**Protocol #**



**Regis College Institutional Animal Care and Use Committee (IACUC)**

**Animal Care and Use Protocol (ACUP)**

**Principal Investigator:**

**Principal Researcher:**

**Project Title:**

**Attending Veterinarian Consultation** (You must consult the veterinarian during ACUP development and must **submit your application to the Veterinarian for pre-review at least 2 weeks before the submission deadline**)**:**

[ ]  Tiffany Borjeson, DVM (IACUC@regiscollege.edu) **Date:**

**Notification of IACUC Chair** (must notify prior to submission)**:**

[ ]  Steven Threlkeld, PhD (IACUC@regiscollege.edu) **Date:**

***IACUC Orientation***

*Is this your first submission to the IACUC as Principal Investigator?* [ ]  yes [ ]  no

If yes, *contact IACUC chair or Attending Veterinarian for an orientation.*

#

**Type of animal experimentation protocol**:

[ ]  New

[ ]  De novo for Protocol #

[ ]  Significant change to an approved project

This document has been locked to facilitate completion and data entry into the form. Please contact the IACUC Chair or the Attending Veterinarian if you need to unlock the form to expand a table or section of the form.

**1. Nature and Purpose of Proposed Studies**

1. **Lay Summary**

*Describe the specific aims and details of animal use for research and/or teaching in non-scientific terms (e.g. Boston Globe Level language). The lay summary is used by community representatives on the IACUC and also may be used by Public Relations in the event of an external inquiry into the project. Define all acronyms. Do not copy and paste from a grant proposal. Do not include information that is not relevant to the use of live animals (e.g., details of in vitro experiments).*

**Background and Significance** (1-4 sentences)

**Question being addressed** (1-4 sentences)

**How will the results of the study be used?** (1-4 sentences)

**Summarize the Specific Aims** (derived from the grant proposal/research plan/teaching plan)

1. **Technical Abstract**

*Use the following outline to create a structured technical abstract that provides a clear and concise overview of the proposed work. It must include enough detail to allow the reviewers to understand the rationale for the project, the specific objectives of the work, and the animal-related experiments that will be performed. It is not necessary to include excessive detail about the ex vivo analysis of tissues.*

* Background: *Present the ideas and reasoning behind the proposed work.*
* Objective/Hypothesis: *State the objective/hypothesis to be tested or teaching goals. Provide evidence or rationale that supports the objective/hypothesis.*
* Specific Aims: *State the specific aims of the study or teaching application.*
* Study Design: *Briefly describe the study design including appropriate controls.*

1. **Experimental Design**

*If applicable, please include a flowchart(s) or diagram(s) to explain the proposed animal experiments, including the study groups, treatment time points, and euthanasia time points. Begin with the arrival of animals in the facility and/or the first procedure. End with euthanasia. Note when individual animals will be used for more than one procedure.*

**Insert diagram below**

**2. Justification of the Proposed Animal Model**

**a. Are there non-animal alternatives available to accomplish your goals?** [ ]  yes [ ]  no

If yes, provide a brief narrative as to why those alternatives are not being used.

1. **Will you be using an established (published) animal model?** [ ]  yes [ ]  no

If yes, provide literature citations.

If no, provide the rationale for development of the model? (Note: the Attending Veterinarian must be involved in all new animal model development)

1. **Have you used this animal model system before?** [ ]  yes [ ]  no

If yes, describe any refinements you have implemented to reduce the number of animals used or to reduce the amount of pain or distress experienced by individual animals?

1. **Does the proposed animal model system have the potential to negatively affect the long-term health and well-being of the study animals?** (Examples include: tumor implantation, which can lead to cachexia(wasting) and/or chronic pain; cardiac failure, which may lead to respiratory distress; arthritis, which may inhibit motion and the ability to feed.) [ ]  yes [ ]  no

If yes, describe all anticipated negative consequences of the animal model?

If yes, also describe how will the animals be monitored for these outcomes?

