\*\*Animal Use Protocol Amendment Request\*\*

**Date:**  Click here to enter a date.

**Principal Investigator:** Click here to enter text. **IACUC Protocol No.:** Click here to enter text.

Campus Mail Address: Click here to enter text.

Email: Click here to enter text.

**Title of Project:** Click here to enter text.

**What type(s) of changes in protocol are being proposed?** (*Check all that apply*):

[ ]  Change in animal species / [strain](#strain)

[ ]  Change in animal numbers

[ ]  [Add/ repeat experiments](#experiment)

[ ]  [Add an exogenous agent](#exogenous)

[ ]  Change in animal procedure (*add / modify / remove*)

[ ]  Change in hazardous agent use

[ ]  Change in anesthesia or analgesia

[ ]  Change in method of euthanasia

[ ]  Change in pain or distress category

[ ]  Change in location of animal usage

[ ]  Change in funding source

[ ]  Change in project title

[ ]  Other (describe): Click here to enter text.

1. **Clearly state (list) and describe all proposed changes in detail.** *Refer to page 4 for guidance, as applicable.*

Click here to enter text.

1. **Are additional animals being requested as part of this amendment?**  [ ]  YES [ ]  NO

*If yes, please specify the species / strain, the total number being requested and discuss how this was determined to be the minimal number required to obtain statistically significant results.*

Click here to enter text.

1. **Justify the need for these proposed changes. Briefly describe how the proposed changes relate to the original goals of the approved protocol.**

Click here to enter text.

1. **Consideration of Alternatives to Potentially Painful / Distressful Procedures**
2. Do any of the following criteria apply to the approved protocol?  [ ]  YES [ ]  NO

*If yes, check all that apply and complete question 4b*. *If no, STOP question b is not required!*

[ ]  USDA Covered Species (*any species other than mice, rats, birds, fish, amphibians, or reptiles*)

[ ]  Pain / Distress Category E

[ ]  Funded by the VA

1. Do the above changes represent *new* procedures that were not in the approved protocol and have the potential for producing more than momentary or slight pain or distress?

  [ ]  YES [ ]  NO *If yes, please complete* [*page 3*](#Addendum)*. If no, STOP page 3 is not required.*

[ ]  This amendment includes *new* survival surgery procedures that have been reviewed by a Veterinary Resources Veterinarian. Click here to enter text. Click here to enter a date.

 Name of the veterinarian Date and Time of consult

[ ]  This research is conducted in the Baltimore VA, is funded by the Department of Veterans Affairs, or the grant supporting this work is administered through the Baltimore BREF and has been reviewed by the VA Veterinary Medical Officer or his designee (Dr. Ned Kriel). Click here to enter text. Click here to enter a date.

 Name of the veterinarian Date and Time of consult

I certify that the use of animals will be in accord with the PHS Policy on Humane Care and Use of Laboratory Animals, The Guide for the Care and Use of Laboratory Animals, the USDA Animal Welfare Act / Animal Welfare Regulations and the policies and procedures established by the University of Maryland Baltimore. I further certify that the work described in this amendment does not unnecessarily duplicate previous work and that no change in this protocol will be implemented without prior IACUC review and approval.

\_\_Click here to enter text.\_ Click here to enter a date.

Signature of Principal Investigator Date

*\*\*no signature is required if submitted via the PI’s UMB e-mail address.*

**AUP Amendment Addendum: Consideration of Alternatives to Potentially Painful / Distressful Procedures**

*Please complete this addendum if you checked YES to question 4a&b above. Otherwise, please discard this page if not applicable.*

1. What are the potentially painful or distressful procedures being proposed in this amendment?

 Click here to enter text.

