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**IACUC USE:**

PROTOCOL NUMBER:

APPROVED:

## **INSTITUTIONAL ANIMAL CARE & USE COMMITTEE (IACUC)**

## **PROTOCOL APPLICATION FOR USE OF VERTEBRATE ANIMALS**

*Click* [**?**](https://nam05.safelinks.protection.outlook.com/?url=https%3A%2F%2Fresources.uta.edu%2Fresearch%2Fregulatory-services%2Fanimal-subjects%2Fiacuc-protocol-application-guidance.php&data=02%7C01%7Cjkissling%40uta.edu%7C89d0ac55f2e14fb5e72908d7af06c179%7C5cdc5b43d7be4caa8173729e3b0a62d9%7C0%7C0%7C637170315851671015&sdata=F60MtibeC8i96bP62KjHReIHgvmYRwy6wsnT%2BaopU70%3D&reserved=0) *for additional guidance filling out this form or go to our webpage on* [*IACUC Protocol Application Guidance*](https://nam05.safelinks.protection.outlook.com/?url=https%3A%2F%2Fresources.uta.edu%2Fresearch%2Fregulatory-services%2Fanimal-subjects%2Fiacuc-protocol-application-guidance.php&data=02%7C01%7Cjkissling%40uta.edu%7C89d0ac55f2e14fb5e72908d7af06c179%7C5cdc5b43d7be4caa8173729e3b0a62d9%7C0%7C0%7C637170315851671015&sdata=F60MtibeC8i96bP62KjHReIHgvmYRwy6wsnT%2BaopU70%3D&reserved=0)*.*

1. **Principal Investigator/Project Director:**

Name:       Department:

Address:       Office Telephone:

E-mail:

1. **Co-PI(s) (All other personnel can be listed later in the protocol):**

Name:       Department:

Name:       Department:

1. **Protocol title:**
2. [**?**](https://nam05.safelinks.protection.outlook.com/?url=https%3A%2F%2Fresources.uta.edu%2Fresearch%2Fregulatory-services%2Fanimal-subjects%2Fiacuc-protocol-application-guidance.php&data=02%7C01%7Cjkissling%40uta.edu%7C89d0ac55f2e14fb5e72908d7af06c179%7C5cdc5b43d7be4caa8173729e3b0a62d9%7C0%7C0%7C637170315851671015&sdata=F60MtibeC8i96bP62KjHReIHgvmYRwy6wsnT%2BaopU70%3D&reserved=0) **Funding Source:**       BlueSheet #       Project ID/Account #
3. [**?**](https://nam05.safelinks.protection.outlook.com/?url=https%3A%2F%2Fresources.uta.edu%2Fresearch%2Fregulatory-services%2Fanimal-subjects%2Fiacuc-protocol-application-guidance.php&data=02%7C01%7Cjkissling%40uta.edu%7C89d0ac55f2e14fb5e72908d7af06c179%7C5cdc5b43d7be4caa8173729e3b0a62d9%7C0%7C0%7C637170315851671015&sdata=F60MtibeC8i96bP62KjHReIHgvmYRwy6wsnT%2BaopU70%3D&reserved=0) **Has the project been peer reviewed?:** Yes [ ]  No [ ]

 Describe:

1. **Animal locations:** Housing:       Laboratory

Overnight [ ]  Day use only [ ]  Overnight [ ]  Day use only [ ]

 Zoo:

Field:

***Note: Items #7 - 11 should be answered for each species of animal to be used.***

**7.** **a.** Species:       Strain/Stock:       Common Name:

**b.** Source (check all that apply):

[ ]  [ACF Approved Vendor](https://resources.uta.edu/research/_documents/rs_documents/List%20of%20Approved%20Animal%20Vendors%20Feb%202018.docx)

[ ]  Breeding Protocol (IACUC Protocol #     )

[ ]  Transfer from another institution (Requires Material Transfer Agreement. Email Agreements Manager to initiate.)

[ ]  Other, please explain. If using multiple sources, please explain that here:

 **c.** Duration of project (years):

 **d.** Maximum # of animals to be housed at one time:

 **e.** Total # of animals through course of project:

1. **Training**
2. Give a detailed description of your training plan to ensure proficiency of research personnel performing animal procedures. Will training involve any live or deceased animals? (Even if all personnel are currently trained, please provide a plan for future additional personnel.):

*Note: The ACF Staff and Attending Veterinarian (AV) are available to provide general hands-on training including some basic procedures, as well as aseptic surgery technique using animals from the ACF’s Training Protocol. More advanced procedures may require you to include additional animals in this protocol for training.*

1. How many live animals are needed for training?
2. If utilizing live animals for training, what will the source be (e.g., the ACF Training Protocol, a vendor, a breeding protocol, another PI’s protocol)? If planning to source animals from the ACF Training Protocol, please contact the ACF Manager at acf@uta.edu prior to submission for scheduling and availability of animals.