**3. Description of Procedures Performed in Live Animals**

1. **Summary of procedures to be performed**

*Provide a clear and concise sequential list of* ***all*** *procedures involving the use of live animals that will be easily understood by all members of the committee. Please use non-scientific terminology. Detailed descriptions of surgical and non-surgical but potentially painful or distressful procedures are to be included in the applicable appendices. Complete descriptions of procedures which do not involve surgery and do not present pain or distress should be described in detail below, including the use of any sedatives or anesthetics (e.g. use of sedation for restraint prior to imaging or EKG)*

*Examples of procedures: tail snips, surgery, tumor induction, blood collection, metabolism procedures, behavioral studies, injections of chemical/biological agents, etc. If additional procedures will be performed as part of the present protocol, please add additional items as needed.*

1. Procedure name:

 Brief description:

1. Procedure name:

 Brief description:

1. Procedure name:

 Brief description:

1. Procedure name:

 Brief description:

1. Procedure name:

 Brief description:

1. Procedure name:

 Brief description:

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1. Procedure name:

 Brief description:

1. Procedure name:

 Brief description:

1. **Euthanasia**

*Briefly list the primary and, where applicable, secondary methods of euthanasia. A secondary method is a second procedure that is used to confirm euthanasia. (Example: administration of an anesthetic as primary method followed by thoracotomy as a secondary method) Additional details regarding euthanasia will be entered in section 11.*

|  |  |  |  |
| --- | --- | --- | --- |
| Species | Primary Method1 | Pharmaceutical agent(drug name, dose, route) *if applicable* | Secondary Method2*(Typically rodents, after CO2 or anesthesia)* |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |

1 *Examples: asphyxiation, barbiturate overdose, exsanguination under anesthesia, hypothermia (neonates only)*

2 *This typically applies to rodents only. Examples: bilateral thoracotomy, cervical dislocation, decapitation, exsanguination*

If any of the drugs/agents included in the table above are not pharmaceutical grade, provide information regarding justification, source and formulation.

|  |  |  |
| --- | --- | --- |
| Drug/Agent name (from table above) | Justification | Preparation(*e.g. diluents, sterilization, pH balancing, storage and labeling*) |
| Drug:      Source:       | [ ]  Pharmaceutical grade not available[ ]  Scientific necessity (specify)      [ ]  Other (specify)       |       |
| Drug:      Source:       | [ ]  Pharmaceutical grade not available[ ]  Scientific necessity (specify)      [ ]  Other (specify)       |       |

1. **Collection of tissue or body fluid from live animals**

*Will tissue or body fluids be collected from live animals (excluding tail snips)?*

*[ ] yes [ ] no*

*If yes, complete the table below*:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **Tissue or Body Fluid** | **Method of Collection** | **Amount and Frequency of Collection** | **Agents\* Administered Prior to Specimen Collection** |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
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|       |       |       |       |       |

*\*Anesthetic, analgesic, sedative, or tranquilizer*

1. **Multiple Survival Surgical Procedures**

Will the animals be subjected to more than one survival surgery taking place during separate periods of anesthesia?

[ ]  Yes [ ]  No

*If Yes, list the surgical procedures sequentially and justify why it is scientifically necessary to operate on these animals more than once.*

1. **Other procedures.** *Check all that apply*

*Ensure that each item checked is described in Section 2 above. Complete and attach Appendix 2 for any procedures noted below which present the potential for inducing pain or distress.*

[ ]  Perform behavioral studies

[ ]  Study the effects of trauma

[ ]  Use electric shock

[ ]  Study pain

[ ]  Study pain in alert animals

[ ]  Employ the use of forced exercise

[ ]  Induce cancerous tumor growth

[ ]  Induce organ or system failure

[ ]  Exposure to infectious agents(s) (complete Appendix 4)

[ ]  Exposure to human biological agents (complete Appendix 4)

[ ]  Study the effects of diet or environmental changes (describe in 7.f)

[ ]  Study temperature changes (describe in 7.f)

