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Institutional Animal Care and Use Committee

**New Protocol Review Form – Clinical Research**

*Last updated 8/20/2020*

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| **Section 1: General Information** |

**Protocol Information**

IACUC Protocol Title:

IACUC Protocol Number:

Previous IACUC Protocol Number:

Office Use:

Approval Date:

Expiration Date:

**Principal Investigators Name**

Lead Principal Investigator (PI):

Department:

Interoffice Mail Code:

Phone Number:

**Primary Contact Information**

[ ]  Same as PI

Contact Person:

Department:

Interoffice Mail Code:

Phone Number:

**Alternate Contact Information (to be used in emergencies when the primary contact is unavailable)**

[ ]  Same as PI

Alternate Contact Person:

Department:

Interoffice Mail Code:

Phone Number:

**Directions:**

* **Important:** Save this form to your computer’s hard drive before completing it, or your responses may not be captured!
* It is recommended that you read the entire form before completing. This form must be completed and submitted (as a Word document) electronically. Submit to the IACUC Protocol management online system. Retain a copy of your completed form for your records.
* Please respond to all questions in this form. If a particular question does not apply to your study, please indicate this. Type responses in the designated shaded boxes or check the designated check boxes.
* Download and complete all relevant appendices.
* For questions, contact the IACUC Administrative Office at IACUC@vt.edu or 540/231-0931.

**Section 2: Assessment of Unnecessary Duplication**

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| **Section 2: Use of Client Owned Animals** |

The animals used on this protocol will be client owned. The owners will be provided a consent form that describes the experiment and any possible adverse effects. Animals will not be allowed to participate on the protocol without a signed consent form. The consent form is provided under Supporting Documents. No Virginia Tech owned or non-client owned animals will participate on this protocol.

[ ]  As the PI I agree to the above statement**.**

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| **Section 3: Assessment of Unnecessary Duplication** |

1. If this study is an extension of previous work, briefly explain why more work needs to be done.

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1. Provide a narrative description of how you came to the conclusion that this study does not unnecessarily duplicate previous work (e.g., current/ongoing scientific literature assessments, recent scientific meetings, consultation with peers).

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| **Section 4: Justification of Species Selection** |

1. List the type of animals to be used on this protocol.

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| Species  |
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1. Why was the species was chosen:

[ ] The results will be directly applicable to the health or care of this species.

[ ] Other (please describe):

1. Explain why a “lower order species” or non-animal alternatives cannot be used to achieve the desired results.

[ ]  The results will be directly applicable to the health or care of this species.

[ ]  Other (please describe):

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| **Section 5: Justification of Number of Animals** |

A key principle in the ethical use of animals in research and testing is that the number of animals used in each project is the minimum necessary to obtain valid and meaningful results. In determining the numbers of animals required, which of the following are applicable:

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| [ ]  | A statistical assessment (power analysis) was performed. Describe the statistical method/test used to determine appropriate group sizes/animal numbers, and state if a statistician was consulted to assist in the determination:       |
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| [ ]  | The numbers of animals or group sizes have been established by federal guidelines/requirements. |
| [ ]  | This is a pilot study that uses the minimum number of animals required to provide meaningful, but not statistically significant, data. |
| [ ]  | Other (please describe):       |
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| **Section 6: Pain Category** |

Please indicate which pain category your experimental procedures will cause the client animals to experience. Do not include normal patient care procedures. Check all that apply:

**Pain Category Descriptions**

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| [ ]  | C: Use of procedures that cause no or slight/momentary pain or distress (e.g., observational studies; injection of non-irritating agents; blood collection from peripheral vessels; collection of cells or tissues following euthanasia). |
| [ ]  | D: Use of procedures that would cause more than slight/momentary pain or distress, but are performed using appropriate anesthetics, analgesics, or tranquillizers to relieve pain (e.g., minor or major surgical procedures [survival or non-survival] performed under anesthesia; collection of cells or tissues prior to euthanasia; painful procedures performed under sedation/anesthesia (skin or organ biopsy, lymph node aspirate, cerebrospinal fluid collection). |
| [ ]  | E: Use of procedures that cause more than slight/momentary pain or distress, but that cannot be performed using anesthetics, analgesics, or tranquilizers without adversely affecting the study (e.g., toxicity and lethal disease studies in which the animals are allowed to die without intervention and mortality is the endpoint). Mechanical restraint may, depending upon duration and type of restraint, be considered a category "E" procedure. **Approval to conduct a Category E study requires detailed justification. \*In addition to approval of a category E protocol through the IACUC, if the protocol is to be performed at VMCVM, the VMCVM must also approve any category E clinical research before research may be initiated at the hospital.**  |
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| **Section 7: Justification for Category E Procedures** |

Provide an explanation for the requirement to perform experimental painful or distressful procedures without appropriate pain relieving or sedating medications.

[ ] N/A

[ ]  All procedures are for the benefit of the animal and have been approved and described to the owners in the signed consent form. Use of pain relieving or sedating medications will negate the effects of the experimental treatment.

[ ] Other: describe:

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| **Section 8: Evaluation of Alternatives** |

**\*Complete this section only for experimental procedures that will cause pain category D or E.**

The Federal Animal Welfare Act and PHS Policy require that researchers evaluate the existence of alternatives when procedures cause more than slight or momentary pain or distress for the animal. Examples of alternatives include less sentient animal models, computer models, audio-visual training programs, and refinements to proposed procedures.

1. Which database sources or methods were used to evaluate the existence of viable alternatives? You must **include two or more databases** in your search.