1. A literature search for alternatives to the potentially painful or distressful procedures (*listed above*) was performed. Search methods and sources are documented in table below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name of Database Searched:**(*Minimum of 2*) | **Date search was performed:** (*mm/dd/yy*)  | **Years covered by the search:** *(from yyyy to yyyy)* | **Search Strategies used:**(*including scientifically relevant terminology and Boolean operators*) | # of hits: | # of relevant hits:  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

Database Resources: [UMB HS-HSL Databases](http://www.hshsl.umaryland.edu/resources/databases/index.cfm) and [AWIC](https://www.nal.usda.gov/awic/databases)

1. Did the literature search reveal less painful or distressful alternatives to the potentially painful or distressful procedures that are proposed?

[ ]  No alternatives, refinements, replacements or reduction methods were found.

[ ]  Yes, but they cannot replace the procedures that are proposed. *See below explanation*.

1. If yes, identify the painful or distressful procedures(s) and provide a BRIEF explanation why the alternatives found to this potentially painful or distressful procedure(s) were not acceptable alternatives.

Click here to enter text.

1. List other sources of information used to refine this protocol, as applicable.

Click here to enter text.

NOTE: Keep copies of computer database search results in your protocol file for a minimum of three years after the protocol has expired to demonstrate your compliance with the law if regulatory authorities or the IACUC should choose to audit your project.

**DO NOT SUBMIT THIS PAGE – PLEASE REMOVE / DELETE.**

**Adding a new experiment?** *Cut and paste the following questions under item 1*.

**Experiment #** – Insert Title

**Briefly describe the objective of this experiment.**

**Describe what will happen to the animals from start to finish.** *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. Although not required, a flowchart may be an effective presentation of the planned procedures. Detailed animal procedures should NOT be described in this section.*

**What is the longest that any one animal will be involved in an experiment?**

**List each experimental and control group, including the group size for each group (n=?).**

**Discuss what criteria were used to determine that the group size(s) proposed utilizes the minimal number of animals to generate statistically significant data** (*e.g., power analysis, reports in the literature, previous experience, etc.*).

**Indicate whether the experiment must be repeated and justify the number of repetitions.**

**Indicate the species to be used, and how many will be used** *(e.g., X # mice per experiment x X # strains of mice).*

**Adding a new exogenous agent**? *Cut and paste this table under item 1 and complete. Remember to add a Hazardous Agent Addendum, if applicable*.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Substance** | **Dose Range** *(mg/kg)* | **Route** | **pharmaceutical****grade\****(yes / no)* | **Hazardous Agent?***(No or Option below\*)* | **Purpose***(anesthetic, analgesic, paralytic, experimental, etc.)* |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| \*Scientifically justify use of non-pharmaceutical grade compounds: |
| [ ]  \*I confirm any non-pharmaceutical grade compounds will be reconstituted and stored per the [*IACUC Guidelines on the use of Non-pharmaceutical Grade Compounds in Animal Use Protocols*](https://www.umaryland.edu/oawa/Policies-Procedures-Guidelines).  |

*\*CL1 – Chemical Level 1; CL2 – Chemical Level 2; Refer to* [*EHS Hazardous Chemical Use in Animal Research*](https://www.umaryland.edu/ehs/research-safety/chemical-safety/hazardous-chemical-use-in-animal-research/) *website for guidance.*

 *RAD – Radioactive Material*

 *PO – Pathogenic Organism (ABSL1, ABSL2 or ABSL3)*

 *RM – Recombinant Material (ABSL1, ABSL2 or ABSL3)*

**Adding a new strain**? *Cut and paste this table under item 1 and complete.*

|  |  |
| --- | --- |
| **Strain** | **Brief description of relevance to the proposed research** |
|  |  |
|  |  |

 *\*\*Please add rows to this table by placing cursor at end of last row and clicking return.*

**Do any of the above strains exhibit any known phenotypic variations that could potentially affect animal health, well-being or longevity?** [ ]  YES\* [ ]  NO

 \*If yes, please describe:

**Do any of the above strains require phenotype induction, e.g., pharmacologically activated, siRNA, viral induced, etc.?** [ ]  YES\* [ ]  NO

\*If yes, please describe: