INSTITUTIONAL REVIEW BOARD

APPLICATION FOR REVIEW OF PROJECTS INVOLVING VERTEBRATE ANIMAL SUBJECTS

FOR INTERNAL USE ONLY **TU IRB APPLICATION NUMBER:_____**

The Thomas University Institutional Review Board (IRB) requires that students, faculty and researchers submitting an IRB application to conduct research involving vertebrate animals as subjects complete the appropriate online Collaborative Institutional Training Initiative (CITI) certification courses available at https://www.citiprogram.org/index.cfm?pageID=14&languagePreference=English&region=1
Please be sure to select Thomas University as the affiliate institution on the CITI website to see the list of required courses per research area.

Please note: Handwritten applications will *not be* accepted.

Application Type: ___NEW ___ RESUBMISSION Date Application Submitted to IRB: ____/___/_____
___FOR ACADEMIC TEACHING PURPOSES ONLY *(FACULTY ONLY)*

Title of Project: _____

Name of Principal Investigator: _____
Department:
Address:
Phone:
Fax:
Email:

Co-Investigator(s): List the full name(s), title(s) and department(s) of all Co-Investigator(s) – Cite ***both your and their experience*** with this kind of research – include your name within the co-investigator(s) group to distinguish your experience among the group as the principal investigator. (If no one but you will be collecting data, state that fact.)

Attending Veterinarian(s): List the full name(s), title(s) and department(s) of all *Attending Veterinarian(s)*, and cite their experience with this kind of research.

Faculty Sponsor: _____
Department:
Phone:
Email:

IRB Submission: Have you submitted this study to any other IRB? **No____Yes____**

A. What IRB(s)? List name of Institution(s)_____

B. What category of review was the project submitted as?_____

C. Status of review (i.e. approved, not approved, pending). If the project was approved, please attach a copy of the approval letter.

Joint Institutional Research: Describe how permission has been obtained from cooperating institution(s) – i.e., school, hospital, prison, or other relevant organization. *(Attach letters of permission and approval.)*

Does this cooperative research require additional IRB permission from another institution?
_____YES _____NO

Estimated date to begin data collection: (pending IRB approval)_____

Duration of project: (Please remember you may not begin data collection without IRB approval)
Start Date:_____ ***Ending Date:***_____

Sponsorship:

____Project **does not require funding** from an outside source or a commercial sponsor

____Project **requires funding** from an outside source or a commercial sponsor

a. Commercial sponsor clinical contact name_____

b. Commercial sponsor clinical contact telephone number_____

c. Funding source:_____

____Funding obtained

____Funding application pending

____Funding application to be submitted, deadline_____

Please explain the *scientific merit* of the study in the space provided:

General Outline of Proposed Study

A. Describe the research design – include objectives, procedures *(include number of times observations, examinations, tests, etc. will be conducted)* and expected results. **Specifically include the following:**

1. **The specific objective of the proposed use of animals** (i.e., teaching basic cardiovascular physiology to students).
2. Rationale for using the specific species of animals that will be used, and the number of animals that will be used– include the total number of animals in each experimental and control group. You may find that diagrams such as flow charts may help with this descriptive section.
3. Specific aims for the proposed research.

4. How the data will be analyzed or tested statistically.

B. Aims and objectives- ***In lay or non-technical terms*** (language understood by a non-scientific member of the community), provide a 1-2 paragraph overview of the aims and objectives of this study. Avoid scientific jargon and define all abbreviations. Include a justification for how this study promotes animal or human health or advances scientific knowledge. (**Note:** This overview is a legal requirement of the Animal Welfare Act.)

C. USDA regulations require that investigators consider ***alternatives to the use of animals*** for their research. Please provide a brief rationale for why animals are required for this study. *Please offer a brief rationale for why the proposed species is/are the most appropriate for this study*.

D. Will any aspects of live vertebrate animal experimentation be performed at another institution?
___No ___ Yes (If **YES,** the other institution must approve your protocol. Attach a copy of that approval to this application.)