*Note: Animals that have undergone surgery may not be used for survival surgery training. It is preferable to utilize deceased animals for training purposes if possible. Other sources may include older animals, animals that have undergone non-terminal procedures, or animals obtained specifically for training purposes. Please note that any live animals factored in for training purposes must be included in your number of requested animals and reported to the IACUC in follow-ups/annual reports as applicable.*

1. For instructional protocols (teaching classes), please describe what alternative activities will be conducted for students who do not complete the required training in a timely manner; (If this section does not apply to you, please enter “N/A” here):
2. [**?**](https://nam05.safelinks.protection.outlook.com/?url=https%3A%2F%2Fresources.uta.edu%2Fresearch%2Fregulatory-services%2Fanimal-subjects%2Fiacuc-protocol-application-guidance.php&data=02%7C01%7Cjkissling%40uta.edu%7C89d0ac55f2e14fb5e72908d7af06c179%7C5cdc5b43d7be4caa8173729e3b0a62d9%7C0%7C0%7C637170315851671015&sdata=F60MtibeC8i96bP62KjHReIHgvmYRwy6wsnT%2BaopU70%3D&reserved=0) **USDA Classification** **of Animal Use**

***\*****Include total anticipated period of project funding and animal use. Anticipated use of animals more than three years beyond approval date should be included, even though new IACUC approval will be required. At any point after you start the study, if you think that you need more animals in a certain category than initially requested (even if the total number of approved animals remains the same) please submit an* [*IACUC Amendment Form*](https://resources.uta.edu/research/regulatory-services/animal-subjects/forms.php) *to* *regulatoryservices@uta.edu**. For further explanation regarding USDA Classifications, see instructions in Appendix A of this application.*

|  |  |
| --- | --- |
| Project Period\* | **Number of Animals by Category:** |
| From (mo/yr) | To (mo/yr) | USDA Category **C** | USDA Category **D** | USDA Category **E** |
|       |       |       |       |       |

1. **Objective and Procedures**
	* 1. **Research objective:** In the space provided, give a brief description in *layperson’s* (high school) language of the objective and significance of the project/course (full scientific description is required later in protocol).

* 1. **Procedures performed on animals**: In the space provided, give a brief description in *layperson’s* (high school) language of the procedures that will be performed on animals in this project (full scientific description is required later in protocol).

1. [**?**](https://nam05.safelinks.protection.outlook.com/?url=https%3A%2F%2Fresources.uta.edu%2Fresearch%2Fregulatory-services%2Fanimal-subjects%2Fiacuc-protocol-application-guidance.php&data=02%7C01%7Cjkissling%40uta.edu%7C89d0ac55f2e14fb5e72908d7af06c179%7C5cdc5b43d7be4caa8173729e3b0a62d9%7C0%7C0%7C637170315851671015&sdata=F60MtibeC8i96bP62KjHReIHgvmYRwy6wsnT%2BaopU70%3D&reserved=0) **Special requirements for maintaining animals**: Yes [ ]  No [ ]

If yes, describe and justify the special requirements below, such as caging, single housing, bedding, type of water, or dietary requirements. If no, animals are to be maintained according to the standard operating procedure of the animal facility.

Other special instructions for animal care staff:

See [Cage Density SOP](https://resources.uta.edu/research/regulatory-services/animal-subjects/iacuc-policies-and-procedures.php)

1. [**?**](https://nam05.safelinks.protection.outlook.com/?url=https%3A%2F%2Fresources.uta.edu%2Fresearch%2Fregulatory-services%2Fanimal-subjects%2Fiacuc-protocol-application-guidance.php&data=02%7C01%7Cjkissling%40uta.edu%7C89d0ac55f2e14fb5e72908d7af06c179%7C5cdc5b43d7be4caa8173729e3b0a62d9%7C0%7C0%7C637170315851671015&sdata=F60MtibeC8i96bP62KjHReIHgvmYRwy6wsnT%2BaopU70%3D&reserved=0) **Animal Transportation** (OUTSIDE the central Animal Care Facility OR between buildings on UT Arlington campus OR outside UT Arlington campus)**:** Yes [ ]  No [ ]

Transportation of animals must conform to all institutional guidelines/policies and federal regulations.

If yes, please complete and submit alongside this application the [Request for Transportation of Animals](https://resources.uta.edu/research/regulatory-services/animal-subjects/forms.php) form.

1. **For Field Research Protocols Only**. If this section does not apply to you, please enter “N/A” here:
	* + - 1. **Live Trapping** – Include type of trap used, length of time animals will remain in the trap (provide range), what type of survival support is provided in the trap (e.g.: type of bedding to be used, water, food, water change when collecting fish, etc.), what provisions will be made to protect animals in live traps in the event of inclement weather, how will animals be sheltered from direct sun, etc.
				2. **Captivity –** If held in captivity longer than 12 hours, how long and under what conditions?
				3. **Biopsy Techniques** – Describe in detail any biopsy techniques such as tissue collection, blood collection, etc. For blood collection, provide the following information: Site, quantity per bleed, frequency of bleeding, how long/total number of bleeds. For tissue collection, provide the following: age of animal, method used to collect tissue (i.e.: toe clip, ear punch, etc.), amount of tissue to be collected.
2. **Treatment and disposition of animals**
	* + - 1. **Animal Illness** – ACF Staff will contact the Attending Veterinarian and the Principal Investigator (or designee) to discuss treatment options.

