

**Date:**

1. **PROJECT DATA**
2. Principal Investigator:
3. Department:
4. Phone:       Email:
5. Project Title:
6. New Submission? [ ]  …or… Renewal? [ ]
7. Project Dates:
8. Is this research currently funded? Yes [ ]  No [ ]

If yes, please list the sponsor(s):

TU Proposal No.(s), if any:

If not, are you attempting to secure funding for the research? Yes [ ]  No [ ]

 If yes, please list the sponsor(s):

 TU Proposal No.(s), if any:

*\*Note: If this project is sponsored by USDA NIFA or NIH, Responsible Conduct of Research (RCR) training must be completed by all personnel. Projects sponsored by NSF require all undergraduate, graduate, or postdocs receiving salary/stipend support to complete RCR training. Towson University offers this training through CITI. Attach all RCR certificates one completed.*

1. List the names of all individuals authorized to conduct procedures involving animals under this proposal and identify key personnel [e.g., co-investigator(s), research assistants, etc], providing their department, phone, and e-mail:

*\*Note: All personnel must complete the appropriate CITI training modules prior to application submission. Please attach all certificates to the end of this application.*

g. How are risks minimized for those conducting the study (PI, students, etc)?

1. **ANIMAL REQUIREMENTS**
2. Genus *[e.g., Mus]:*

1. Species *[e.g., musculus]:*
2. Strain, subspecies, or breed *[e.g., C57BL/6]:*
3. Common name *[e.g., Black6]*:
4. Approximate age, weight or size:
5. Sex:
6. Bacteriological status *[e.g., germfree (axenic), defined flora (gnotobiotic), specific pathogen free (SPF), conventional]:*
7. Viral status
8. Source(s) *[e.g., name of vendor or breeder, or bred in-house]*:
9. Primary housing location(s): *[Facility manager must certify in that the facility has the resource capability to support the study. If animals will be housed in lab or anywhere else outside central facility for more than 12 hours, provide building and room number.]*

1. Describe any applicable conditions, enrichment, and feeding regimens for animals in housing.

1. Location(s) where manipulation will be conducted:
2. Number of animals to be used:

Year 1:       Year 2:       Year 3:

1. Total number of animals to be used:
2. **TRANSPORTATION**

Transportation of animals must conform to all institutional guidelines and federal regulations. **Note that animals are *not* University property until received on campus.** If animals will be transported on public roads or out of state, describe methods you will use to comply with [USDA regulations](https://www.aphis.usda.gov/animal_welfare/downloads/AC_BlueBook_AWA_FINAL_2017_508comp.pdf). If animals will be transported between facilities, describe the methods and containers that will be used. If animals will be transported within a facility, include the route and elevator(s) that will be used.

1. **STUDY OBJECTIVES**

Briefly explain the aim of the study and why the study is important to human or animal health, the advancement of knowledge, or the good of society in language that a layperson can understand. Specify the scientific vs. education goals or expected outcomes. Please also comment on whether the study unnecessarily duplicates other studies.

1. **RATIONALE FOR ANIMAL USE**
2. Explain your rationale for animal use. *[The rationale should include reasons why it is necessary to use animal models.]*

1. Justify the appropriateness of the species selected. *[The species selected should be the lowest possible on the phylogenetic scale.]*

1. Justify the number of animals to be used. *[The number of animals should be the minimum number required to obtain statistically valid results. Include justification for group size through a power analysis when possible or if you propose to carry out a pilot study with a small number of animals, explain how this may help you design a study with a larger animal number.]*

1. **DESCRIPTION OF EXPERIMENTAL DESIGN & ANIMAL PROCEDURES**

Briefly explain the experimental design and specify all animal procedures. All procedures to be employed in the study must be described. 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. A flowchart may be an effective presentation of the planned procedure.

*A best practice is to provide an acceptable range of the specific items described below to allow flexibility in the use of professional judgment and avoid non-compliance due to work conducted off protocol as a result of overly restricted parameters.*

Include the following specific information, if applicable:

* **Animal identification methods** *[e.g., ear tags, tattoos, collar, cage card, implant, etc.]*.

* **Methods of restraint** *[e.g., restraint chairs, collars, vests, harnesses, slings, etc.]*. Describe how animals are restrained for routine procedures like blood withdrawals. Prolonged restraint must be justified with appropriate oversight to ensure that distress is minimized. Describe any sedation, acclimation or training to be used.

* **Experimental injections or inoculations** *[substances, e.g., infectious agents, adjuvants, etc.; dose, sites, volume, route, and schedule]*.

* **Blood withdrawals** *[volume, frequency, withdrawal site, and methodology]*.