E. How did you determine that the proposed work does not unnecessarily duplicate previous work? (If this is an exercise for teaching please state that fact, likewise state if you need to repeat previous studies and why it is necessary):

F. "Pain and Distress Classification" - Animal Welfare; Final Rules; 9 CFR Parts 1 and 2 and Animal Welfare Act as Amended (7 USC, 2131-2156):

Pain and Distress Classification Table (PC-100)

CLASS - I No Pain or Distress	CLASS – II Relieved Pain or Distress	CLASS - III Unrelieved Pain or Distress
Class I is the classification for procedures which involve no pain or minimal transient distress to the animals (i.e., a study where there are purely injections of a non-painful solution).	Class II is the classification for procedures where possible pain or distress is controlled by the appropriate use of anesthetic, analgesic, or tranquilizer drugs - (i.e., surgical procedure studies).	Class III is the classification for studies where there is likely to be significant pain or distress which cannot be controlled by the use of pain relieving drugs. (i.e., pain studies or experiments where the use of drugs would negate the objective).

In Table PC-101, please provide the following information as it relates to the vertebrate or laboratory animal subjects in your project:

TABLE PC-101

Pain and Distress Classification *(Note the Pain and Distress Classification Table - PC-100 for Pain Class Reference.)*	**Species and *Common Name***	**Strain**	**Number of Animal Subjects Used in This Project or Study**	**Total Number of Female Subjects**	**Total Number of Male Subjects**	**Source**

G. Please answer the following questions for any section of the proposed project or experimental procedures implementation, where there will be ***significant unavoidable pain or distress*** which ***cannot be relieved by the use of analgesics, tranquilizers or anesthetics*** *(Pain "Class III" in question F, above)*.

1. What is the scientific justification for the proposed procedure(s)?

2. Have you consulted the Attending Veterinarian during the planning of this study?
___Yes ___ No (If **NO,** please explain why the veterinarian **has not been** consulted.)

H. Will animals be subjected to prolonged restraint (i.e., rat in tethers), or housed in cages, which do not meet the requirements of the "Guide for the Care and Use of Laboratory Animals?"
___ No ___Yes (If **YES,** please answer the following questions.)

1. What type of restraint will be used? *(Metabolic cages, tethering, chairing, etc.)*

2. What is the total duration of the restraint portion of the experimental procedure?

3. What is the scientific justification for the particular procedure?

I. Are surgical procedures to be preformed in the study?
___ No ___Yes (If **YES,** please answer the following questions.)

1. Are there survival surgical procedures in this project?
   ___ No ___Yes

2. Will multiple survival surgeries be performed on the same animal?
   ___ No ___Yes (If **YES**, please answer the following questions.)

   a. List the species of animal that will be used in the surgeries:

   b. List the number of animals that will be used in the surgeries:

   c. List the type of surgeries that will be performed for each group of animals that will participate in multiple surgeries:

   d. List the time intervals between these surgeries for the animal participants:

J. Are invasive procedures used for the collection of tissue or body fluids from live animals?
___ No ___Yes (If **YES**, please answer the following questions.)

1. List the fluid(s) or tissue(s) to be collected:

2. List the amount (s) of fluid(s) and/or tissue(s) to be collected:

3. Explain the method that will be used in order to obtain the collection of the fluid(s) or tissue(s):

4. List any drugs (i.e., tranquilizers) that will be used to facilitate collection of the fluid or tissue. Please include the dosage and route of administration:

K. All tranquilizers, anesthetics and analgesics to be used for either surgical or non-surgical procedures must be listed in the following tables:

Table K-101: SUMMARY OF ALL DRUGS FOR ANESTHESIA AND/OR RESTRAINT

Animal Species	Drug	Route	Dose (mg/kg)	Frequency

Table K-102 SUMMARY OF ALL DRUGS FOR PAIN ALLEVIATION (ANALGESIA)

Animal Species	Drug	Route	Dose (mg/kg)	Frequency/Duration

L. List the personnel name(s) and title(s) or position(s) on the investigative research team who are responsible for administering the above noted analgesics.

M. If not providing analgesics you must justify why pain/distress relief is not appropriate or available as required by law. Please list the procedure, scientific justification, and state the number of animals affected during the experimental procedures.