If you have other instructions for the ACF, please enter them here. If not, enter N/A:

* + - * 1. **Death of Animal** - ACF Staff will email the Principal Investigator (or designee) and hold carcass in refrigerator for 3 days before moving to freezer for final disposal/incineration.
				If you have other instructions for the ACF, please enter them here. If not, enter N/A:
1. **Wild** or **exotic** species Yes [ ]  No [ ]  Permits? Yes [ ]  No [ ]

Please list permits if applicable:

1. [**?**](https://nam05.safelinks.protection.outlook.com/?url=https%3A%2F%2Fresources.uta.edu%2Fresearch%2Fregulatory-services%2Fanimal-subjects%2Fiacuc-protocol-application-guidance.php&data=02%7C01%7Cjkissling%40uta.edu%7C89d0ac55f2e14fb5e72908d7af06c179%7C5cdc5b43d7be4caa8173729e3b0a62d9%7C0%7C0%7C637170315851671015&sdata=F60MtibeC8i96bP62KjHReIHgvmYRwy6wsnT%2BaopU70%3D&reserved=0) **Surgery**: Survival [ ]  Multiple [ ]  Terminal [ ]  None [ ]  If none, skip to next question.
2. Where will surgical procedures be performed (building/room)?

*Note: Major survival surgery involving non-rodent, USDA-covered species must be conducted in a dedicated surgical facility/space (not in a laboratory) operated and maintained under aseptic conditions.*

1. [**?**](https://nam05.safelinks.protection.outlook.com/?url=https%3A%2F%2Fresources.uta.edu%2Fresearch%2Fregulatory-services%2Fanimal-subjects%2Fiacuc-protocol-application-guidance.php&data=02%7C01%7Cjkissling%40uta.edu%7C89d0ac55f2e14fb5e72908d7af06c179%7C5cdc5b43d7be4caa8173729e3b0a62d9%7C0%7C0%7C637170315851671015&sdata=F60MtibeC8i96bP62KjHReIHgvmYRwy6wsnT%2BaopU70%3D&reserved=0)If performing [Multiple Survival Surgeries](http://www.nap.edu/openbook.php?record_id=12910&page=30) on a single animal, please provide scientific justification, citing

 the number of surgeries to be performed:

1. Deviations from Surgery SOP: Investigators are required to follow the [UTA IACUC SOP for Surgery and Post-Surgical Care](https://resources.uta.edu/research/regulatory-services/animal-subjects/iacuc-policies-and-procedures.php) unless a deviation is reviewed and approved by the IACUC. If you request a deviation from the SOP, please describe here; otherwise, enter “N/A.”
2. Brief description of surgical procedures (full description is required later in protocol):

1. [**?**](https://nam05.safelinks.protection.outlook.com/?url=https%3A%2F%2Fresources.uta.edu%2Fresearch%2Fregulatory-services%2Fanimal-subjects%2Fiacuc-protocol-application-guidance.php&data=02%7C01%7Cjkissling%40uta.edu%7C89d0ac55f2e14fb5e72908d7af06c179%7C5cdc5b43d7be4caa8173729e3b0a62d9%7C0%7C0%7C637170315851671015&sdata=F60MtibeC8i96bP62KjHReIHgvmYRwy6wsnT%2BaopU70%3D&reserved=0)[**Restraint**](http://www.nap.edu/openbook.php?record_id=12910&page=29) (Chairs, slings, tethers, stanchions, metabolism cages or other devices)? Yes [ ]  No [ ]

 *If yes, answer a-e:*

1. Method:
2. Duration:
3. Frequency:

**d.** Frequency of observation during restraint:

 **e.** Person responsible for observation:

1. [**?**](https://nam05.safelinks.protection.outlook.com/?url=https%3A%2F%2Fresources.uta.edu%2Fresearch%2Fregulatory-services%2Fanimal-subjects%2Fiacuc-protocol-application-guidance.php&data=02%7C01%7Cjkissling%40uta.edu%7C89d0ac55f2e14fb5e72908d7af06c179%7C5cdc5b43d7be4caa8173729e3b0a62d9%7C0%7C0%7C637170315851671015&sdata=F60MtibeC8i96bP62KjHReIHgvmYRwy6wsnT%2BaopU70%3D&reserved=0)[**Food /Fluid Restriction**](http://www.nap.edu/openbook.php?record_id=12910&page=30)**?** Yes [ ]  No [ ]

 If food, or fluid, or both food and fluid, will be restricted, describe method for assessing the health and

 well-being of the animals. *[Amount earned during testing and amount freely given must be recorded and*

 *assessed to assure proper nutrition. This record should be made available to the IACUC on request]*

1. **Anesthetics, analgesics, or sedation used?**  Yes [ ]  No [ ]

***Procedures that may cause more than momentary or slight pain or distress (during or following the procedure) must be accompanied by appropriate sedation, analgesia, or anesthesia unless scientifically justified and approved by the IACUC.***

* + - * 1. If utilizing anesthesia for potentially painful/distressful procedures, confirm you will adhere to the methods, procedures, and species-specific drug formulary as described in the [Anesthesia in Laboratory Animals SOP](https://resources.uta.edu/research/regulatory-services/animal-subjects/iacuc-policies-and-procedures.php).

