Academic Research
Environmental Health and Safety
WEST TEXAS A&M UNIVERSITY

APPLICATION FOR VERTEBRATE ANIMAL USE (AVAU)
(REVISED 9.7.2023)

NOTE: BEFORE COMPLETING THIS FORM, READ INSTRUCTIONS HERE.

This application applies to ☐ Research ☐ Teaching

Application Date:

If this application covers a clinical study involving privately owned animals, please attach a copy of the client consent form.

If this application applies to teaching, please attach syllabus. The syllabus should provide evidence that these activities are associated with this course.

Title of project or activity:

Submitted to (Name of Funding Agency, if applicable):
Agency Deadline:

If funding is External, please provide the SRS#:

If this project has been approved previously by the Committee, please indicate the ID# of the previous application and expiration date:

A COPY OF THIS APPROVED PROTOCOL WILL AUTOMATICALLY BE SENT TO THE ANIMAL HOUSING FACILITY NAMED IN THE CONFIDENTIAL SECTION OF THIS DOCUMENT.

Please retain a copy and, AS APPROPRIATE, submit a copy with your application to various University offices through which applications must be routed, or send a copy directly to the review group or project officer in the Funding Agency for your project.

DO NOT WRITE BELOW THIS LINE. APPLICATION CONTINUES ON NEXT PAGE.

☐ Approved ☐ Approved with modification (Attached) ☐ Not approved

This institution has an Animal Welfare Certificate on file with APHIS.

X IACUC Chair Date

IACUC#:_____
Date Proposal Received:_____
Date Sent to IACUC:_____
Approval Date:_____
Expiration Date:_____

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CONFIDENTIAL

INFORMATION ON PAGES 2 AND 3 IS CONSIDERED PRIVATE AND NOT SUBJECT TO RELEASE UNDER THE PUBLIC RECORDS ACT. PLEASE PROVIDE THE APPROPRIATE INFORMATION IN THE SPACES PROVIDED BELOW. DO NOT INCLUDE THIS INFORMATION IN ANY OTHER PORTION OF THE APPLICATION. THE REST OF THE APPLICATION IS CONSIDERED PUBLIC AND IS SUBJECT TO RELEASE.

Principal Investigator or Instructor (PI): PI Phone Number

Department: Fax Number

Mailing Address:

E-mail address:

After-hours emergency contact and phone number:

Duration of Project/Course to (IACUC) approval is for 3-years maximum)

Have all personnel completed the online **CITI training?** (An RCR refresher course is required annually along with other required trainings due every 3 years– contact AR-EHS for additional requirements.)

☐ Yes ☐ No – Please explain why not.

Have all personnel completed the **initial risk assessment survey?** (This assessment is required annually.)

☐ Yes ☐ No – Please explain

To the best of your knowledge, are the animals to be used in this project free of disease associated with health risk to animal workers?

☐ Yes ☐ No – Please describe safety precautions that will be used to protect personnel.

What type of animals are involved in this project or activity?

☐ Livestock ☐ Companion Animals ☐ Laboratory (mice, rats, etc.)

☐ Wildlife Exotic animals ☐ Other, Specify

Provide number of animals and justification for the number of animals needed.

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Provide a one-paragraph summary of the project or activity.

Describe briefly what you will be doing with the animals.

List species chosen and the justification for the species chosen.

1. Animal Housing

1a. Will animals be housed? ☐ Yes ☐ No

If no, explain why not (i.e. field studies, client owned) For Field studies, give location. Please be specific.

☐ Cage ☐ Indoor pen ☐ Metabolism crate ☐ Tie stall

☐ Outdoor pen ☐ Free range ☐ Other – please specify

b. What is the **physical address** of where the animals will be housed?

c. Where will procedures (including surgeries) be performed? (Physical address, including building and room number.)

d. Will animals be maintained at any time in Investigator's lab or any off-campus site? ☐ Yes ☐ No

If yes, how long? Building Room Number

If greater than 12 hours, provide justification. These arrangements must be approved by the IACUC.

e. For animals that are transported away from the animal facility to an investigator's lab or to any off-campus site, describe containment of animals, method of transport and how it is appropriate for the species being transported. Transportation must conform to all federal regulations and guidelines. Transportation log.