ALTERNATIVES TO THE USE OF ANIMALS FOR PAINFUL PROCEDURES

N. The USDA is now requiring that 3 separate database searches be conducted for each procedure that may cause more than momentary pain or distress. The date ranges for each database search are also required. Please provide the following information indicated within the tables below, for each procedure. *(You may duplicate the table below if necessary to accommodate additional database searches conducted beyond the minimum of the 3 mandatory individual searches.)*

N-101.1: ***Database Search Alpha (Minimum Required)***

Procedure:
Databases searched (minimum of 3): i.e., *Agricola, etc.*
Date search conducted:
Date range of search (month/year): **From:** **To:**
Keywords used:

N-101.2: ***Database Search Beta (Minimum Required)***

Procedure:
Databases searched (minimum of 3): i.e., *Agricola, etc.*
Date search conducted:
Date range of search (month/year): **From:** **To:**
Keywords used:

N-101.3: ***Database Search Gamma (Minimum Required)***

Procedure:
Databases searched (minimum of 3): i.e., *Agricola, etc.*
Date search conducted:
Date range of search (month/year): **From:** **To:**
Keywords used:

N-101.4: **Additional Resources *(Excluding Database Search Engines):***

Current books/journals (specify):
Professional communication with colleagues (specify):
Animal Welfare Information Center (AWIC-http://www.nal.usda.gov/awic/):
Attending Veterinarian:

N-101.5: Additional Resources *(Excluding Database Search Engines):*

Current books/journals (specify):
Professional communication with colleagues (specify):
Animal Welfare Information Center (AWIC-http://www.nal.usda.gov/awic/):
Attending Veterinarian:

O. Are hazardous agents such as radio-isotopes, infectious agents, mutagens, or other toxic substances used in the proposed study? The ***principle investigator*** is responsible for contacting the appropriate offices regarding Thomas University's policies on the use of hazardous agents:
___**No** ___**Yes** (If **YES**, please answer the following questions.)

Ionizing Radiation: Does the animal project involve ionizing radiation, fluoroscopy imaging, or administration or use of radioactive nuclides ***in vivo***?

___**No** ___**Yes** *(If **YES,** an Environmental Health and Safety (EH&S) review is required. Please contact the EH&S Radiation Safety Office for an "Application to Use Ionizing Radiation in Research" **(RSC-6 Form)** and provide them with a copy of the animal protocol.)*

Use of Hazardous Materials: Does the project involve the use of potentially hazardous materials such as:

1. The use of recombinant DNA techniques involving animals (i.e., generation of new transgenic animals, use of genetically modified cell lines, delivery of nucleic acids)?
___**No** ___**Yes**

2. The use of toxic, carcinogenic or infectious agents **in animals?** ___**No** ___**Yes** (*If **YES**, an Environmental Health and Safety (EH&S) review is required. Please contact the EH&S Office.*

3. ***Other***- Please describe the (1) ***test substance***; (2) ***the dosage and administration method***; and (3) ***expected result(s) of the administration***:

P. Are controlled substances (i.e., narcotics or barbiturates) used? ___**No** ___**Yes** (*If **YES**, please answer the following questions.)*

1. Please describe the methods that will be used in order to secure the controlled substances.

2. Please list the individual(s) that will be responsible for the security, usage and record of the controlled substances during and after the experiment. Please indicate their position on the team or title, and their previous experience in performing the security of controlled substances.

3. How will you dispose of any remaining controlled substances following the conclusion of the experiment?

DISPOSITION OF ANIMALS

Q. Describe the method of euthanasia or alternative to euthanasia. ***Procedures listed must be in compliance with the current American Veterinary Medical Association recommendations for euthanasia - (J. Am. Vet. Med. Assoc. (1993) 202: 229 – 249).***

Table DA- 101: EUTHANASIA

Animal Species	Method/Drug	Drug Dose	Drug Route

1. Who is responsible for this task? Please indicate their position on the research team or title.

2. What is their experience and training in performing the euthanasia task with animals?

3. ALTERNATIVE TO EUTHANASIA - If animals are not to be euthanized at the end of the project, specify what will happen to them. *Alternatives to euthanasia include adoption or transfer to another investigator.*

Additional Attachments *(Checklist)*:

____Copy of principal investigator(s)' curriculum vitae attached ***(See the following CV Waiver Statement)***

____***CV Attached Waiver Principal Investigator:*** A copy of CV as an attachment can be waived if the principal investigator has previously submitted a copy of their CV within the last two years and that CV resides on file with the IRB, or the investigator is a student who is under the guidance of a faculty sponsor.