[ ]  Change the light cycle (describe in 7.f)

[ ]  Purchase pregnant female animals (complete Appendix 5 if dams will deliver live pups)

**4. Substances Administered to Animals** *(not anesthetics/analgesics)*

*Identify all therapeutic drugs, experimental/study agents, chemicals, or other materials administered to live animals by injection, intubation, implantation, or surface application in the appropriate tables below. Do not include anesthetics and/or analgesics which are mentioned in an applicable appendix.*

1. **Experimental/study agents, therapeutic drugs, chemicals**

**Species #1:**       (*Please duplicate table if agents will be administered to multiple species.)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name and Purpose | Source  | Pharmaceutical Grade? (*If no, justify below)* | 1. Dose (mg/kg) and/or volume2. Route (e.g. ip, im, po)3. Frequency (e.g. sid, bid) | 4. Timing of administration (e.g. pre-op, intra-op, post-op)5. Expected duration of effect |
| Agent:      Purpose:[ ]  Experimental [ ]  Therapeutic  |  | [ ]  Yes [ ]  No | 1. Dose      2. Route      3. Frequency       | 4. Timing      5. Duration       |
| Agent:      Purpose:[ ]  Experimental [ ]  Therapeutic |  | [ ]  Yes [ ]  No | 1. Dose      2. Route      3. Frequency       | 4. Timing      5. Duration       |
| Agent:      Purpose:[ ]  Experimental [ ]  Therapeutic |  | [ ]  Yes [ ]  No | 1. Dose      2. Route      3. Frequency       | 4. Timing      5. Duration       |
| Agent:      Purpose:[ ]  Experimental [ ]  Therapeutic |  | [ ]  Yes [ ]  No | 1. Dose      2. Route      3. Frequency       | 4. Timing      5. Duration       |
| Agent:      Purpose:[ ]  Experimental [ ]  Therapeutic |  | [ ]  Yes [ ]  No | 1. Dose      2. Route      3. Frequency       | 4. Timing      5. Duration       |

1. **Justification for the use of non-pharmacological grade agents**

*Federal regulations require the use of pharmaceutical-grade medications wherever possible, even for acute procedures. All materials administered by parenteral routes, (e.g., intravenous, intramuscular, intraperitoneal and intracranial) must be sterile unless otherwise approved by the IACUC.*

*See* [*http://grants.nih.gov/grants/olaw/faqs.htm#useandmgmt\_4*](http://grants.nih.gov/grants/olaw/faqs.htm#useandmgmt_4) *(F.4.) for rationale and elaboration.*

|  |  |  |
| --- | --- | --- |
| Drug/Agent name (from table above) | Justification | Preparation(*e.g. diluents, sterilization, pH balancing, storage and labeling*) |
|       | [ ]  Pharmaceutical grade not available[ ]  Scientific necessity (specify)      [ ]  Other (specify)       |       |
|       | [ ]  Pharmaceutical grade not available[ ]  Scientific necessity (specify)      [ ]  Other (specify)       |       |
|       | [ ]  Pharmaceutical grade not available[ ]  Scientific necessity (specify)      [ ]  Other (specify)       |       |
|       | [ ]  Pharmaceutical grade not available[ ]  Scientific necessity (specify)      [ ]  Other (specify)       |       |
|       | [ ]  Pharmaceutical grade not available[ ]  Scientific necessity (specify)      [ ]  Other (specify)       |       |

1. **Biological Agents.** *If you will inject transplantable tumors, cell lines, blood products, agents prepared by recombinant methods, or other biological materials into animals you must attach documentation of testing for murine pathogen viruses. The veterinarians will provide further information regarding testing requirements.*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Agent****Name** | **Source** | **Viral****testing** **date** | **Dose** | **Route** | **Volume** | **Diluent/****Media** | **Frequency****of injection** |
|       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |

**5. Description of Animals**

**a. List all animals including strain, sex, etc.**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Species** | **Strain** | **Sex** | **Age/****Type** | **# to be purchased** | **# to be born on-site (or fetuses for in utero studies)1** | **Total # to be used2** | **USDA pain category3** |
|       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |
|  |
| **Total # of animals**  |       |

1 *“# to be born on-site” Includes all animals which are born on-site and fetuses used in pregnancy/in utero studies), even if they are not used for experiments or breeding*

2 *“Total # to used” = # to be purchased + # to be born on-site*

3*Indicate the appropriate pain category based on the table below and the approximate number of animals in each category. If multiple procedures will be performed on an animal, the animal is placed in the category appropriate for the most painful/distressful procedure.*

|  |  |
| --- | --- |
| **Category** | **Definition**  |
| B | Used only for breeding purposes (no procedures) |
| C | Minimal, transient or no pain or distress (use of anesthesia for chemical restraint for imaging, etc.) |
| D | Pain or Distress Relieved by Appropriate Measures, such as use of anesthesia or analgesia |
| E | Unrelieved Pain or Distress  |

**b. Justification for the number of animals requested for each species listed above.**

*Describe the strategy used to determine the number of animals required for the experiments described in this protocol. Statistical power analyses should be used to justify animal numbers whenever possible.*

**Check all that apply and provide specific answers to the associated questions**:

[ ]  **Pilot study or preliminary project – Group variances unknown**

*Describe the information used to estimate how many animals are needed.*

[ ]  **Group Sizes determined statistically- power analysis**

*Describe the statistical analysis used to estimate the number of animals needed (n). This is usually based on the expected size of the treatment effect, the variance associated with the measurement, and the desired statistical power.*

[ ]  **Group sizes based on quantity of harvested cells or amount of tissue required**

*Describe how the amount of tissue or cells required was determined and explain how much tissue is needed based on the number of experiments you will conduct and how much tissue you expect to obtain from each animal.*

*Example: Need 10 g tissue. Can get 2 g tissue per animal = 5 animals required*

[ ]  **Product testing**

*If the number of animals needed is based on U.S. Food and Drug Administration (FDA) guidelines, provide the citation from the regulations, the IND tracking number, or relevant FDA correspondence.*

[ ]  **Other**

*Please describe alternate method for sample size determination.*

**6. Animal Procurement**

* 1. **Source(s) of animals**:

[ ]  Commercial Vendor (specify):

[ ]  In-house Breeding Colony

[ ]  Non-Commercial (e.g. academic) Source (specify)\*:

**7. Animal Husbandry**

* 1. **Housing Location/Facility**

 *(specify)*:

1. How many animals will be housed within the facility at any one time? *(Include separate estimates for each species)*

**c. Social Housing** (*Check all that apply*)

*Social animals should be housed in stable pairs or groups of compatible individuals unless they must be housed alone for experimental reasons or because of social incompatibility. If both group and single caging will be used, provide specifics in 7.f.*

[ ]  Group caging [ ]  Single caging

Justify the need for single caging.

**d. Food and Water:**

[ ]  Standard diet [ ]  Non-standard diet *(Provide details in 7.f.)*

**e. Enrichment:**

Is it acceptable to provide standard enrichment as appropriate for the species (e.g. chews, toys, and nesting materials)?

[ ] Yes [ ] No

Justify if standard enrichment is not allowed.

**f. Non-Standard Husbandry**

*Describe any non-standard husbandry requirements.*

[ ]  *Special food or water (specify)*

[ ]  *Altered day/night cycles (specify)*

[ ]  *Altered cage change cycles (specify)*

[ ]  Other *(specify)*

**g. Identification**

How will individual animals be identified? (*Check all that apply*.)