* **Radiation** *[dosage and schedule]***.**

* **Food or fluid restriction** If food or fluid, or both food and fluid, will be restricted, describe method for assessing the health and wellbeing of the animals. *[Amount earned during testing and amount freely given must be recorded and assessed to assure proper nutrition.]* If you are seeking a departure from the recommendations of the *Guide*, provide a scientific justification.

* **Pharmaceutical-grade and Non-pharmaceutical-grade compounds** Identify any drugs, biologics, or reagents that will be administered to animals. If these agents are not human or veterinary pharmaceutical-grade substances, provide a scientific justification for their use and describe methods that will be used to ensure appropriate preparation and administration.

* **Other procedures** *[e.g., survival studies, tail biopsies]*.

* **Resultant effects**, if any, that the animals are expected to experience *[e.g., pain or distress, ascites production, etc.]*.

* **Other potential stressors** *[e.g., noxious stimuli, environmental stress]* **and procedures to monitor and minimize distress**. If a study is USDA Classification E, describe any non-pharmaceutical methods that will be used to minimize pain and distress.

* **Experimental endpoint criteria** *[e.g., tumor size, percentage body weight gain or loss, inability to eat or drink, behavioral abnormalities, clinical symptomatology, or signs of toxicity]* must be specified when the administration of tumor cells, biologics, infectious agents, radiation or toxic chemicals are expected to cause significant symptomatology or are potentially lethal. List the criteria that will be used to determine when euthanasia is to be performed. Death as an endpoint must be scientifically justified.

* **Veterinary care** Indicate the plan of action in case of animal illness *[e.g., initiate treatment, call investigator prior to initiating treatment, euthanize]*.

* **Surgical procedures.** Is surgery proposed? Yes [ ]  No [ ]

*[If yes, provide details of survival and non-survival surgical procedures in Section VII below]*

1. **SURGERY**

If surgery is proposed, complete the following:

1. Identify and describe the surgical procedure(s) to be performed. Include preoperative procedures *[e.g., fasting, analgesic loading],* and monitoring and supportive care during surgery. Include the aseptic methods to be used.

1. Identify the individual(s) that will perform surgery and their qualifications, training, and/or experience.

1. Identify the location where surgery will be performed. *[building(s) and room(s)]*

1. If survival surgery, describe postoperative care that will be provided and frequency of observation. Identify the responsible individual(s) and location(s) [building(s) and room(s)] where care will be provided. Include detection and management of postoperative complications during work hours, after hours, weekends and holidays.

1. If non-survival surgery, describe how euthanasia will be provided and how death will be determined.

1. Are paralytic agents used during surgery? If yes, please describe how ventilation will be maintained and how pain will be assessed.

1. Has major or minor survival surgery been performed on any animal prior to being placed on this study? *[Major survival surgery penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic functions or involves extensive tissue dissection or transection (such as laparotomy, thoracotomy, craniotomy, joint replacement, or limb amputation)].* If yes, please explain.

1. Will more than one survival surgery be performed on an animal while on this study? If yes, please justify.

1. **PAIN OR DISTRESS CLASSIFICATION AND CONSIDERATION OF ALTERNATIVES**

1. Complete the grid below for pain or distress classificationfor USDA covered species.See Appendix 1 for classification definitions and examples.
2. *Attachment 1, Explanation for USDA Classification E, must be completed for animals listed in Classification E.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Species****(common name)** | **USDA Classification**\***B, C, D or E** | **Number of animals used each year** | **3 years total number of animals** |
| **Year 1** | **Year 2** | **Year 3** |
|  |  |  |  |  |  |
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|  |  |  |  |  |  |
|  |  |  |  |  |  |
| **Total number of animals**  |  |

3. Consideration of Alternatives

If any procedures fall into USDA's Classification D or E, causing more than momentary or slight pain or distress to the animals, describe your consideration of alternatives and your determination that alternatives are not available. **At least two legitimate scientific databases must be searched (e.g. Animal Welfare Information Center, Medline, etc).** Delineate the methods and sources used in the search.

**Literature search references must include (1) databases searched, (2) the date of the search, (3) period covered, and (4) the keywords used.** Alternatives include methods such as:

* Refinement- refining existing tests by minimizing animal distress,
* Reduction- reducing the number of animals necessary for an experiment (but not below that needed for statistical significance), or
* Replacement- replacing whole‑animal use with *in vitro* or other tests or use a species lower on the phylogenetic scale e.g. fish instead of mammals, etc.

If you use ascites production to produce antibodies, you must provide the reason for not using an *in vitro* system. Note that you must certify in Section XII.5. that no valid alternative was identified to any described procedures which may cause more than momentary pain or distress, whether relieved or not.