 N/A (no painful/distressful procedures) [ ]  Yes [ ]  No [ ]  If no, provide justification:

Person(s) responsible for monitoring post-anesthesia recovery?

* + - * 1. If utilizing analgesia for potentially painful/distressful procedures, confirm you will adhere to the methods, procedures, and species-specific drug formulary as described in the [Analgesia in Laboratory Animals](https://resources.uta.edu/research/regulatory-services/animal-subjects/iacuc-policies-and-procedures.php) SOP.

 N/A (no painful/distressful procedures) [ ]  Yes [ ]  No [ ]  If no, provide justification:

Under what circumstances will incremental doses of analgesics be administered?

* 1. Provide names of agents/drugs that will be used, and corresponding dose. If using agent(s) other than those listed in IACUC SOPs, *also* provide the route, method of administration, and frequency:
	2. If any of the agents listed are not human or veterinary [pharmaceutical-grade substances](http://www.nap.edu/openbook.php?record_id=12910&page=31), provide a scientific justification for their use and describe methods that will be used to ensure appropriate preparation and administration (purity, sterility, etc.):
1. **a. List all other drugs, biologics, substances, or reagents to be used that are not listed in question above:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Substance | Dose (mg/kg) | Route | Times/Day | #Hours/Day | Pharmaceutical Grade (Y or N) |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
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1. [**?**](https://nam05.safelinks.protection.outlook.com/?url=https%3A%2F%2Fresources.uta.edu%2Fresearch%2Fregulatory-services%2Fanimal-subjects%2Fiacuc-protocol-application-guidance.php&data=02%7C01%7Cjkissling%40uta.edu%7C89d0ac55f2e14fb5e72908d7af06c179%7C5cdc5b43d7be4caa8173729e3b0a62d9%7C0%7C0%7C637170315851671015&sdata=F60MtibeC8i96bP62KjHReIHgvmYRwy6wsnT%2BaopU70%3D&reserved=0)If these agents are not human or veterinary [pharmaceutical-grade substances](http://www.nap.edu/openbook.php?record_id=12910&page=31), provide a scientific justification for their use and describe methods that will be used to ensure appropriate preparation and administration (purity, sterility, etc.):
2. **a.** Describe the post-procedure care (survival procedures only):

 **b.** Where are the animals held post-procedure?

1. Person(s) responsible for post-procedure observation:
2. How will the animals be monitored? Describe a specific monitoring plan:
3. **a.** Neuromuscular blocking agents: Yes [ ]  No [ ]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Drug | Dose (mg/kg) | Route | Times/Day | #Hours/Day |
|       |       |       |       |       |
|       |       |       |       |       |
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1. If neuromuscular blocking agents are being used without general anesthesia, provide justification:

1. [**?**](https://nam05.safelinks.protection.outlook.com/?url=https%3A%2F%2Fresources.uta.edu%2Fresearch%2Fregulatory-services%2Fanimal-subjects%2Fiacuc-protocol-application-guidance.php&data=02%7C01%7Cjkissling%40uta.edu%7C89d0ac55f2e14fb5e72908d7af06c179%7C5cdc5b43d7be4caa8173729e3b0a62d9%7C0%7C0%7C637170315851671015&sdata=F60MtibeC8i96bP62KjHReIHgvmYRwy6wsnT%2BaopU70%3D&reserved=0)Describe in sufficient detail the [**Experimental Endpoints**](http://www.nap.edu/openbook.php?record_id=12910&page=27) of the study *(The experimental endpoint of a study occurs when the scientific aims and objectives have been reached):*
2. [**?**](https://nam05.safelinks.protection.outlook.com/?url=https%3A%2F%2Fresources.uta.edu%2Fresearch%2Fregulatory-services%2Fanimal-subjects%2Fiacuc-protocol-application-guidance.php&data=02%7C01%7Cjkissling%40uta.edu%7C89d0ac55f2e14fb5e72908d7af06c179%7C5cdc5b43d7be4caa8173729e3b0a62d9%7C0%7C0%7C637170315851671015&sdata=F60MtibeC8i96bP62KjHReIHgvmYRwy6wsnT%2BaopU70%3D&reserved=0) **a. Humane Endpoints for the animals**: (See UTA IACUC SOPs: [Assessment of Pain and Distress](https://resources.uta.edu/research/regulatory-services/animal-subjects/iacuc-policies-and-procedures.php), [Tumor Scoring](https://resources.uta.edu/research/regulatory-services/animal-subjects/iacuc-policies-and-procedures.php), [Euthanasia and Humane Endpoints](https://resources.uta.edu/research/regulatory-services/animal-subjects/iacuc-policies-and-procedures.php)) Procedures such as pharmacological or surgical procedures might lead to severe discomfort, distress, pain and/ or injury to the animals. If applicable, please describe in sufficient detail the indicators for [humane endpoints](http://www.nap.edu/openbook.php?record_id=12910&page=27) and euthanasia (e.g., untreatable infection, respiratory distress, failure to eat, tumor size):
3. What interventions will be utilized to minimize pain and/or distress (ex. analgesia, euthanasia, none)?
4. Under what circumstances or at what time points will interventions be utilized?
5. Are there circumstances under which the interventions will need to be withheld? Yes [ ]  No [ ]

If yes, describe what will be withheld, and provide the scientific justification for withholding the intervention:

1. [**?**](https://nam05.safelinks.protection.outlook.com/?url=https%3A%2F%2Fresources.uta.edu%2Fresearch%2Fregulatory-services%2Fanimal-subjects%2Fiacuc-protocol-application-guidance.php&data=02%7C01%7Cjkissling%40uta.edu%7C89d0ac55f2e14fb5e72908d7af06c179%7C5cdc5b43d7be4caa8173729e3b0a62d9%7C0%7C0%7C637170315851671015&sdata=F60MtibeC8i96bP62KjHReIHgvmYRwy6wsnT%2BaopU70%3D&reserved=0) **Final Disposition of Animals** check all that apply:

 [ ]  euthanized [ ]  release to former habitat [ ]  adoption (see [UTA Animal Adoption Policy and Form](https://resources.uta.edu/research/regulatory-services/animal-subjects/iacuc-policies-and-procedures.php))

 [ ]  other (explain:      )

1. Person(s) performing euthanasia:
	1. Deviations from Euthanasia SOP: Investigators are required to follow the [UTA IACUC Euthanasia and Humane Endpoints SOP](https://resources.uta.edu/research/regulatory-services/animal-subjects/iacuc-policies-and-procedures.php) and current [AVMA Euthanasia Guidelines](https://www.avma.org/KB/Policies/Documents/euthanasia.pdf) unless a deviation is reviewed and approved by the IACUC. If you request a deviation from the SOP or Guidelines, please describe here and provide scientific justification; otherwise, enter “N/A.”
2. [**?**](https://nam05.safelinks.protection.outlook.com/?url=https%3A%2F%2Fresources.uta.edu%2Fresearch%2Fregulatory-services%2Fanimal-subjects%2Fiacuc-protocol-application-guidance.php&data=02%7C01%7Cjkissling%40uta.edu%7C89d0ac55f2e14fb5e72908d7af06c179%7C5cdc5b43d7be4caa8173729e3b0a62d9%7C0%7C0%7C637170315851671015&sdata=F60MtibeC8i96bP62KjHReIHgvmYRwy6wsnT%2BaopU70%3D&reserved=0) **Hazards to personnel** (check all that apply and provide description of hazard and safety precautions):

[ ]  Radioisotope

[ ]  Carcinogen

[ ]  Biohazard

[ ]  Chemical Hazards

[ ]  Other

1. [**?**](https://nam05.safelinks.protection.outlook.com/?url=https%3A%2F%2Fresources.uta.edu%2Fresearch%2Fregulatory-services%2Fanimal-subjects%2Fiacuc-protocol-application-guidance.php&data=02%7C01%7Cjkissling%40uta.edu%7C89d0ac55f2e14fb5e72908d7af06c179%7C5cdc5b43d7be4caa8173729e3b0a62d9%7C0%7C0%7C637170315851671015&sdata=F60MtibeC8i96bP62KjHReIHgvmYRwy6wsnT%2BaopU70%3D&reserved=0) **Personnel (**See UTA IACUC [Training Requirements](https://resources.uta.edu/research/regulatory-services/animal-subjects/iacuc-training.php))

|  |  |  |
| --- | --- | --- |
| Name | Email | Role in the protocol (e.g., supervisory, performing all procedures, performing surgery only, observation only, administrative only, etc.) |
|       |       |       |
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1. Body fluids or tissuesfrom these animals may be utilized by other investigators with approved IACUC protocols.

Yes [ ]

No [ ]  Please explain why not:

1. **Controlled Substances** Yes [ ]  No [ ]

 *If yes, please initial assurance:*

 I am responsible for procurement, storage, administration, and record keeping for all

 controlled substances Initial:

1. **Summary and Judicious Use of Animals:**

In this section, include an expanded summary to describe your work to the Institutional Animal Care and Use Committee. **This will be the core of the protocol application**, so do not exclude any of the items listed below.

*Do not submit a grant proposal, abstract, teaching syllabus, or reprint in place of the summary statement. Use language appropriate for a scientist outside your field.*

*Outside review of scientific and/or educational content of the protocol application may be necessary if no peer review is complete or planned, particularly if the animal use falls under USDA category D or E.*

* + - * 1. [**?**](https://nam05.safelinks.protection.outlook.com/?url=https%3A%2F%2Fresources.uta.edu%2Fresearch%2Fregulatory-services%2Fanimal-subjects%2Fiacuc-protocol-application-guidance.php&data=02%7C01%7Cjkissling%40uta.edu%7C89d0ac55f2e14fb5e72908d7af06c179%7C5cdc5b43d7be4caa8173729e3b0a62d9%7C0%7C0%7C637170315851671015&sdata=F60MtibeC8i96bP62KjHReIHgvmYRwy6wsnT%2BaopU70%3D&reserved=0)Describe the objective and significance of the project/course, including the probable benefits of this work to human and/or animal health, the advancement of knowledge, or the good of society.