2. List **all personnel**; **including the PI**, who will care for and work with the animals. **For each person, please include the following required information:**

--Indicate their role in the project.
--List name, contact email, animal-related experience and training for procedures being performed in sufficient detail to allow the IACUC to determine that individuals are qualified; listing of degrees is not sufficient.
--Provide specific information for those performing euthanasia, and if applicable, for those performing anesthesia and/or surgery FOR SECTION A.
--Provide attending Veterinarian's name and contact information. (**Required**)

3. If applicable, list experts in the area of investigation with whom you have consulted. Provide name, position, and briefly describe area of expertise.

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PRINCIPLE INVESTIGATOR ASSURES:

That she/he will abide by West Texas A&M University policies for the care and use of animals; the provisions of the Guide for the Care and Use of Laboratory Animals; and all federal, state and local laws and regulations governing the use of animals in research; and that she/he understands that emergency veterinary care will be administered to animals showing evidence of pain or illness, in addition to routine veterinary care as prescribed for individual species in the Standard Operating Procedures;

That all manipulations involving live animals will be performed under her/his supervision or that of another qualified individual listed on this protocol;

That all personnel having direct animal contact, including the investigator, have been trained in humane and scientifically acceptable procedures in animal handling, administration of anesthetics, analgesics, and euthanasia to be used in this project, and have completed the WTAMU Animal Welfare training module, or are under the direct (in-lab) supervision of a trained individual, and that employees will be allowed adequate time to attend training sessions;

That personnel with animal or animal tissue contact participate in the Occupational Health and Safety Program;

That this proposed animal use does not unnecessarily duplicate previous activities:

That she/he will obtain approval from the IACUC before initiating any changes in this study, including changes in personnel or location of animal use;

That she/he will notify the IACUC and the attending veterinarian regarding any unexpected study results that adversely impact the animals, including any unanticipated pain or distress, morbidity, or mortality.

I have read, understand, and will comply with the assurance statements.

Signature of P.I. Date

Any deviation from an approved protocol, violations of pertinent policies, guidelines or laws could result in immediate suspension of this project.

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NON-CONFIDENTIAL SECTION

INFORMATION ON THE FOLLOWING PAGES IS CONSIDERED PUBLIC AND IS SUBJECT TO RELEASE UNDER THE PUBLIC RECORDS ACT. **PLEASE DO NOT PROVIDE INFORMATION FROM THE SECTION ABOVE OR OTHER INFORMATION THAT SHOULD REMAIN CONFIDENTIAL.**

SECTION A. Animal Care and Use (Completion of this section is required for all applications)

1. Describe in non-scientific terms the purpose and importance of this animal use activity.

2. Describe in non-scientific terms how animals will be used. Include all manipulations and procedures. This description should allow the IACUC to understand what happens to an animal from the time of acquisition to the endpoint of the activity.

3. Consideration of Alternatives

Are there procedures or conditions that may potentially cause more than momentary or slight pain or distress? (By definition, this includes all Category D and E studies.) ☐ Yes ☐ No

If yes, there must be a written narrative description of the methods and sources [e.g. biological abstracts, Index Medicus, Current Research Information Service, and/or the Animal Welfare Information Center operated by the National Agricultural Library (phone 301/504-6212)] which were consulted to determine the availability of alternatives (reduction, refinements, replacement).

"Alternative" refers to methods, models, and approaches that result in the reduction of the number of animals used, that incorporate refinements of procedures which result in the lessening of pain or distress to animals, or that provide for the replacement of animals with non-whole animal systems or the replacement of one animal species with another, particularly if the substituted species is non-mammalian or invertebrate.

a. Literature search for alternatives: list the databases, years searched in each database, keywords used, and date the search was performed (or attach the summary sheet with this information). Keywords should include those likely to yield information on alternatives to the potentially painful or distressful procedures or conditions that are part of this protocol.

b. Other information services utilized (list):

c. Other methods or sources used (briefly describe). Names of consultants should be listed in the confidential section of this application, item number 3.

d. Summarize how the above methods and sources have helped you identify alternatives or determine that alternatives are not available.

4. Provide the following information for all animals in the table below. No animal should be listed more than once; count each in highest proposed category of use. (Note: The last page of the application lists category definitions.)