[ ]  No individual identification will be used

[ ]  Ear tags

[ ]  Tattoos

[ ]  Ear punch

[ ]  Temporary marker (e.g. Sharpie)

[ ]  Toe clipping *(neonatal mice only; requires IACUC approval)*

[ ]  Subcutaneous RFID microchip *(please describe in Procedures – question 3)*

[ ]  Other method *(please describe in Procedures – question 3)*

**8. Animal Transport**

**a. Will live animals be transported outside of the animal care facility?** [ ]  Yes  [ ]  No

If *“yes,” provide the procedure used to transport animals including the route and elevator(s) to be used and complete below.*

**b. Will animals be transported outside of the animal care facility and then returned to their housing room?**

[ ]  Yes [ ]  No

*If “yes,” please justify why the procedures could not be performed within the animal facility and describe the containment measures that will be used to minimize the risk of introducing pathogenic agents from the lab back into the animal facility.*

**9. Emergency Treatment**

*In an emergency, animals will be treated to relieve suffering and preserve life, or if necessary, euthanized.*

[ ]  No therapeutic restrictions exist on the provision of emergency treatment.

[ ]  Do not use the following medications in the provision of emergency treatment (e.g., corticosteroids, antihistamines, antibiotics):

**10. Humane Endpoint Criteria for Euthanasia**

**a. Monitoring of animals**

*Individuals who will be responsible for monitoring animals must be trained to assess and recognize animal pain or distress.*

i. Lab personnel who will be responsible for monitoring animals.

ii. How often will this be done?

**b.** Even though euthanasia may not be planned for a particular project, the IACUC requires establishing both humane endpoints for a project and criteria to euthanize animal(s) prior to the end of the experiment in the event that the animal’s condition falls outside the anticipated experimental parameters. Please define both the humane endpoints and criteria to euthanize animal(s) on this protocol for all animals from time of receipt to their final disposition.

 The following signs of ill health will be used as euthanasia criteria

|  |  |
| --- | --- |
| **Clinical Observation** | **Applicable to this project** |
| Clinical condition that does not respond to treatment (e.g. infected surgical site) | [ ]  |
| Delayed wound healing, dehiscence of surgical site | [ ]  |
| Difficulty in ambulation which render animal unable to access food/water | [ ]  |
| Persistent and progressive dermatitis or self-trauma | [ ]  |
| CNS signs such as tremors, seizures, circles that were not anticipated by the study plan | [ ]  |
| Anorexia >48 hours, other lesions interfering with eating or drinking | [ ]  |
| Sudden behavioral change (e.g. aggression, guarding, hiding) | [ ]  |
| Weight loss of 20% or more from baseline at the start of the experiment or as compared to age/gender/strain-matched controls | [ ]  |
| Markedly discolored urine, excessive urine, or no urine | [ ]  |
| Severe or refractory diarrhea or decreased fecal output > 48 hours | [ ]  |
| Dehydration unresponsive to oral or parental therapy | [ ]  |
| Rough hair coat, hunched posture, distended abdomen, reluctance to move, or lethargy | [ ]  |
| Respiratory signs such as labored breathing, wheezing, or copious nasal discharge | [ ]  |
| Cumulative tumor burden exceeds the IACUC-approved tumor burden | [ ]  |
| Mobility impairment due to tumor burden and/or location of tumor, regardless of tumor size | [ ]  |
| Tumor ulceration, necrosis or infection | [ ]  |
| Ascites due to tumor production which results in a 20% increase in body weight | [ ]  |
| Hemorrhage (blood loss) from any site that is estimated to be >10% total circulating blood volume | [ ]  |
| Any condition that the Attending Veterinarian (or their designee) deems serve enough to warrant euthanizing the animal and/or animals found in a moribund state | [ ]  |
| Additional humane endpoints: | [ ]  |
| Additional criteria for euthanasia: | [ ]  |

11. Disposition of Animals (*Check all that apply)*

[ ]  **Euthanasia (methods described in question 3b above)**

 [ ]  **Animals will/may become moribund and die before they can be humanely euthanized**. Death of animals is a planned experimental endpoint (e.g. toxicity testing), or there is a likelihood that animals may/will become moribund and die (e.g. sepsis studies, organ failure studies).

