**IACUC** **Proposal Amendment Form**

**1. General Information**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| IACUC Protocol Number |  | Amendment Number |  | USDA Pain Category |  |
| Title |  | | | | |
| Principal Investigator |  | | | | |

**2. IACUC Review Status**

**Minor Change(s): Administrative Review**

Change in personnel other than the PI e.g. additions, provided personnel are qualified, adequately trained, and meet other criteria as required by the IACUC and deletion of those who are no longer working on the protocol

Change/Addition of funding agency

Increase in animal numbers by <10%

Change or addition of animal housing or procedure rooms, provided such rooms are approved by the IACUC and the facility manager concurs with the use of the space for the purposes of the protocol

Correction of grammar or typographical errors

Update contact information

Change in source of the animal(s) if it is to an approved vendor and the animal health status is pre-approved by the veterinarian. This will be done in consultation with the Attending Veterinarian and Vivarium Operations Manager

**Significant Change(s): Veterinary Verification and Consultation (VVC)**

Change/addition of another strain of the same animal species

Change in age or sex of the animals

Change of strain (from immunocompetent to immunocompromised)

Increase in sampling frequencies, sampling volumes, restraint times, or other activities **NOT EXCEEDING** SOP or IACUC approved limits

Change to Anesthesia, analgesia, sedation, or same group of experimental substances.

Change to Euthanasia method to any method considered acceptable or acceptable with conditions (provided conditions are met) in the AVMA Guidelines for the Euthanasia of Animals.

Change toDuration, frequency, or number of procedures performed on an animal.

**Significant Change(s): DMR/FCR Process (IACUC)**

Change in the Principal Investigator

Addition of personnel for Pain Category E Studies (provide documentation that new personnel have read the protocol with signature in appendix)

Change in the objective of the study

Increase in the potential for pain or distress

Increase in sampling frequencies, sampling volumes, restraint times, or other activities **EXCEEDING** SOP or IACUC approved limits

Change of species

Addition of invasive or non-invasive procedures

Switching from non-survival to survival surgery

Change requiring an animal to undergo more than one survival surgery

Increase in animal numbers by > 10%

Increase in biohazard status

Amendments to global protocols

Other (please explain)

Click here to enter text.

**3. Change to Proposal**

**Item 1**

**Section Number and Title:**

**Original Section information from last approved IACUC protocol/ protocol amendment:**

Click here to enter text.

**Requested change** (strikethrough for deletion and use bold font to denote addition changes**):**

Click here to enter text.

**Justification:**

Click here to enter text.

**Keep adding sections as needed**

**Item 2**

**Section Number and Title:**

**Original Section information from last approved IACUC protocol/ protocol amendment:**

Click here to enter text.

**Requested change** (strikethrough for deletion and use bold font to denote addition changes**)**:

Click here to enter text.

**Justification:**

Click here to enter text.

**4. Updated Search for Alternatives**

**Not Applicable** (only applies to Minor changes and to USDA Pain Category B or C procedures)

**Significant Change to the Proposal.** The IACUC is responsible for ensuring that investigators have appropriately considered alternatives to vertebrate animal use, appropriateness of animal species selected, as well as test materials and procedures that may cause unnecessary pain and distress (USDA Pain Category D or E). Please keep the “Three R’s of Animal Research” in mind when completing this section of the form:

**Replacement** – refers to methods which avoid or replace the use of animals in an area where animals would otherwise be used. This includes both absolute replacements (i.e. replacing animals with inanimate systems, such as inanimate models, computer programs, etc.) and relative replacements (i.e. replacing more sentient animals, such as vertebrates animals that current scientific evidence indicates have a significantly lower potential for pain perception, invertebrates, etc.).

**Refinements** – refers to the modification of husbandry, experimental or surgical procedures to minimize pain and distress, and to enhance the welfare of an animal used in science from the time of receipt through euthanasia.

**Reduction –** refers to any strategy that will result in fewer animals being used to obtain sufficient data to answer the research question or in maximizing the information obtained per animal and thus potentially limiting or avoiding the subsequent use of additional animals, without compromising animal welfare.

Provide documentation of the methods and sources used to determine what alternatives are available and/or if alternatives do not satisfy the experimental objectives.

List animal models to be used, potential painful and/or distressful test material administrations, experimental procedures or surgeries, for which the search for alternatives is to be performed:

Click here to enter text.

**A. Describe how and what search for alternatives was conducted**.

Information by literature search – complete the table below.

When performing your search key words to be considered should include “in vitro”, “in silica”, the animal species used, “in vivo”, “alternative”, “pain”, “distress”, the class of compound, relevant experimental and test procedures, as well as all any subject related key words.

A separate literature search should be conducted for each item listed above. Database(s) searched, INCLUDING the date range of the search and the date search was done (<6 months prior to submission). A minimum, to be done is for USDA Pain Category D & E procedures

AND

For proposals that use ***USDA regulated animal species, a minimum of two databases is required for each procedure*** consideration of alternatives to each procedure which may cause pain or distress must state sources consulted. Please check database(s) searched.

National Library of Medicine (NLM’s Medline/PubMed) – http://www.nlm.nih.gov

Elsevier – <http://www.elsevier.com>

Current Research Information Service (CRIS) – http://cris.csrees.usda.gov

Animal Welfare Information Center (AWIC) – http://awic.nal.usda.gov

European Center for the Validation of Alternative Methods Scientific Informational System (ECVAM SIS databases and ECVAM Thesaurus) – <http://ecvam.jrc.ec.europa.eu>

Biological Abstracts – <http://science.thomsonreuters.com>

Google Scholar - – <http://scholar.google.com>

Other: Click here to enter text.

**IACUC Literature Search Summary**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Performed By: |  | Date of Search: | |  | | Dates Covered by Search: |  |
| Key Words Searched | | | Number of Hits per Site  Database 1/Database 2 | | Comments | | |
|  | | |  | |  | | |
|  | | |  | |  | | |
|  | | |  | |  | | |

Information other than literature search (e. historical data generated by the laboratory)

Please attach supporting documentation or explain and provide documentation below:

Click here to enter text.

Consultation with colleagues

Please explain and provide documentation below. Provide individual’s names, credentials and experience with/knowledge of the model, procedure or compound class.

Click here to enter text.

Required by regulatory agency. Identify agency(s) below:

Click here to enter text.

Training or pilot study. Alternatives must be considered. Please describe below:

Click here to enter text.

**B. Results of the search for alternatives conducted.**

Please provide a written narrative of your search results for each listed item below. Indicate if no alternatives were identified in the literature searches or other methods selected above, if consideration for the use of alternatives is limited because the specific test procedures or study design used in this study protocol are required in a living biological system (such as breeding study, etc.), or if alternatives were identified; however, they will not satisfy the experimental objectives.

Click here to enter text.

**5. PI Assurance**

*I hereby certify that the above information is a complete and accurate description of the animal protocol to date. I understand that failure to report significant changes in the protocol or failure to report sick animals may result in violation of Federal and State laws as well as Institutional regulations.”*

Signature of Principal Investigator Date

Signature of Administrative Review Reviewer Date

Signature of Veterinary Reviewer (VVC) Date

Signature of IACUC Reviewer Date