   - **Category B** – Animals being bred or held but not yet used in research (i.e., not used for teaching or research)
   - **Category C** – No stress, pain, or use of pain-relieving drugs (i.e., not more than momentary stress or pain without need for analgesics or anesthetics beyond normal handling for the animal for teaching and research)
   - **Category D** – Involve pain or distress for which appropriate anesthetics or analgesics will be used
   - **Category E** – Involve pain or distress for which appropriate drugs will adversely affect research results

Species and strain (include common name)*	Age and/or weight**	Source***	Category of use (above)	Total number requested for 3 years

*For field studies involving capture methods, anticipated non-target (by catch) species should also be indicated by species or in aggregate as "miscellaneous."
**Give ranges if the specific information is unknown.
***Please choose from the following sources: commercial vendor, client-owned (teaching hospital, non-university farms), random source, university-owned teaching herds/flocks, university-owned research herds or flocks, rental or stock animals, purpose-bred, collected from wild, animals in natural habitat, other (define). DO NOT USE VENDOR OR COLLABORATOR NAMES.

a. Is this a laboratory exercise for the purposes of teaching students? ☐ Yes ☐ No

b. Do you have data from prior studies that is sufficient to calculate the sample size? ☐ Yes ☐ No

c. How did you determine the number of animals to be used in this study?
☐ PI's decision (no outside resources)
☐ CVM Population Medicine Statistics Consultant
☐ Contractual Agreement with Grantor
☐ Other. Please specify:

d. Using the specifics of your experimental plan (or demonstration or course syllabus, as applicable), demonstrate how the numbers of animals required to achieve your scientific (or teaching) objectives for this project (i.e., the numbers given in Sec. A.4.) were calculated. Include details of numbers of animals per group, control groups, treatment groups, pilot studies, and potential experimental failure. Information may be provided in the form of a table or flow chart. (NOTE: You must submit an amendment to exceed this allotment of animals.)

SECTION B. Invasive sample collection from live animals (blood/urine/feces/tissue/other [define])

Species	Sample	Site(s) of sample collection	Method(s)	Volume(s)	Frequency of collection

Provide details for any sample collection procedures that may not be clear from the table or Section A.2.

SECTION C. Substance Administration

Anesthetics, analgesics, tranquilizers and euthanasia agents should be listed in Sections D and F. Dietary manipulations should be described in detail in Section A.2., and Section D.8., if applicable.

1. Will anything be administered to animals? ☐ Yes ☐ No If Yes, list specific agents below and provide dosage information (mg/kg body weight and volume), unless provided in Section A.2.

☐ Radioisotopes? List/dosage:

☐ Pathogenic or viable organisms? List/dosage:

☐ Toxic chemicals? List/dosage:

☐ Carcinogens? List/dosage:

☐ *Transplantable tumors? List/dosage:

☐ Biological materials such as tissue, sera, or cell lines? List/dosage:

☐ Recombinant DNA? List/dosage:

☐ Others not listed above? List/dosage

*If materials have been derived or passed through rodent species, product must be free of infectious agents (Mouse Antibody Production (MAP]/Rat Antibody Production (RAP]/Hampster Antibody Production [HAP] testing are diagnostic assays used as indicators of viral contamination of rodent products).

2. For each of the above, describe in detail the precautions taken to protect people and animals in the environment, including handling practices for contaminated excreta, bedding and toxic metabolites.

3. Describe the effects of these agents on the experimental animal. Potential for pain or distress should be addressed in Section D.

4. Safety plan approved by WTAMU Academic Research and Environmental Health and Safety?

☐ Yes ☐ No

5. Radiological approval needed?

☐ Yes ☐ No

Does the safety plan reflect the location of this experiment and the experimental protocol? ☐ Yes ☐ No

If no, contact WTAMU Academic Research and Environmental Health and Safety, (phone: 806-651-2270).

SECTION D. Potential Pain and Distress

Use this section to discuss all procedures or conditions that may be accompanied by pain, distress, or discomfort. Include discussion of infectious or spontaneous disease studies and transgenic animals, even if clinical signs or abnormal phenotypes are not expected. This section is applicable to animals listed in Categories, C, D, E.

1. List each procedure or condition with potential for pain, distress, or discomfort, and give the species and number of animals affected. Describe the clinical signs or abnormalities that are expected or possible.

2. Describe the monitoring plan for pain and distress, including frequency and duration of checking for health or behavioral abnormalities.

3. Describe how pain, distress, and discomfort will be minimized, consistent with scientific objectives. (Use Section D.6. to describe use of anesthetics, analgesics, tranquilizers, or other palliative therapies.) Include the actions to be taken, and the specific criteria/endpoints for euthanasia, if applicable. (Examples include not eating for >24 hours, loss of >15% of normal body weight, self-mutilation, non-weight bearing for >24 hours, etc. In some cases, it may be appropriate to euthanize animals at the first sign of clinical abnormality.) Describe euthanasia procedures in section F.