1. *Provide a scientific justification,*
2. *Estimate how many (i.e. rate or percentage) will die at the end of the experiment, and*
3. *Indicate the procedures that will be used to minimize non-euthanasia deaths.*

[ ]  **Animals will be transferred to another protocol.**

*Provide details:*

**12. Assurance that the Proposed Work Does not Unnecessarily Duplicate Previously Published Work on the Same Topic**

In accordance with USDA regulations, PHS [9 CFR Part 2.31 (8)] and the Animal Welfare Act, I have conducted a literature search covering the period **from       to** using the following **databases** and **keywords.**

**Keywords** *(Scientific search terms related to the proposed model)*

**Databases**

      and

**I have concluded that the activities described in this protocol are not unnecessarily duplicative of previous experiments, including my own.**

*Please note; OVID, Medline and PubMed search engines use the same database. You may use one of these databases plus one other database, such as Agricola.*

**13. Search for Alternatives to Painful/Distressful Procedures**

The Animal Welfare Act (Title 7, U.S. Code), as written and approved by Congress, emphasizes minimizing pain and distress. It states in Section 13(a)(3)(B):

*“… that the principal investigator consider alternatives to any procedure likely to produce pain or distress in an experimental animal;”*

The Regis College IACUC concurs with the USDA (9CFR, Part 2, Sec. 2.31 (d)(1)(ii)) that a multiple database literature search meets the requirement of the Animal Welfare Act as the IACUC members, including the non-affiliated member, a visiting USDA Animal Care Inspector, or a member of the public can follow a printed search strategy, view the list of databases and keywords, and verify that the investigator has made a good faith effort to demonstrate whether or not alternatives exist and why he/she will or will not adopt them.

**Accordingly, please document your searches for alternatives, below. Please document separate searches for each painful or distressful procedure. A minimum of two different databases are required. *The IACUC strongly encourages you to include at least one database specifically for alternatives in addition to PubMed.* For example:**

* AWIC-Animal Welfare Information Center, <https://awic.nal.usda.gov/>
* ALTWEB, <http://altweb.jhsph.edu/resources/searchalt/>
* Guide to Searching for Alternatives to the Use of Laboratory Animals,<http://www.frame.org.uk/the-frame-alternatives-laboratory/>
* Alternatives to Laboratory Animals, <http://www.atla.org.uk/>
* University of California Center for Animal Alternatives, <http://www.lib.ucdavis.edu/dept/animalalternatives/>

Skin and body cavity penetrations (laparotomy, thoracotomy, craniotomy, and entry into a joint space) are examples of procedures considered to be potentially painful. Prolonged restraint and procedures that result in limited mobility, malaise, etc. are examples of procedures considered to be potentially distressful. Refer to the procedure list (Item 3a, above) for a list of potentially painful/distressful procedures.

**[ ]  No alternatives exist. This must be documented by completing the following:**

I certify that I have reviewed the pertinent sources and have found no valid alternatives to any of the proposed procedures which may cause more than momentary pain or distress. The methods and sources used in my searches included the following databases and keywords:

[ ] Literature search conducted

Procedure 1:

Databases searched:       and

Keywords used:

Years searched:

Date search was performed:

Procedure 2:

Databases searched:       and

Keywords used:

Years searched:

Date search was performed:

Procedure 3:

Databases searched:       and

Keywords used:

Years searched:

Date search was performed:

Procedure 4:

Databases searched:       and

Keywords used:

Years searched:

Date search was performed:

Procedure 5:

Databases searched:       and

Keywords used:

Years searched:

Date search was performed:

[ ]  Consultation with colleagues

*Provide names, affiliations, credentials, and dates of contact. Describe the colleague’s area of expertise and why this colleague is qualified to provide an opinion on alternatives to the proposed painful/distressful procedures.*

[ ]  Other information services utilized.

*Elaborate, providing specific information.*

[ ]  Alternatives exist, but are not appropriate for these studies.

*Elaborate, providing specific information.*