BUTLER UNIVERSITY

**INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE**

**PROTOCOL FOR ANIMAL USE**

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| **(For IACUC Use Only)**Protocol Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date Received: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date Approved: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

The Butler University Institutional Animal Care and Use Committee (IACUC) is dedicated to the task of protecting the welfare of all animals involved in public health, behavioral and biomedical research, and other related activities which are directly or indirectly carried out by the faculty, students and employees of the University.

All research involving vertebrate animals must be approved by the IACUC prior to initiation of work on a project. **No animals may be ordered for a project until approval has been granted.**

**INSTRUCTIONS: For your convenience, this document was prepared in Word as a form. You may enter information in the space indicated. All fields will adjust to allow spacing as needed.**

Principal Investigator:       Department/College:

(*must be Butler faculty*)

Campus Address:       Phone:       E-mail:

Emergency Telephone Number:

Project Title:

Primary Purpose: Research [ ]  Teaching [ ]

1. Training: Federal law requires that all personnel be trained prior to initiating projects with living animals and that their training be documented. The IACUC mandates that all personnel must complete the web modules from the Collaborative Institutional Training Initiative (CITI) web site. In addition, all personnel on any three year update of an existing protocol must also take the new CITI training modules for working with animals. Instructions for logging onto the CITI website are available on the IACUC website: <https://www.butler.edu/osp/animal-care>

**Everyone must complete the module** "CITI-Working with the IACUC". Then complete the appropriate module(s) for the species that you are working with.
The CITI website is:<http://www.citiprogram.org/>
Each person creates their own personalized username and password.

1. The Principal Investigator must ensure that other personnel associated with this protocol (including students and unsupervised personnel) are qualified and trained to handle animals. Please list all personnel associated with this protocol:

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| --- | --- | --- | --- |
| **Name** | **Procedures this person will perform** | **This person’s experience performing these procedures or how they will be trained** | **Initials** |
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The IACUC requires that all the persons listed above review and understand the procedures described in this protocol. Confirmation that these reviews have occurred is required before animals may be ordered for this study. When completed, please have all personnel on the study review and initial by their name that they have read and understand the protocol.

1. In addition, the Principal Investigator and personnel must complete the Qualifications for Animal Use form. The form can be found at <http://www.butler.edu/urp/compliance/IACUC_forms.htm>:
	* The Principal Investigator has completed the Qualifications for Animal Use form: Yes [ ]  No [ ]
	* All other personnel on the study have completed the Qualifications for Animal Use form: Yes [ ]  No [ ]
2. Project Narrative: Describe the purpose (objective) of the project, experimental procedures (such as surgery, injections, blood collections, etc.) and/or drugs involved, and a statement about the merit (educational and/or scientific) of the project.

1. Anticipated duration of the proposed project:

 Start Date:       Proposed End Date:

1. Species to be used:

Age:       Weight:       Sex: M [ ]  F [ ]  Either [ ]

Animals will be housed in: Gallahue 280 [ ]  Other:

Caging: Individual [ ]  Group [ ]  Group Size:

Number to be acquired:       Source/Vendor:

 Collection permit needed? Yes [ ]  No [ ]

If yes, select one or more: Local [ ]  State [ ]  Federal [ ]

Approximate average daily inventory:

Special instructions relative to care, feeding, etc.:

1. Estimated number of animals needed for this project:

 Year 1       Year 2       Year 3

 Total

1. Will any of the following be used?

Carcinogens Yes [ ]  No [ ]

Pathogens Yes [ ]  No [ ]

 If yes, human [ ]  or animal [ ] ?

Radiolabeled compounds Yes [ ]  No [ ]

If yes to any of these, describe the product and special handling procedures below. For radioisotopes, coordinate with the University’s Environmental Programs Manager. For pathogens, obtain approval from Butler’s Institutional Biosafety Committee.

1. Select the pain and/or distress category that best applies to this project. Examples of procedures concerning pain and/or distress are categorized on the final page of this protocol. If this study may cause more than minor pain or distress (Categories D or E), the investigator **MUST** consider procedures that cause less potential pain or distress.

B [ ]  C [ ]  D [ ]  E [ ]

1. If pain or distress will be alleviated by analgesic, anesthetic, or tranquilizing drugs (Category D), list drug(s), dose(s), route(s) of administration, and indicate when they will be administered.

If pain or distress cannot/will not be alleviated by use of anesthetic, analgesic, or tranquilizing drugs, justify this study and describe euthanasia criterion below.

1. Will surgical procedures be performed? Yes [ ]  No [ ]

 If yes, complete the following items:

 Survival surgery? Yes [ ]  No [ ]

Building and rooms where survival surgery and postoperative recovery will take place:

1. Disposition of animals:

[ ]  Request euthanasia be performed by the Animal Care Technician.

[ ]  Euthanasia to be performed/supervised by:

 Identify method of euthanasia (e.g., drug, dose, route of administration):

The animal’s death **must** be verified before disposing of the carcass. Identify method of euthanasia verification (e.g., cervical dislocation, creation of bilateral pneumothoraces, observe for absence of movement/breathing for 5 minutes):

[ ]  Euthanasia will not be performed. State final disposition of the animals:

1. Regulations require that the Principal Investigator provide the IACUC with documentation demonstrating that alternatives to procedures that may cause more than momentary pain or distress to the animals have been considered and that activities do not unnecessarily duplicate previous experiments. A thorough literature search regarding alternatives meets this Federal mandate. An alternative is any procedure which results in the reduction in numbers of animals used, refinement of techniques, or replacement of animals.

* 1. Give rationale for using vertebrate animals, as opposed to using tissue culture and/or computer models.

* 1. Justify the number of animals to be used (a table or block design can facilitate review of this section).

* 1. Give rationale for the species being used, as opposed to invertebrates.

* 1. Address why alternative procedures either do not exist or were rejected. State the methods and/or sources that were used to determine that alternatives are not available or scientifically unacceptable.

* 1. Identify the databases you searched and explain why they are appropriate to corroborate parts a – d above.

Date of the search:

Years covered by the search:

Key words used for the search:

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| I certify that the above statements are true and that this study does not unnecessarily duplicate previous experiments. I further certify that I will make written notification to the IACUC of any changes in the proposed project prior to proceeding with any animal experimentation. Modification of any type, use of additional animals of any species, new procedures or methods, etc., in the above project requires re-review by the IACUC. I understand that the IACUC may require modifications or that I may be asked to answer IACUC questions regarding this protocol in order to gain approval. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature of Principal Investigator DateReturn completed/signed protocol as a scanned single pdf file to:  IACUC@butler.edu.**Please retain a copy of your completed protocol.** |
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| Categories of Biomedical Experiments Based onEthical Concerns for Non-human Species **Classification B** Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes.Examples: * Studies in which only breeding occurs (parents + offspring) including animals that will be culled and not used in experiments;
* Newly acquired animals;
* Animals held under proper captive conditions or wild animals observed in their natural habitat.

**Classification C** Animals upon which teaching, research, experiments, or tests will be conducted involving no pain, distress, or use of pain-relieving drugs.Examples: * Manual restraint that is no longer than would be required for a routine examination;
* Behavioral testing without stress or non-interfering observation of behaviors;
* Simple invasive procedures (e.g. adminstration of oral medications, routine injections of non-irritating substances, blood collection from a common peripheral vein or catheterization of same);
* Euthanasia (if method meets recommendations of the most recent AVMA Panel on Euthanasia);
* Tissue procurement from euthanized animals.

**Classification D** Animals upon which experiments, teaching, research surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will be used.Examples: * Induction of minor behavioral stress or behavioral studies on restrained animals;
* Blood collection by orbital sinus or other invasive routes that requires anesthesia for collection;
* Administration of drugs, chemicals, toxins, or organisms that would be expected to produce pain or distress but which will be alleviated by analgesics;
* Using food or fluid restriction in which animals do not develop dehydration;
* Survival surgery performed on anesthetized performed by trained personnel in which post-op analgesics are given;
* Perfusion or tissue procurement from anesthetized animals prior to death;
* Non-survival surgery performed on anesthetized animals.

**Classification E** Animals upon which teaching, experiments, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs will adversely affect the procedures, results or interpretation of the teach, research, experiments, surgery, or tests.Examples: * Procedures producing pain or distress unrelieved by analgesics such as toxicity studies, microbial virulence testing, radiation sickness, and research on stress, shock, or pain;
* Studies using food or fluid deprivation that will produce dehydration or produce an altered physiological or biochemical state in the test subject;
* Surgical and postsurgical sequella that produces unrelieved pain or distress;
* Studies where death is the end-point;
* Diseases are induced and infected animals are permitted to succumb rather than treated or euthanized.

**NOTE REGARDING CLASSIFICATION E: An explanation of the procedures producing pain or distress in these animals and the justification for not using appropriate anesthetic, analgesic or tranquilizing drugs must be provided on Appendix A. This information is required to be reported to the USDA, will be available from USDA under the Freedom of Information Act, and may be publicly available through the Internet via USDA's website.** |
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**Appendix A**

**Explanation for USDA Classification E**
(This report is required to accompany USDA Form 7023 to support any USDA Classification E listings.)
This document must be typed.

Name of investigator:

Animal Study Proposal title:

Species and number of animals listed in Classification E for each year:

Species:
Number of animals:

year 1 -

year 2 -

year 3 -

Total:

Description of project including reason(s) for species selection:

Provide a scientific justification to explain why the use of anesthetics, analgesics, sedatives or tranquilizers during and/or following painful or distressing procedures is contraindicated:

Signature of investigator:
Date:

Signature of IACUC Chairperson:
Date: