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| **KSU IACUC****USE ONLY** | Review Date:        | Protocol #:        |
| Approval Date:        | Length of Approval:        |
| Continuing Review Date:        | FULL Committee Review Date:        |

**Kennesaw State University**

**Institutional Animal Care and Use Committee**

**CONTINUING REVIEW and/or MODIFICATION FORM**

**SECTION I: GENERAL INFORMATION**

|  |  |
| --- | --- |
| Type of submission: | [ ]  Continuing Review (Complete Sections I and II)  Indicate if 1st [ ]  or 2nd [ ]  renewal  |
|  | [ ] [ ]  Modification (Complete Sections I and III) |
|  | [ ] [ ]  Continuing Review & Modification (Complete Sections I, II, III)  Indicate if 1st [ ]  or 2nd  [ ]  renewal |

|  |  |  |
| --- | --- | --- |
| Principal Investigator (PI):       | Phone:       |  |
| Protocol Title:       |  |
| Protocol Number:       | E-mail Address:       |
| Department:       |  |
| Approval Date of Initial ACUP:       |

**Signatures**

**Certification of the Principal Investigator:**

*As the individual responsible for this project, I confirm that the information contained in this ACUP is true and accurate and, to the best of my knowledge, conforms with the procedures described in the NIH Guide for the Care and Use of Laboratory Animals, with PHS policy, the Animal Welfare Act, and the KSU IACUC Policies and Procedures Manual. I have considered alternatives to the biological models used in this project, and have found these other methods unacceptable on scientific or educational grounds. I confirm that this project does not unnecessarily duplicate previous experiments. No change will be made to the procedures, care, or housing as described in the approved version of this ACUP document without prior written notification to and approval by Kennesaw State University’s Institutional Animal Care and Use Committee. I understand that failure to comply with IACUC policies and procedures will jeopardize the University's Animal Welfare Assurance on file with NIH, and may lead to revocation of my privileges to conduct animal research at Kennesaw State University.*

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Signature of Principal Investigator Date

**For Office for Responsible Research/IACUC Use Only:**

Chair’s signature below indicates that the project has been approved by the IACUC.

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IACUC Approval Signature Date

**For PI Use Only:**

Nature of the modification:

**SECTION II: CONTINUING REVIEW INFORMATION**

**SECTION 1 - Key Personnel**

 [ ] [ ]  Yes [ ] [ ]  No Have there been any personnel/staff changes since the last IACUC approval was granted? If yes, complete the following sections (Additions/Deletions) as appropriate.

***PLEASE NOTE: A change in PI requires submission of a new Animal Care and Use Proposal.***

|  |  |  |  |
| --- | --- | --- | --- |
| Add | Delete | Last Name | First Name |
| [ ]       | [ ]       |       |       |
| [ ]       | [ ]       |       |       |
| [ ]       | [ ]       |       |       |
|       |       |       |       |

**SECTION 2 - Training**

The specific duties personnel will perform on the project. List specific duties (including performing euthanasia) of new personnel added to the project and the relevant experience and training. This information is intended to inform the committee of the training and background of new personnel.

|  |  |  |
| --- | --- | --- |
| Name & Degree(s) | Specific Duties on Project | TRAINING & EXPERIENCE RELATED TO PROCEDURES PERFORMED |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |

**SECTION 3 - Animal Usage**

|  |  |  |  |
| --- | --- | --- | --- |
| Species | Humane UseCategory | Total Number Approved to Date - Including Approved Modifications | Number Used to Date – Including In Use, Ordered and On Site |
|       |       |        |        |
|        |       |        |        |
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|       |       |       |       |

**SECTION 4 - Nature of the Study (Check all applicable items.)**

[ ]  Antibody Production       [ ]  Neuromuscular Blockers

[ ]  Blood/Tissue Collection       [ ]  Prolonged Restraint

[ ]  Breeding/Transgenic Breeding       [ ]  Special Events

[ ]  Inducement of Behavioral Stress       [ ]  Survival (Chronic) Study

[ ]  Inducement of a Disease State       [ ]  Teaching

[ ]  Multiple Surgeries       [ ]  Terminal (Acute) Study

[ ]  Other (please specify):

**SECTION 5 - Wildlife Permits:** If wildlife permits are required, please provide the permit number or please provide permitting agency.

**SECTION 6 - Protocol Status:** (Indicate the status of this project.):

 [ ]  Request Protocol Continuance

 [ ]  [ ]  A. Active - project ongoing.

 [ ]  B. Currently inactive - project initiated but presently inactive.

 [ ]  C. Inactive - project never initiated but anticipated start date is      .

**SECTION 7 - Is this project federally funded?** [ ]  Yes [ ]  No

 If *Yes*, please list source.

**SECTION 8 - Progress Report**: If the status of this project is 6A (active - project ongoing) or 6B (project was initiated, but is presently inactive), provide a brief update on the progress made in achieving the specific aims of the protocol.

