + 1. Database Searches | | | | | | | *Perform at least 2 database searches* | | |
| *Check the checkboxes that apply to indicate which databases were used:* | | | | | | | | |
|  | Altweb |  | CRIS | | | |  | PsycINFO |
|  | TBASE |  | National Agricultural Library (AGRICOLA) | | | |  | TOXLINE |
|  | NORINA |  | CORDIS | | | |  | MEDLINE via PubMed |
|  | CRISP |  | BIOSIS Previews | | | |  | Web of Science |
|  | Other: | | Click here to enter text. | | | | | |
| * + 1. Date(s) the database search was performed: *(Must be within the last 3 months)* | | | | | | Click here to enter text. | | | |
| * + 1. Time period covered by the search: *(e.g., 1985 to present)* | | | | | | Click here to enter text. | | | |
| * + 1. Keywords used in the search | | | | | | | | | |
| Click here to enter text. | | | | | | | | |
| *The more keywords you use the more specific your search will be; however, being too specific may lead to no results being found.  In that case, reduce the number of terms used.* | | | | | | | | |
| * + 1. In some circumstances, conferences, colloquia, subject expert consultants or other sources may provide relevant and up-to-date information regarding alternatives in lieu of or in addition to a database search. If a consultant was used for considering alternatives, provide the following information to document the source of information/consultation. | | | | | | | | | |
| Expert Consultant’s Name: | | | | Click here to enter text. | | | | |
| Consultant’s Qualifications/Expertise: | | | | Click here to enter text. | | | | |
| Content of Consultation: | | | | Click here to enter text. | | | | |
| Date(s) of Consultation: | | | | Click here to enter text. | | | | |
| * + 1. Database Search Narrative Description | | | | | | | | | |
| *Complete the following sections, providing adequate information for the IACUC to assess that a reasonable and good faith effort was made to determine the availability of alternatives or alternative methods.* | | | | | | | | |
| 1. **Discussion of Search Results** | | | | | | | | |
| *Summarize the results of the database search. If similar experiments are found, describe the aspects of your research project that are novel and are not unnecessarily duplicative of other published work. If alternative methods or procedures representing refinements to your procedures were found, discuss why those alternatives cannot be used.* | | | | | | | |
| Click here to enter text. | | | | | | | |
| 1. **Replacement** | | | | | | | | |
| *Discuss efforts to partially or fully replace animals with in vitro models, computer simulation, or use of a less sentient species (e.g. insects). If available replacements exist but are not acceptable, explain why.* | | | | | | | |
| Click here to enter text. | | | | | | | |
| 1. **Reduction** | | | | | | | | |
| *Describe the steps you have taken to* *reduce the number of animals to the minimum required to obtain scientifically valid data.* | | | | | | | |
| Click here to enter text. | | | | | | | |
| 1. **Refinement** | | | | | | | | |
| *Explain how the experimental design and procedural techniques for this study are refined to minimize pain and distress in the animals that will be used. Describe methods that refine animal use by lessening or eliminating pain or distress and, thereby, enhancing animal well-being (e.g. use of appropriate anesthetic and analgesic agents).* | | | | | | | |
| Click here to enter text. | | | | | | | |

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| **Section 3: Experimental Design** |
| *Provide a concise description of the experimental design, describing all experiments to be performed.*   |  | | --- | | *For each experiment:*   1. *Provide the* ***rationale*** *behind the experiment or the hypothesis being tested.* 2. *Define the* ***groups including strains, genetically modified, etc. and number of animals per group*** *needed for the experiment(s), including both experimental and control animals and list the procedures to be performed on each group.  A table may be an effective way to present this information.* 3. *Explain* ***how the number of animals for the experiment was determined*** *to be adequate for the generation of statistically significant data (i.e., power analysis, previous publications).* 4. *Describe the* ***sequence and timing*** *of all live animal procedures to be performed, according to the groups defined above.  Provide a timeline, diagram or flowchart if appropriate.* 5. *Define the* ***procedural endpoints*** *for each group of animals defined in above (i.e., what determines when the live animal portion of the experiment is complete and animals are euthanized.)* |  * *DO NOT cut and paste from a grant application, journal article or abstract.* * *DO NOT provide a detailed description of the procedures here. These details should be in Sections 4 and 5.* * *DO NOT provide detailed descriptions of analytical methods or procedures that do not involve the use of animals.* |
| Click here to enter text. |

