**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): (DMR/Veterinarian Review Only)**

[ ] Change/addition of another strain of the same animal species

[ ] Increase in animal numbers by < 10%

[ ] Change in age or sex of the animals

[ ] For addition/removal in personnel not including the PI (for addition of personnel CV required)

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

[ ] 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

[ ] Change of species

[ ] Change of strain (from immunocompetent to immunocompromised)

[ ] 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

[ ] Pre-, Intra- or Post-operative care that has potential to increase pain and/or distress

[ ] Increase in animal numbers by ≥ 10%

[ ] Extension of study duration with or without increased potential for pain/distress

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

[ ] Change in method of euthanasia

[ ] 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** (use strikethrough or bold font to denote 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** (use strikethrough or bold font to denote 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)

[ ]  **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 | 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 Veterinary Reviewer Date

Signature of IACUC Reviewer Date