____Copy of all other investigator(s)' curriculum vitae attached ***(See the following CV Waiver Statement)***

____***CV Attached Waiver All Other Investigators:*** A copy of CV as an attachment can be waived if all other additional investigators have previously submitted a copy of their CV within the last two years and that CV(s) reside on file with the IRB or the investigators are students who are under the guidance of a faculty sponsor.

Assurance of Principal Investigator:

I understand experiments involving laboratory animals are not to be conducted unless approved by the Thomas University Institutional Review Board on the issue Vertebrate or Laboratory Animals in Research. I will comply with all requests for information in connection with animal care and use as may be required by governmental and institutional guidelines. I will request and permit veterinary care for animals showing evidence of pain or illness, and I certify that the information provided on this form reasonably summarizes the nature and extent of the proposed involvement of laboratory animals.

I will ensure that all personnel handling animals are adequately trained in the handling and restraint of all species used, as well as, in the proposed experimental procedures, and the applicable sections of the Animal Welfare Act. I will contact the appropriate entity or governing body for any training or assistance required.

In compliance with the Animal Welfare Act, I will instruct all personnel to inform me at once if they have concern about the welfare or the treatment of any of my laboratory animals. If the situation is not resolved, I will contact the Attending Veterinarian(s), who will investigate the concern and help to create a resolution.

As the Principal Investigator on this project, I certify by my signature below that the information provided in this application is accurate and fully describes any and all procedures regarding vertebrate or laboratory animal subjects under, which I will conduct this research.

I, the undersigned, agree to accept responsibility for my co-investigators and other personnel involved on this project, in regards to their compliance with the above stated policies.

I will retain the documentation of the experiment, experimental data, reports and all procedures performed for ***at least three years after*** the proposed activity has been completed or discontinued.

The IRB is obligated to continually review this activity. Therefore, I agree to furnish progress reports to the committee when requested.

I, the undersigned, understand and agree that ***upon approval of this application***, should complaint of a *violation of any procedures* as proposed within this document occur, as deemed through investigation by the Thomas University IRB or bodies employed by Thomas University, this application *will be reversed and denied continuation of approval, and the termination of the research under this proposal will be so ordered and enforced to the fullest extent of the law.*

Please note: Signature of this application form by the primary investigator provides written assurance that the primary investigator attests that they have read and understand all abovementioned statements concerning Thomas University policy for research or similar activities involving vertebrate animals or laboratory animals as subjects; federal, state and county regulations and laws where applicable; and certify that they will uphold all regulations and policies as required and prescribed by law, along with the guidelines of PL89-544, the Animal Welfare Act, and the National Institute of Health Guide for the Care and Use of Laboratory Animals, and the Thomas University policy as stated herein*.*

_____ _____

Principal Investigator's Signature (SEAL) ***Date***

For faculty supervisor approval:

I believe that the research can be safely completed and conducted within the outlined guidelines of PL89-544, the Animal Welfare Act, and the National Institute of Health Guide for the Care and Use of Laboratory Animals. Furthermore, I have read the enclosed proposal, and I am willing to supervise the investigator(s).

_____ _____

Faculty Sponsor's Signature (SEAL) ***Date***

RESPONSE TO APPLICATION FOR APPROVAL OF RESEARCH INVOLVING VETEBRATE ANIMAL SUBJECTS

All responses to research will be provided to the ***principal investigator*** in writing from the Thomas University Institutional Review Board. According to the complexity of the research, a response from the board (full review of application) may take up to, ***but not exceed,*** three weeks. Should further, appropriate review by officials of the institution be deemed necessary, it could delay a response from the Institutional Review Board for an additional two week period beyond the initial three week period. In addition, the request for an expedited review by the principal researcher ***does not exclude*** the possibility of a determination of a ***full committee review***. This is held at the discretion of the Institutional Review Board and its Chairperson. When at all possible and should the research request exhibit those criteria that merit an expedited review that option ***will be exercised*** by the Institutional Review Board.

For questions, please contact the Thomas University IRB at irb@thomasu.edu.