* + - * 1. [**?**](https://nam05.safelinks.protection.outlook.com/?url=https%3A%2F%2Fresources.uta.edu%2Fresearch%2Fregulatory-services%2Fanimal-subjects%2Fiacuc-protocol-application-guidance.php&data=02%7C01%7Cjkissling%40uta.edu%7C89d0ac55f2e14fb5e72908d7af06c179%7C5cdc5b43d7be4caa8173729e3b0a62d9%7C0%7C0%7C637170315851671015&sdata=F60MtibeC8i96bP62KjHReIHgvmYRwy6wsnT%2BaopU70%3D&reserved=0)Provide a detailed description of the procedures to which the animals will be subjected. Describe the first procedure performed on the animal and all procedures up to and including euthanasia.

* 1. [**?**](https://nam05.safelinks.protection.outlook.com/?url=https%3A%2F%2Fresources.uta.edu%2Fresearch%2Fregulatory-services%2Fanimal-subjects%2Fiacuc-protocol-application-guidance.php&data=02%7C01%7Cjkissling%40uta.edu%7C89d0ac55f2e14fb5e72908d7af06c179%7C5cdc5b43d7be4caa8173729e3b0a62d9%7C0%7C0%7C637170315851671015&sdata=F60MtibeC8i96bP62KjHReIHgvmYRwy6wsnT%2BaopU70%3D&reserved=0)Provide your reason/justification for selecting the species. Are other animals, especially lower species, suitable for these studies?

* 1. If applicable, provide justification if using only male or only female animals (or enter “N/A”).
	2. Provide justification for the number of animals requested. How did you calculate the number in each group that are required to achieve statistical significance? How did you calculate the total number you are requesting?
1. [**?**](https://nam05.safelinks.protection.outlook.com/?url=https%3A%2F%2Fresources.uta.edu%2Fresearch%2Fregulatory-services%2Fanimal-subjects%2Fiacuc-protocol-application-guidance.php&data=02%7C01%7Cjkissling%40uta.edu%7C89d0ac55f2e14fb5e72908d7af06c179%7C5cdc5b43d7be4caa8173729e3b0a62d9%7C0%7C0%7C637170315851671015&sdata=F60MtibeC8i96bP62KjHReIHgvmYRwy6wsnT%2BaopU70%3D&reserved=0)Describe your qualifications and experience, as well as the personnel/research team’s, *specifically with the proposed animal model and procedures* included in this protocol.

1. **Procedures with the Potential to Cause Pain and/or Distress (Category D or E)**

With respect to the procedures proposed that have the potential to result in pain and/or distress (e.g. surgery, anxiety/depression models, etc.), how have you determined that there are no alternative procedures that could be used instead?

**Note:** The use of [USDA Covered Species](https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/sa_awa) requires completion of a Literature Search – See Appendix B of this application.

1. **Conflicts of Interest (COI)**

Does the principal investigator or any protocol personnel (internal and external) have an affiliation, arrangement, or financial interest that could be perceived as a conflict of interest? If yes, please describe.

If the principal investigator or any protocol personnel (internal and external) have an active research conflict of interest management plan, please describe if the COI may be perceived as related to the research and provide a copy of the management plan.

***\*Note****: “****Financial Interest”*** *is defined as anything of monetary value (existing or potential), whether or not the value is readily ascertainable. “****Conflict of Interest”*** *is defined as a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.*

***\*Note:*** *All Covered Individuals in GMR research are required to have a current COI disclosure on file in* [*Mentis*](https://mentis.uta.edu/public/#coi/disclosure/my) *(this must be complete prior to approval of the protocol). Covered Individuals are those with responsibilities for the conduct, design, or reporting of this research study.*

1. **Animal Use Guidelines:** Principal Investigators (PIs) can consult the website of the societies relevant to their study for access to guidelines. It is the PI’s responsibility to be familiar with the guidelines applicable to a given project.

Place an ‘X’ in the first column next to each guideline that has been reviewed as part of this research:

|  |  |
| --- | --- |
| [ ]  | [*Guide for the Care and Use of Laboratory Animals, 8th edition*](https://www.aaalac.org/the-guide/)*.* National Research Council, 2011. **(“The Guide” applies to all studies involving live, vertebrate animals.)** |
| [ ]  | [*Guidelines to the Use of Wild Birds in Research*](https://www.aaalac.org/pub/?id=E9019213-EE55-98AB-F68E-EF2B10C31360)*.* The Ornithological Council, 2010.  |
| [ ]  | [*Guidelines for the Use of Fishes in Research*](https://www.aaalac.org/pub/?id=DCA7747C-FBCC-D8B2-F93C-F9249E530DCA), American Fisheries Society, 2014.  |
| [ ]  | *[Guidelines of the American Society of Mammalogists for the Use of Wild Mammals in Research and Education](https://www.aaalac.org/pub/?id=E9018E7B-F482-C1E4-934B-A415AE4ED86B)*, American Society of Mammalogists, 2016. |
| [ ]  | [*Guidelines for Use of Live Amphibians and Reptiles in Field and Laboratory Research*](https://www.aaalac.org/pub/?id=E90180D2-EE29-8F8B-A493-AC0C8F911AAC), Herpetological Animal Care and Use Committee (HACC) of the American Society of Ichthyologists and Herpetologists, 2004. |

**PRINCIPAL INVESTIGATOR ASSURANCES.** *(Signify your agreement by checking each box)*

1. I have a working knowledge of the “Guide for the Care and Use of Laboratory

Animals” and the USDA “Title 9 Animal Welfare Act” and its revisions [ ]