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| [ ]  | AGRICOLA | [ ]  | Biological Abstracts |
| [ ]  | Current Contents Connect | [ ]  | PubMed (Medline) |
| [ ]  | VetCD (IndexVeterinarius) | [ ]  | Other(s) (please identify):       |

1. Give the key words used in conducting the database search and number of hits. I.e. anesthesia and mouse and lupus and alternative and number of hits 512, etc.

1. Date(s) when the search was conducted:
2. Years included in the search criteria:
3. What alternatives (replacements, reductions, and refinements) were identified?

NOTE: the use of pain relieving drugs for surgical and other procedures is considered a refinement.

1. If alternatives were identified but will not be used, please provide justification.

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| **Section 9: Animal Well-Being & Harm/Benefit Analysis** |

1. Explain how you will minimize expected animal pain and distress and enhance animal well-being (e.g., use of sedatives, tranquilizers, or anesthetics).

[ ]  Trained individuals will perform procedures reducing the stress of the animals and enhancing their well-being through minimal contact times and efficient procedures.

[ ]  Anesthesia and sedation will be given to relieve pain/distress during procedures.

[ ]  Other: describe

2. Please assess whether the "harm" caused to the client animals is justified, please explain the benefits to humans or animals or both from the proposed research activity that would outweigh the "harm".

[ ] No harm will come to the animal due to participating in this study. The study hopes to improve the quality of their lives and/or improve the quality of other animals or humans from the results of the study.

[ ] Other: Describe

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| **Section 10: Experimental Design** |

Describe the experimental design of this study. Please include the following for each experiment if you have more than one on this protocol:

**1. Experiment number (i.e. 1, 2, 3) and brief description (two sentences):**

**2. Treatment groups and number of animals in each group:**

**3. Total number of animals to be used given as an equation to include replicates and extra/replacement animals. ex. 4 treatment groups x 10 animals per group x 2 doses = 80 animals + 2 extra animals as back up (only if needed):**

**4. A time line of the experiment to start on first day of the animal inclusion on the experiment to the end of experiment giving only the name of the procedure to be done. The description will be in Section 11. (You may attach your timeline to the submission and state “see attached time line”.) Ex on approximate Day 0 dependent on treatment group treatment given Day 0-28 monitored Day 1, 5, 8, 10, 14, 20 and 28 blood drawn, fecal sample, physical, Day 28 follow-up appointment.**

Describe any additional experiments following the above format:

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| **Section 11: Procedures** |

1. Experimental Procedures: Describe all procedures that are for study purposes including any adverse effects. (Note procedures that are part of normal hospital care and not part of the experimental procedures do not have to be described. Example: If a biopsy is to be performed regardless if participating on this project then a description of the biopsy procedure is not necessary). \*For surgical procedures please only give possible adverse effects and say “see appendix B for description.” \*Attach any monitoring sheets that will be used on this protocol at submission to IACUC.

1. Normal hospital care procedures:

[ ] All non-experimental procedures will be performed per normal hospital standard care procedures.

[ ] Other: Describe:

1. Sedation/Anesthesia /Analgesia Agents

[ ] All sedation/anesthesia /analgesia will be given per normal hospital standard care procedures.

[ ]  Other: Complete an Appendix G if the agents are being used experimentally.

4. Please refer to the information below to determine if your study involves multiple major survival surgeries, and mark the appropriate response.

A major surgery is defined as one that penetrates and exposes a body cavity (e.g., abdomen, thorax, or skull) or produces substantial impairment of physical or physiologic functions. Multiple survival surgeries involve completion of a surgery from which the animal recovers from anesthesia, and then a subsequent surgery from which the animal recovers from anesthesia.

[ ]  The study does not involve multiple major survival surgeries.

[ ]  The study involves multiple major survival surgeries. The surgeries are required as part of routine veterinary care to protect the health or well-being of the animal and approved by the owner of the animal.

5. [x]  Death will not be used as an endpoint in this study. An example of a death as an endpoint study: An infectious disease study where an animal is allowed to die without intervention to obtain data points versus humanely euthanized.

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| **Section 12: Humane Endpoints** |

1. Humane Endpoints:

[ ]  All humane endpoints are determined by the owner. In order to make an informed decision the PI or personnel on the protocol will keep the owner informed of the animal’s progress and any changes in health. \*Attach any monitoring sheets under supporting documents that will be used on this protocol at submission to IACUC.

[ ]  Other: Describe:

1. Monitoring:

[ ] While the animal is housed at VMCVM the animal will be monitored by the PI or VMCVM staff for development of significant signs of illness or toxicity **at appropriate intervals daily, including weekends and holidays**.

[ ] Other: Describe:

Please provide contact information for the personnel who will be responsible for monitoring the condition of the animals.

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| Name | **Virginia Tech PID***(Typically the part of an official VT e-mail address that precedes @vt.edu.)* | Phone Number |
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| **Section 13: Study Personnel** |

1. If any personnel do not have experience with the exact species and procedures indicated, please describe how they will be trained. If training is required the person providing the training will be experienced and proficient at the procedure.

[ ]  Minimally the trainees will observe the procedures three times or until comfortable to perform, then they will minimally perform the procedure three times supervised or until the trainer feels that they are competent to perform the procedure unsupervised. At that point they can perform the procedure unsupervised.

[ ]  N/A all individual are trained

[ ]  Other:

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| **Section 14: Animal Disposal** |

1. Final disposition of animals:

[ ]  Determined by the animal’s owner.

[ ]  Other: Describe:

1. If applicable, how will animal carcasses be disposed of? (check all that apply)

[ ]  Returned to owner for disposal.

[ ]  Disposed of by the hospital.

[ ]  Other: Describe:

1. Any special requirements when disposing?

[ ]  Yes, describe:

[ ]  No

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