1. **ANESTHESIA, ANALGESIA, TRANQUILIZATION, OTHER AGENTS**

For animals indicated in Section VIII.1. Classification D, specify the anesthetics, analgesics, sedatives or tranquilizers that will be used. *[A best practice is to provide an acceptable range of the specific items to allow flexibility in the use of professional judgment and avoid non-compliance due to work conducted off protocol as a result of overly restricted parameters.]* Include the name of the agent(s), the dosage range, route(s) and schedule of administration. Describe tracking and security of controlled drugs (Drug Enforcement Agency requirements).

1. **METHOD OF EUTHANASIA OR DISPOSITION OF ANIMALS AT END OF STUDY**

What will happen with animals at the completion of the study? Will some be adopted out or euthanized? If euthanasia is used, please clarify when and why that would be used (e.g. animal in distress and pain level) and what constitutes that end.

Indicate the proposed method of euthanasia if euthanasia is required. If a chemical agent is used, specify the dosage range and route of administration. If the method of euthanasia is **not** consistent with the AVMA Guidelines for the Euthanasia of Animals, provide scientific justification as to why such method must be used. Indicate the method of carcass disposal below.

\*Note: If planning to adopt animals at the conclusion of the study, investigators must follow University procedures on adoption of animals posted on the website and consult with the Veterinarian.

#### SPECIAL CONCERNS OR REQUIREMENTS OF THE STUDY

List any special housing, equipment, animal care or any departures from the *Guide* *[e.g., special caging, water, feed, waste disposal, environmental enrichment, etc.]*.

1. **PRINCIPAL INVESTIGATOR CERTIFICATIONS**
2. I certify that the information provided in this form is complete, accurate, and that no animals will be harmed to support the scientific and/or teaching objectives outlined.
3. I certify that I am familiar with and will comply with all pertinent institutional, state, and federal rules and policies.
4. All investigator CITI training certificates are attached to this proposal. I certify that if there is change in [erspmme; at any time, the IACUC will be notified in writing with all updated information and CITI certifications.
5. I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research.
6. For all USDA Classification D and Eproposals(see section VIII.1.): I certify that I have reviewed the pertinent scientific literature and the sources and/or databases as noted in Section VIII.3.and have found no valid alternative to any procedures described herein which may cause more than momentary pain or distress, whether it is relieved or not.
7. I certify that I will obtain approval from the IACUC before initiating any significant changes (including but not limited to changes in use of analgesic/anesthetic, in the species used – more than 10% increase in number of animals contact the IACUC for advice in this study.
8. I certify that I will notify the IACUC regarding any unexpected study results that impact the animals. Any unanticipated pain or distress, morbidity or mortality will be reported to the attending veterinarian and the IACUC.

**Principal Investigator**

 Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Appendix 1 - USDA Classifications and Examples**

**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:**

* Breeding colonies of any animal species (USDA does not require listing of rats, mice, birds) that are handled in accordance with IACUC approval, the *Guide* and other applicable regulations. Breeding colony includes parents and offspring.
* Newly acquired animals that are handled in accordance with IACUC approval and applicable regulations.
* Animals held under proper captive conditions or wild animals that are being observed.

**Classification C:** Animals upon which teaching, research, experiments, or tests will be conducted involving no pain, distress, or use of pain-relieving drugs.

**Examples:**

* Procedures performed correctly by trained personnel such as the administration of electrolytes/fluids, administration of oral medication, blood collection from a common peripheral vein per standard veterinary practice [dog cephalic, cat jugular] or catheterization of same, standard radiography, parenteral injections of non-irritating substances.
* Manual restraint that is no longer than would be required for a simple exam; short period of chair restraint for an adapted nonhuman primate.

**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:**

* Surgical procedures conducted by trained personnel in accordance with standard veterinary practice such as biopsies, gonadectomy, exposure of blood vessels, chronic catheter implantation, and laparotomy or laparoscopy.
* Blood collection by more invasive routes such as intracardiac or periorbital collection from species without a true orbital sinus *[e.g., guinea pigs]*.
* Administration of drugs, chemicals, toxins, or organisms that would be expected to produce pain or distress but which will be alleviated by analgesics, anesthetics, tranquilizers, or supportive care.

**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 teaching, 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.
* Surgical and postsurgical sequella from invasion of body cavities, orthopedic procedures, dentistry or other hard or soft tissue damage that produces unrelieved pain or distress.
* Negative conditioning via electric shocks that would cause pain in humans.
* Chairing of nonhuman primates not conditioned to the procedure for the time period used.

**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 **Attachment 1**. This information is required to be reported to the USDA, will be available from USDA under the Freedom of Information Act (FOIA), and may be publicly available through the Internet via USDA’s website.

**Attachment 1** - **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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_