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| **Section 4: Non-Surgical Procedures** | | |
| *Describe in detail all non-surgical procedures to be performed on live animals.*   * *Procedures described here must be referenced in Section 3.* * *Animal monitoring and management (as applicable) must be addressed in Section 6.* * *Each subsection below should be completed as it applies to the protocol.* * *If a subsection does not apply, state “N/A” (Not Applicable).* | | |
|  | N/A - Non-surgical procedures will not be performed on live animals **(*skip this section)***. | |
| 1. **Terminal Procedures** | | |
| * + 1. Euthanasia followed by Tissue Harvest: | |
| Click here to enter text. |
| * + 1. Cardiac Perfusion: | |
| Click here to enter text. |
| 1. **Blood and Tissue Collection in Live Animals** | | |
| Click here to enter text. | |
| 1. **Behavioral Studies** | | |
| Click here to enter text. | |
| 1. **Methods for Administering Experimental Agents in Live Animals** | | |
| * *Describe all non-surgical methods that will be used to administer experimental agents in animals (e.g., tail-vein injection, retro-orbital injection, oral gavage; etc.).* * *Provide details such as total volume (agent + vehicle) in any one injection; location of repeated injections (e.g. rotating IP injection sites to minimize soreness); size of gavage needle, etc.*   *DO NOT list surgical methods (e.g., implantation of cannulae, stereotaxic injections) – this should be described in Section 5* | |
| Click here to enter text. | |

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| 1. **Induction of Anesthesia/Sedation for Non-surgical Procedures in Live Animals** | | | | |
| 1. Indicate how anesthesia/sedation is induced for non-surgical procedures: | | | |
| Click here to enter text. | | |
| 1. Describe how the level of anesthesia/sedation is assessed to be adequate to begin the non-surgical procedure: | | | |
| Click here to enter text. | | |
| 1. Describe how animals are monitored throughout the non-surgical procedure: | | *(e.g., respiration pattern, response to noxious stimulation (paw pinch, etc.), heart rate/pattern, EKG, blood pressure, temperature, etc.)* | |
| Click here to enter text. | | |
| 1. Discuss any supplemental anesthesia dosing that may be required: | | | |
| Click here to enter text. | | |
| 1. If animals will be placed on artificial ventilation, describe the range of respiration rates and tidal volumes. | | | |
| Click here to enter text. | | |
| 1. For survival non-surgical procedures, describe how animals are monitored for recovery from anesthesia/sedation and when animals are returned to their home cages. Estimate how long it will take for the animal to recover from anesthesia/sedation *(i.e., ambulatory and feeding, etc.)*. | | | |
| Click here to enter text. | | |
| 1. **Non-invasive Imaging Procedures in Live Animals** | | | | *(e.g., MRI, CT scan, ultrasound)* |
| Click here to enter text. | | | |
| 1. **Other Non-surgical Procedures in Live Animals** | | | | |
| Click here to enter text. | | | |
| 1. **Post-procedural Care for Non-Surgical Procedures in Live Animals *(if applicable)*** | | | | |
| Click here to enter text. | | | |

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| **Section 5: Surgical Procedures** | | | | | |
| *Describe in detail all surgical procedures to be performed.*   * *Procedures described here must be referenced in Section 3.* * *Animal monitoring and management (as applicable) must be addressed in Section 6.* * *Each subsection below should be addressed as it applies to the surgical procedure, for each type of surgical procedure that will be performed.* * *If a subsection does not apply, state “N/A” (Not Applicable).* | | | | | |
|  | N/A - Surgical procedures will not be performed on live animals **(*skip this section)***. | | | | |
| 1. **Pre-operative Care** | | | | | |
| Describe any care given to the animals prior to the surgery: | | | | *(e.g., fasting, sedation, pre-operative physical exam or blood work, etc.)* |
| Click here to enter text. | | | | |
| 1. **Induction of Anesthesia for Surgical Procedures in Live Animals** | | | | | |
| * 1. Indicate how anesthesia is induced: | | | | |
| Click here to enter text. | | | |
| 1. Describe how the level of anesthesia is assessed to be adequate to begin the procedure: | | | | |
| Click here to enter text. | | | |
| 1. Describe how animals are monitored throughout the procedure (e.g., respiration pattern, response to noxious stimulation such as a paw pinch, heart rate/pattern, EKG, blood pressure, body temperature, etc.). Discuss any supplemental anesthesia dosing that may be required. | | | | |
| Click here to enter text. | | | |
| 1. If animals will be placed on artificial ventilation, describe the range of respiration rates and tidal volumes: | | | | |
| Click here to enter text. | | | |
| 1. **Aseptic Techniques** | | | | | |
| 1. Preparation of the surgical space: | | | | |
| Click here to enter text. | | | |
| 1. Preparation of the surgeon: | | | *(e.g., surgical scrub of hands, donning surgical attire, sterile gloves, etc.)* | |
| Click here to enter text. | | | |
| 1. Preparation of the animal: | | | *(e.g., clip fur, clean surgical site with antiseptics, use of sterile drapes, application of eye ointment, etc.)* | |
| Click here to enter text. | | | |
| 1. Sterilization of instruments | | | | |
| 1. Describe how instruments will be sterilized: | | *(e.g., autoclave, glass bead sterilizer, chemical sterilant, etc.)* | |
| Click here to enter text. | | |
| 1. Will instruments be used in multiple animals? If so, describe how sterility will be maintained. | | | |
| Click here to enter text. | | |
| 1. **Description of Surgical Procedures** | | | | | |
| *Please check the checkboxes that apply to indicate if terminal and/or survival surgery will be performed in live animals.* | | | | |
| * 1. Terminal Surgery | | | | |
|  | Animal will not recover from anesthesia after completion of the surgery. | | | |
| *Provide details of the surgical procedures that will be performed during the terminal surgery. State the surgical endpoints.* | | | |
| Click here to enter text. | | | |
| * 1. Survival Surgery | | | | |
|  | Animal will recover from anesthesia after completion of surgery. | | | |
| *Provide details of the surgical procedures that will be performed during the survival surgery. State the surgical endpoints.* | | | |
| Click here to enter text. | | | |
| 1. **Methods to Prevent Dehydration & Hypothermia** | | | | | |
| Click here to enter text. | | | | |
| 1. **Post-Operative Care and Analgesic Usage** | | | | | |
| *For survival surgeries, provide details of the post-operative care that will be provided to the animals following surgery.* *Describe how animals are monitored for recovery from anesthesia and when animals are returned to their home cages. Estimate how long it will take for the animal to recover from anesthesia (i.e., ambulatory and feeding).* | | | | |
| Click here to enter text. | | | | |

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| **Section 6: Adverse Effects & Animal Monitoring and Management** | | | |
| *Describe the possible adverse effects that may arise during the course of this study.*   * *If a subsection is does not apply, state “N/A”* * *NOTE: “N/A” only applies to experiments in which naive animals will undergo a terminal surgical procedure or be euthanized for tissue harvest without any prior experimental manipulation.* | | | |
| 1. **Clinical Signs & Symptoms of Pain/Distress and other** [**Adverse Effects**](http://www.research.uci.edu/ora/acup/instructionsAppSubmission.htm#sect6a) | | | |
| Briefly summarize all possible adverse effects or phenotypic abnormalities that may present in the animals as a result of study procedures, agents, disease processes, genetic alterations, etc. (i.e., tumor formation, ascites, neurologic deficits, infection, diabetes, etc.). Describe the clinical signs and symptoms that may appear in the animals, including any associated pain, distress or discomfort. | | |
| Click here to enter text. | | |
| 1. **Monitoring and Managing** **Pain & Distress** | | | |
| 1. Describe the monitoring parameters that will be used to assess pain, distress and discomfort in animals (i.e., signs, symptoms and species-specific behaviors): | | *(e.g.,* *decreased activity and appetite, abnormal posture, etc.)* |
| Click here to enter text. | |
| 1. Provide details of the management plan that will be used to assess and treat pain, distress and discomfort in the animals, including any special procedures that will be used (e.g., periodic weighing of animals) and any interventions that will be performed to relieve pain, distress and discomfort in the animals: | | *(e.g., analgesics, antibiotics, special housing/bedding, etc.)* |
| Click here to enter text. | |
| 1. Describe the frequency in which laboratory staff will be monitoring the animals, in addition to the daily general observations made by Rinker vivarium staff. | | |
| Click here to enter text. | |
| 1. Monitoring of animals (e.g., daily observations, treatments performed by research staff) must be documented.  Monitoring records must be made available to Rinker veterinary staff and IACUC members upon request. Describe how monitoring will be documented: | | *(e.g., lab notebook, log placed in animal room, electronic records, etc.)* |
| Click here to enter text. | |
| 1. **Euthanasia Criteria** | | | |
| *Describe the criteria that will be used to determine that an animal must be removed from the study and euthanized. (Refer to the Euthanasia Policy for recommended criteria)* | | |
| Click here to enter text. | | |

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| **Section 7: Table of Drugs and Agents Used in Live Animals** | | | | |
| *List* ***all*** *drugs or agents that will be administered to live animals, along with the details of their use in the applicable sections below.* | | | | |
| *Drug/Agent* | * *Do not list euthanasia drugs here (euthanasia drugs should be in Section 8)* * *NOTE: Rodent biological materials, including cell lines, may require testing for pathogens prior to use.* | | | |
| *Dose Range* | *Express dosages as a range and as mg/kg of body mass, wherever possible.* | | | |
| ***\*****Route* | *Indicate the routes of administration using the following abbreviations:* | *SQ* | *Subcutaneous* |
| *IV* | *Intravenous* |
| *IM* | *Intramuscular* |
| *IP* | *Intraperitoneal* |
| *PO* | *Per os (by mouth)* |
| *IH* | *Inhalation* |
| *Other* | *Other not listed* |
| *Frequency* | *Specify how often it will be administered in each animal (e.g., every 8 hours, once a week, etc.)* | | | |
| *Duration* | *Specify how long the drug or agent will be administered (e.g., one time, 3 days, 2 weeks, etc.)* | | | |
| *If more space is needed, please submit Drug and Agent information in a separate Word Document.* | | | | |