1. The proposed work does not unnecessarily duplicate previous experiments, based

upon a current literature search: [ ]

1. All personnel involved in this project will be trained in the protocol and its procedures prior to beginning work with live animals [ ]
2. I and all personnel on the project have read any pertinent safety information, IACUC

requirements, and security procedures (See ACF Manager) [ ]

1. I shall be responsible for maintaining records of all animals used and the procedures

carried out [ ]

1. Any discomfort, distress or pain that may be associated with this research will be held

to the absolute minimum [ ]

1. Alternatives to any procedures that may cause pain or discomfort have been considered [ ]
2. I will strictly adhere to all DEA regulations involving receiving, storage, use, documentation

and disposal of all controlled substances utilized in my animal care program [ ]

1. I will immediately notify the ACF Manager about any signs of animal illness, pain, or distress

as well as any unanticipated animal deaths [ ]

1. In accordance with UTA’s Policy for Disclosure, Management, and Reporting of Conflicts of Interest in Research (RA-PO-02), as an Investigator who proposes or conducts animal research, I have submitted a new (or recertified an existing) Conflict of Interest Disclosure: https://mentis.uta.edu/public/#coi/disclosure/my [ ]

As Principal Investigator, I am aware that I have the ultimate responsibility, on a day-to-day basis, for the proper care and treatment of the laboratory animals. I agree to adhere to all federal, state and local laws and regulations governing the use of animals in teaching and research. I further assure the University of Texas at Arlington Animal Care and Use Committee (Committee) that the minimal number of animals will be used for the project and that every possible step will be taken to minimize stress or pain to the animals. I have carefully considered and concluded that no reasonable alternatives to the use of animals could be applied to this project, and that this project is not an unnecessary duplication of any previously published work.

I will submit appropriate annual review information for this project and obtain formal approval from the Committee prior to implementation of any changes in this protocol.

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Principal Investigator Date

## **INSTITUTIONAL ANIMAL CARE & USE COMMITTEE (IACUC)**

#### PROTOCOL APPLICATION FOR USE OF VERTEBRATE ANIMALS

#### APPENDIX A:

#### Instructions for classification of animal discomfort, distress, and pain level

For the purposes of protocol review and reporting, the USDA has established categories of research based upon a summation of the associated discomfort, distress and/or pain. Each protocol application must include assignment of a USDA classification to each unique experiment or instructional activity.

**Category C: Animals subjected to procedures that cause no pain or distress, or procedures that cause only momentary or slight pain or distress and do not require the use of pain-relieving drugs.**

These include housing and restraining animals for observation or examination; tattooing, blood sampling, injection of nontoxic material; standard approval methods of euthanasia that induce rapid unconsciousness; short periods (few hours) of food and water deprivation and single group behavioral observations. Studies on anesthetized animals that do not regain consciousness are included in this category; this includes acute, non-survival experiments (no survival surgery in Category C classification).

**Category D: Animals subjected to potentially painful or stressful procedures that are alleviated by appropriate anesthetics, analgesics, tranquilizers, removal from study, euthanasia or other approved methods.**

These include cannulation of vessels or body cavities performed under anesthesia; minor surgical procedures under anesthesia; minor surgical procedures under anesthesia such as biopsies, laparoscopy and others where post-surgical pain/distress is absent or minimal; major surgical procedures, under anesthesia and permitting recovery, that result in minor post-surgical pain (as determined by the IACUC and veterinarian); studies using noxious stimuli from which escape is possible; using tumor implants/hybridomas; domestic animal production methods ( tail docking, neutering, dehorning, debeaking, etc.); prolonged periods (several hours or more) of physical restraint or deprivation of the animal’s environmental necessities, such as maternal deprivation, aggression, or predatory-prey interactions; procedures which alter perceptual or motor functions; studies in which diseases or toxicities are induced, and those in which animals are treated or euthanized when clinical symptoms begin to appear. Animals in Category D studies experience pain/discomfort, but the necessary treatments to alleviate the symptoms are available and provided, or the animals are euthanized (adherence to acceptable veterinary practices, i.e., post-op analgesia, fluid therapy and required veterinary nursing care).

*Comment: During and after Category D studies, it is unacceptable for animals to show anorexia, dehydration, abnormal discharges, hyperactivity, increased/recumbency or dormancy, increased vocalization, self-mutilation, aggressive defensive behavior, or demonstrate social withdrawal and self isolation. For Category D procedures, investigators must address, within their protocol, intervention/treatment for these possible responses.*

**Category E: Animals subjected to potentially painful or stressful procedures that are not alleviated by anesthetics, analgesics, tranquilizers or other approved methods. Withholding these interventions must be scientifically justified & approved by the IACUC.**

The designation of this category is cause for extremely close scrutiny by the IACUC and requires that the investigator include in Section 32.2 a full explanation and justification for this pain level. Such studies include application of noxious stimuli from which escape is impossible; exposure to noxious stimuli and agents whose effects are unknown; foot pad or intradermal or intraperitoneal injections of Freund’s complete adjuvant; new experiments which have a high degree of invasiveness (with no veterinary involvement); surgery without anesthetics; induction of aggressive behavior leading to self-mutilation or fighting; toxicity testing where death is the end-point; induction of diseases where infected animals are permitted to succumb rather than be euthanized or treated therapeutically; using a euthanasia method not recommended by the AVMA.