4. If painful or distressful procedures or conditions will NOT be relieved with anesthesia, analgesia, tranquilization, other palliative therapies or humane endpoints, provide scientific justification.

5. If death is intended to serve as an endpoint (i.e., if animals must be allowed to die from an experimental condition or procedure), provide scientific justification.

6. If painful or distressful procedures or conditions are relieved with anesthesia, analgesia, tranquilization, or other palliative therapies:

a. For each species to be used, list procedure or condition in which anesthesia, analgesia, tranquilization or other palliative therapies will be used. Providing drug, dose, route, frequency of administration, and anticipated duration of therapeutic effect. Include all medications, such as pre- and post-anesthetics, antibiotics, paralytics, etc. (If applicable, describe surgery in next section.)

Species	Procedure or Condition	Agent	Dosage, route	Frequency	Duration

b. Describe monitoring procedures to ensure adequacy and safety of anesthesia or tranquilization.

c. Describe monitoring procedures for recovery from anesthesia or tranquilization.

d. How will adequacy of post-operative/post-procedural analgesia or other pain-relieving therapies be ensued?

7.Physical restraint (more than one hour): Describe physical restraint methods. How will potential distress be minimized (e.g., sedation, acclimation/training)?

8.Field Studies Only. Describe trapping or other capture methods used in field studies, unless discussed inSection A.2. Explain how pain, distress and discomfort are minimized.

9.Exceptions to standards: Describe and justify any exceptions to federal regulations or standards, and give the species of animal and number to be used. (Examples of exceptions: use of animal in more than one protocol involving a major operative procedure from which it is allowed to recover, deprivation of food or water; maintaining animals at temperatures and/or humidities outside the ranges specified by the standards; not cleaning and/or sanitizing at required frequencies; not providing diurnal lighting as required; not meeting space requirements;exceptions from the exercise plan for dogs.)

SECTION E. Contingency Plan

The new regulations for contingency planing and training of personnel were published in the Federal Register on December 3, 2021. The Contingency planning rule took effect on January 3, 2022.

All facilities must have a written Contingency Plan (research facilities, dealers, exhibitors, intermediate handlers, and carriers).

All employees must be trained (and documented) within 30 days of hire and/or any substantive change to the plan. This training must be documented at a minimum of once a year for all employees.

Annual Review: The Contingency Plan must be reviewed at least on an annual basis. This will be done utilizing WTAMU's annual PI review.

Is there a current contingency plan in place for this facility? Choose one

Have all employees been trained on the plan and documented that they have received training? Choose one

Please describe where the contingency plan and training documents are stored for this facility. This will aid in future USDA/ APHIS inspections.

SECTION F. Surgery

Surgery and postoperative monitoring and records must be in accordance with IACUC guidelines. Refer to the IACUC Guidelines on Intra and Post-Operative Monitoring and Record Keeping. Contact the University Attending Veterinarian (see committee information for additional information or forms.) Be sure personnel qualifications for those performing surgery and postoperative care are adequately trained; described in the Confidential Section, number 2.

1. Will surgery be survival or non-survival?

☐ Survival ☐ Non-Survival (animal does not recover from anesthesia prior to euthanasia)

2. Describe, in detail, the surgical procedure(s) for each species to be used. Include description of presurgical preparation and method of closure, if applicable.

3. If the animal will recover from anesthesia, how long will the animal be maintained after recovery?

4. Describe, in detail, the postoperative care, including any specialized care. (Use of analgesics should be described in Section D., above.)

5. Will individual animals undergo more than one surgical procedure? ☐ Yes ☐ No

If yes, provide scientific justification. (Multiple major survival surgeries should be justified in Section D.9.)

SECTION G. Euthanasia/Disposition

1. Provide the following information for all euthanasia of animals. (Death must be confirmed for all methods.) Complete this section regardless of whether euthanasia is an expected endpoint of the study, or whether euthanasia is required to relieve pain or suffering due to unexpected injury or illness.

Species	Method/Agent	Dosage, route

2. Justify methods that vary from those recommended by the most recent report of the American Veterinary Medical Association (AVMA) Panel on Euthanasia. Decapitation and cervical dislocation require justification.

3. If these animals are not to be euthanized as part of your protocol, what will become of them?

Categories:
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. 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 connection 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 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 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 stress.

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.