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| 1. **Anesthetic, Analgesic, and Paralytic Agents** | | | | | |
| Species | Drug/Agent | Dose Range | *\**Route | Frequency | Duration |
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| 1. **Therapeutic Agents** | | | | | |
| *Therapeutic drugs include antibiotics, fluids, antimicrobials, etc.* | | | | | |
| Species | Drug/Agent | Dose Range | *\**Route | Frequency | Duration |
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| 1. **Experimental Agents** | | | | | | | |
| *Experimental agents include investigational new drugs, placebos, tumor cells, stem cells, gene markers, tracers, radioisotopes, imaging contrast agents, viruses and other biological agents, etc. Agents listed here should be listed in Section 4.D and referenced in Section 3.* | | | | | | | |
| Species | Drug/Agent | Dose Range of Specific Agent | Vehicle Used | Total Volume *(including vehicle)* | *\**Route | Frequency | Duration |
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| 1. **Other Agents** | | | | |
| *Any other agents that are not listed in the previous categories.* | | | | |
| Species | Drug/Agent | Dose Range | *\**Route | Frequency | | Duration |
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| 1. Will non-pharmaceutical grade drugs be used? | | | *\****Yes** | **No** |
|  |  |
| 1. *\**Provide justification for the use of non-pharmaceutical grade drugs in live animals | | | |
| Click here to enter text. | | |
| 1. *\**Describe the procedure for how the drug will be prepared before being given to the animals. | | | |
| Click here to enter text. | | |

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| **Section 8: Euthanasia Methods** | | |
| *Indicate the primary method(s) that will be used to euthanize animals. (Refer to the Euthanasia Policy)  Please check ALL checkboxes that apply.**(This includes methods used to euthanize excess breeding animals that are produced)* | | |
|  | 1. **\*CO2 Overdose with Secondary Physical Method** | |
| NOTE:All rodents euthanized with CO2 need to undergo a secondary physical method of euthanasia to ensure death. | |
| **\***Indicate secondary physical method: |  |

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|  | 1. **Anesthetic Overdose** *(e.g. pentobarbital)* | | | | |
| * 1. List the anesthetic agent(s) that will be used to euthanize animals. Indicate the dose and administration route. | | | | |
| *If more space is needed, please submit information in a separate Word Document.* | | | |
| Species | Agent | Dose  (mg/kg) | Route of Administration |
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| * 1. Confirmation of Death in Animals | | |
|  | Open chest inspection of the heart | |
|  | Exsanguination (cutting a major blood vessel) | |
|  | Physical method *(specify)*: | Click here to enter text. |
|  | Other *(describe below)*: | |
| Click here to enter text. | |

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| 1. **Physical Methods** | | |
| 1. For each physical method that will be used to euthanize animals, provide a description of the method in the blank white section below. | |
|  | Decapitation |
| Click here to enter text. |
|  | Cervical Dislocation |
| Click here to enter text. |
|  | Other Physical Methods*(describe below)*: |
| Click here to enter text. |

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| 1. Provide information about the anesthetic agent that will be used before the physical method of euthanasia | | | | |
| *(To add more rows, place cursor in the last cell on lower right and press the key “Tab”)* | | | |
| Species | Agent | Dose  (mg/kg) | Route of Administration |
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| 1. **\***If animals WILL NOT be anesthetized before the physical method of euthanasia, provide strong scientific justification and a reference. | |
| Click here to enter text. |

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| 1. **Other Methods** | | | |
|  | Cardiac Perfusion | *Describe in Section 4.A.2* |
|  | Other *(describe below)*: | |
| Click here to enter text. | |

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| **Section 9: Roles, Responsibilities, and Experience of the Study Team** | | |
| *List below all study team members who will have contact with live animals.*   * *Personnel listed here need to also be listed in Section F.* * *Describe each person’s specific role and responsibility on the project, including the procedures they will perform.* * *Indicate who will be responsible for the daily care and monitoring of the animals.* * *Provide a description of their qualifications, level of training and expertise.* * *If a study team member does not have relevant experience or training for a particular species or procedure they will perform, describe how they will be trained.* | | |
| *If more space is needed for research personnel, please submit names and qualifications in a separate Word Document.* | | |
| **Lead Researcher:** | | |
| Name | Qualifications, Level of Training, and Research Responsibilities |
| Click here to enter text. | Click here to enter text. |

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| **Research Personnel:** | | |
| Name | Qualifications, Level of Training, and Research Responsibilities |
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