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**SECTION 9 - Problems / Adverse Events**: If the status of this project is 6A (active - project ongoing) or 6B (project was initiated, but is presently inactive), describe any unanticipated adverse events, morbidity or mortality, the cause(s), if known and how these problems were resolved. If NONE, this should be indicated.

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**SECTION 10 - Alternatives to Animal Use**: Alternatives to the use of animals should be considered and used when possible. Since the last IACUC approval, have alternatives to the use of animals become available that could be substituted to achieve your specific project aims? If yes, please specify.

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**SECTION 11 - Alternatives to Potentially Painful Procedures**: Address the following if your project involves USDA Category D or Category E: Procedures that cause the least amount of pain or distress to the animals should be considered and used when possible. Since the last IACUC approval, have alternatives which are potentially less painful or distressful become available that could be used to achieve your specific project aims?

If yes, please specify.

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**SECTION 12 - Duplication**: Activities involving animals must not unnecessarily duplicate previous experiments. Provide written assurance that the activities of this project remain in compliance with the requirement that there must be no unnecessary duplication.

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**SECTION III: PROTOCOL MODIFICATION INFORMATION**

**SECTION 13 - Reason For Modification Request:** (Check all that apply.):

***PLEASE NOTE: A change in PI requires submission of a new Animal Care and Use Proposal.***

[ ] a. [ ]  Yes [ ]  [ ]  No

Is there any change in species, strain, number, USDA Pain/Distress Classification, age, or sex of animals? If yes, please fill in table below. *Note: if an increase in animal number is viewed by the IACUC as significant, the request will be considered a major change, and will require review by the full committee.)*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| GENUS/SPECIES | COMMON NAME | STRAIN, SUBSPECIES OR BREED | # TO BE ADDED | USDA PAIN/DISTRESS CLASSIFICATION | ~ AGE, WEIGHT OR SIZE | SEX |
|       |       |       |        |       |       |       |
|       |       |       |       |       |       |       |
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Please explain the reason for the change. If an increase in animals is requested, please explain how the number needed was determined. The *Guide* recommends that the number of animals should be the minimum number required to obtain statistically valid results. A power analysis is strongly encouraged to justify group sizes when appropriate.

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b. [ ]  Yes [ ]  No Is there any change in personnel?

If yes, please indicate below, including specific role/duties on the project and training for new personnel.

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c. [ ]  Yes [ ]  No Is there any change in animal housing?

If yes, please indicate below.

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d. [ ]  Yes [ ]  No Is there any change in the dose of a drug already in the approved protocol?

If yes, please make the required change to the drug information in the approved protocol. Please explain the

reason for the change.

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e. [ ]  Yes [ ] [ ]  No Is there any other change?

If yes, please describe below in sufficient detail for evaluation independent of any other documents.

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**Major vs. Minor Protocol Modifications**

In an attempt to help Kennesaw State University investigators determine what course of action is necessary when making modifications to an existing animal protocol, we have generated two lists of examples. These lists are in no way complete and are shown here only as a guide to help investigators make informed decisions when modifying existing protocols.

***Please note****: per the Research Compliance Advisory Committee, a change in Principal Investigator (PI) is not a modification, but rather requires submission of a new Protocol Review Form (PRF).*

The following is a list of modifications that the Institutional Animal Care and Use Committee (IACUC) deems as **major** and, as such, require **submission of a “Continuing Review and/or Modification” form by the PI** (via email to iacuc@kennesaw.edu) and **review and approval by the IACUC** (*Please note: if the changes are considered significant enough, the IACUC may require submission of a new ACUP*):

1. Applying the protocol to a new species.
2. Changing the number of animals or stage of life for animals used on the study.
3. Changing the humane use category.
4. Changing the duration, frequency, or number of procedures to be performed on an animal.
5. Changing from terminal to survival or repeat surgery.
6. Changing to a different surgical approach or medical treatment.
7. Changing the dosage or dose of hazardous agent or an infectious or biohazardous material already in the protocol.
8. Addition of a new hazardous agent (e.g., betamercaptoethanol).
9. Addition of a new biohazardous material or new infection protocol (e.g., adenovirus vs. lentovirus).
10. Changing or adding objectives to the study.
11. Changing the anesthetic agent(s) or the use or withholding of analgesics. PIs should give an acceptable range so that a modification is not needed.
12. Changing the method of euthanasia.

The following is a list of modifications that the IACUC deems as **minor** and, as such, require **submission of a “Continuing Review and/or Modification” form by the PI** (via email to iacuc@kennesaw.edu) for **approval by the IACUC Chair:**

1. Changes in personnel other than the principal investigator. When adding personnel, list their role/duties on the project and list their training.
2. Changing the sex of animals used on a protocol.
3. Changing the supply source of animals.
4. Changing the campus housing location.
5. Changing the disposal of animals.
6. Changing the amount of blood drawn if within guidelines.
7. Changing the person monitoring anesthesia (if person is properly trained).