*Comment: Category E projects present an explicit responsibility on the researcher to explore alternative methods before proceeding with the study. Category E projects are considered by some to be highly questionable or unacceptable, irrespective of the significance of the anticipated results. Before the IACUC can review and approve these projects, the justification statements and the veterinary involvement must be clearly presented and understandable.*

## **INSTITUTIONAL ANIMAL CARE & USE COMMITTEE (IACUC)**

**PROTOCOL APPLICATION FOR USE OF VERTEBRATE ANIMALS**

#### APPENDIX B:

[**?**](http://www-test.uta.edu/research/administration/departments/rs/animals-subjects-iacuc/iacuc-Guidance.php#appb) **Literature Search (Alternatives to animal use or procedures involving pain or distress)**

This section only needs to be completed for studies involving [USDA Covered Species](https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/sa_awa).

The purpose of a **Literature Search** is to demonstrate the concept of the “three Rs.” The three Rs are **Reduction** in number of animals used, **Refinement** of methods to minimize pain and distress, and **Replacement** of the animal model with a non-animal model or a species phylogenetically lower.

***INSTRUCTIONS:***

*(1) You must consult at least 3 sources – please see below for recommendations/samples.*

*(2) List the dates for publication year(s) covered.*

*(3) For each source, list the keywords and/or combination of keywords searched.*

*(4) Indicate the number of hits for each keyword(s).*

*(5) If you have any questions or require assistance, please feel free to contact the IACUC at* *regulatoryservices@uta.edu**.*

Date(s) of the Search(es):

1. Source #1:

 Publication year(s) covered:       to

 Keywords Searched / Number of Hits:

1. Source #2:

 Publication year(s) covered:       to

 Keywords Searched / Number of Hits:

1. Source #3:

 Publication year(s) covered:       to

 Keywords Searched / Number of Hits:

1. Additional Sources:

 Attendance of colloquia or conferences (please list the date of the event(s) and the content provided):

 Consultation with subject experts (please list the consultant’s name, qualifications, and date and content of the consult):

1. Search Results:

Did your search identify any known alternatives for animal use? If so, please provide scientific justification for not using the available alternatives:

Did your search identify the possibility of using a less sentient species? If so, describe why you can or cannot use them:

Did your search identify ways to reduce animal numbers? If so, please provide scientific justification for your requested number of animals:

Did your search identify any refinement techniques for minimizing animal discomfort, distress, and pain? If so, please describe why you can or cannot use these techniques:

#### Literature Searches – Sources and Samples Used in Searching for Alternatives

**SOURCES** (*You are not limited to the sources listed here*):

MEDLINE: <http://intapp.medscape.com/px/medlineapp/medline?src=Overture&OVRAW=MEDLINE&OVKEY=medline&OVMTC=standard>

AGRICOLA:

<http://agricola.nal.usda.gov/>

CAB Abstracts:

<http://www.cabi.org/datapage.asp?iDocID=165>

Center for Alternatives to Animal Testing

PubMed:

<http://www.ncbi.nlm.nih.gov/entrez/query.fcgi>

BIOSIS:

<http://www.biosis.org/>

ALTBIB:

<http://toxnet.nlm.nih.gov/altbib.html>

CRIS:

<http://cris.csrees.usda.gov/>

TOXNET:

<http://toxnet.nlm.nih.gov/>

Altweb Anesthesia/Analgesia Database:
<http://apps1.jhsph.edu/altweb/aadb/aadb_search.cfm>

Altweb Humane Endpoints Database:
<http://altweb.jhsph.edu/humane-endpoints.htm>

EMBASE:
<http://www.embase.com/>

SCISEARCH:
<http://library.dialog.com/bluesheets/html/bl0034.html>

Spaceline:
<http://spaceline.usuhs.mil/>

PsycINFO:
<http://www.apa.org/psycinfo/>

AWIOnline:
[*http://www.awionline.org/SearchResultsSite/refine.aspx*](http://www.awionline.org/SearchResultsSite/refine.aspx)

DIALOG:
<http://www.dialog.com/products/guide/science.shtml>

**SAMPLE** (*The following is a sample key word search for a teaching protocol*):

MEDLINE (1966 – 2005)

KEYWORDS: HITS:

Teaching and stereotaxic surgery 30

Computer simulation and stereotaxic surgery 81

Computer simulation and plus maze 0

Teaching and plus maze 1

CRIS (1966 – 2005)

KEYWORDS: HITS:

Teaching and physiology 46

Computer simulation and teaching 0

Teaching and stereotaxic surgery 0

Computer simulation and stereotaxic surgery 0

Computer simulation and plus maze 0

Teaching and plus maze 0

ALTBIB (1980 – present)

KEYWORDS: HITS:

Teaching and stereotaxic surgery 21

Computer simulation and stereotaxic surgery 31

Computer simulation and plus maze 95

Teaching and plus maze 85

Teaching and physiology 35

Computer simulation and teaching 16